**Ministry of Science and Higher Education**



National Research Ethics Review Guideline

**NRERG No. 01/2020**

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**Ethiopia**

# FORWARD

The Ministry of Science and Higher Education (MoSHE), established by proclamation number 1097/2018 in October 2018, is responsible to lead the development of science, higher education as well as the technical and vocational education and training (TVET) in Ethiopia. In pursuing science development operational researches in all disciplines of science in particular need to be conducted in the Ethiopian context to resolve the multi-faceted problems of the country. It is to be noted as well that science and research do always go hand in hand as both have profound mutual relationships. In applying scientific methods to investigate or study and making evidence to establish facts, new conclusions (research process) do need to be conducted in ethical manner in all disciplines of science.

Health research by virtue of the fact that it uses human participant quite often, a national research ethics guideline was developed and used in the past for nearly 25 years when ethical reviews at national level were conducted in the then Ministry of Science and Technology. Now as the Science part has now moved and formed a new Ministry of Science and Higher Education, research ethics part has also moved to be in MoSHE. In its recent restructuring exercise, MoSHE has also considered ethics review as its major pillar and established a designated Directorate and Secretariat to handle Ethics related issues beyond health. The ethical conduct of researches has now become more of standard approach in any scientific discipline and basic requirement to obtain international research grants and later publishing research outputs on reputable journals.

In light of the above facts, the Ministry of Science and Higher Education (MoSHE) of Ethiopia took the lead in developing a new comprehensive National Research Ethics Guidelines. This compiled work consists of five science disciplines each with its specific sections. The first section will be the Health Research Ethics Review Guideline (HRERG), which is updated and designated as its 6th edition. The remaining guidelines developed as first edition include Animal Health Research Ethics Review Guideline (NAHRERG), Plant Research Ethics Review Guideline (PRERG), Environmental Research Ethics Review Guideline (ERERG), and Engineering Research Ethics Review Guideline (ERERG).

We trust that these guidelines will create awareness and practical guidance on ethical dimensions in some of the science disciplines. The guidelines will also be helpful to students, instructors, researchers working on researches involving human, and animal participants, agriculture, the environment and engineering. MoSHE will support the establishment of a Research Ethics Review Committee in all research institutes and higher education centers that review research protocols as per the ethical principles laid in the guidelines.

Finally allow me to thank all the contributors, senior experts in their respective field of science and the Ministry of Science and Higher Education, Research Ethics Directorate for facilitating this very important task. The support rendered by Armaur Hansen Research Institute (AHRI) and Center for Innovative Drug Development and Therapeutic Trials for Africa (CDT- Africa) was commendable.

H.E. Samuel Urkato (PhD)

Minster, Ministry of Science and Higher Education

# PREAMBLE

Ministry of Science and Higher Education (MoSHE) is mandated by proclamation 1097/2018 to coordinate the development of science in Ethiopia. The Science, Technology, and Innovation Policy of Ethiopia states that research is needed to address major health, social and economic problems, contribute to the achievement of national development objectives, and meet the demand for improved technology. Considering that, in its recent restructuring, MoSHE has considered Ethics review as its major pillar and established a designated Directorate and Secretariat to handle Ethics related issues beyond health.

The expansion of higher education, graduate education, research institutions and international partnership in Ethiopia has contributed to the growth of research activities. The purpose of most research undertakings is to generate policy informing data that will provide a strong basis for short and long-term action, while also considering the rights, safety, dignity and wellbeing of research participants. As a member of policy makers and researcher myself, I strongly believe that decisions on health issues really matter. As such, the investigation of diseases, prevention, treatment of individuals, and design of interventions for research participants, need to be evidence-based and ethically sound. Fundamentally, this is what every nation follows to safeguard the public and promote sciences and research.

The Health Research Ethics Review Committee (HRERC) is a reputable committee composed of capable and experienced professionals. Since the first national guideline for research ethics was issued in 1995, the HRERC has revised it five times in order to keep up with the dynamic nature of research ethics and global situations. In addition to this, MoSHE had facilitated the preparation of additional other four sectors research ethics review guidelines. These are Animal Health, Plant, Environmental and Engineering Research Ethics Review Guidelines (1st Edition) were developed. A very good example for the need in the continued revision and evolution of Ethics is the recent COVID-19 pandemic. Covid-19 has made it obvious that the way we review proposals, the way we set the standard of care and monitoring after approvals need to follow all the due diligence while expediting the process. I believe the Six Edition and the other four guidelines will ensure greater coverage including that and protection of research participants in Ethiopia.

As the number of research projects increases in the country, it is expected that research and researchers’ interests will also increase and diversify. Therefore, the need for updating the National Research Ethics Review Guideline is clear/necessary.

Hence, this guideline is applicable to research conducted by all sectors and organizations in Ethiopia. These include, public, private, faith-based, indigenous, and international nongovernmental organizations, bilateral, multilateral, and United Nations organizations. Therefore, it is my believe that this comprehensive national research ethics guideline will have immense influence on building and strengthening an effective research system in Ethiopia.

H.E. Professor Afework Kassu Gizaw (State Minister, Ministry of Science and Higher Education

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# ACRONYMS

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| --- | --- |
| AAUMFIRB | Addis Ababa University Medical Faculty Institutional Review Board |
| AE | Adverse Event |
| AHRI | Armauer Hansen Research Institute |
| CAB | Community Advisory Board |
| CIOMS | Council for International Organization of Medical Sciences |
| COI | Conflict of Interest |
| CV | Curriculum Vitae |
| DACA | Drug Administration and Control Authority |
| DNA | DeoxyriboNucleic Acid |
| DSMB | Data and Safety Monitoring Board |
| EERB | Environment Ethical Review Boards |
| ERC | Ethics Review Committee |
| EPHI | Ethiopian Public Health Institute |
| EFDA | Ethiopian Food and Drug administration Authority |
| EPHA | Ethiopian Public Health Association |
| ERC | Ethics Review Committee |
| ESTA | Ethiopian Science and Technology Agency |
| ESTC | Ethiopian Science and Technology Commission |
| FDRE | Federal Democratic Republic of Ethiopia |
| FHREC | Federal Health Research Ethics Committee |
| FMHACA | Food Medicine and Health Care Administration and Control Authority |
| GDP | Gross Domestic Product |
| GCP | Good Clinical Practice |
| GMP | Good Manufacturing Practice |
| GNI | Gross National Income |
| HIE | Higher Education Institution |
| HRE | Health Research Ethics |
| HRERC | Health Research Ethics Review Committees |
| HS&T | Health Science and Technology |
| IBC | Institutional Biosafety Committee |
| IoT | Institute of Technology |
| IRB | Institutional Review Board |
| LAR | Legally Authorized Representative |
| MOST | Ministry of Science and Technology |
| MoSHE | Ministry of Science and higher education |
| MTA | Materials Transfer Agreement |
| NEC | National Ethics Committee |
| NGO | Non-Governmental Organization |
| ERERC | Environment Research Ethical Review committee |
| PI | Principle Investigator |
| SAE | Serious Adverse Event |
| SOP | Standard Operating Procedures |
| S&T | Science & Technology |
| TOR | Terms of Reference |
| UK | United Kingdom |
| UN | United Nations |
| UNISA | University of South Africa |
| WHO | World Health Organization |

# GLOSSARY OF TERMS

**Academic research-**Research conducted within academic institutions by undergraduate and graduate (i.e., MSc and PhD students) students or staff members, irrespective of the source of funding. *Scientific novelty is usually expected from such research types.*

**Accreditation**- The act of granting credit or recognition for meeting established standards; a process to ensure quality and stimulate continuing improvement.

**Access and benefit-sharing**- One of the three objectives of the Convention on Biological Diversity, as set out in its Article 1, is the “fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding”. The CBD also has several articles (especially Article 15) regarding international aspects of access to genetic resources.

**Adverse Event (AE)-**Any untoward health-related occurrence in a participant administered a health-research intervention and which does not necessarily have to have a causal relationship with this intervention. An AE can be any unfavorable and unintended sign, symptom, or condition temporally associated with the administration of the health-research intervention, whether or not considered related to the intervention. This also includes unfavorable deviations from baseline health.

**Alternatives**- An alternative is likely to mean an alternative method that does not involve using an animal

**Amendment**- A material change to study procedures/any change to the protocol. Such changes, including minor changes, must be reviewed by an IRB before they may be implemented.

**Animal**- Any live non-human vertebrate, that is, fish, amphibians, reptiles, birds and mammals, encompassing domestic animals, purpose-bred animals, livestock, wildlife

**Animal Welfare-**An animal’s quality of life based on an assessment of an animal’s physical and psychological state as an indicator of how the animal is coping with the ongoing situation as well as a judgement about how the animal feels.

**Anonymous/anonymized**-Lacking identification because identifiers or other information that could identify the individual were not collected or were removed. Information may or may not be considered anonymous if there is a reasonable basis to believe that one can use the information to identify and individual, even if one cannot readily ascertain the individual's identity; see further discussion at individually identifiable information. For example, it might be possible to determine a survey respondent's identity from a combination of demographic factors in a survey together with public or proprietary data sources, even if the surveyor did not jointly record the respondent's identity and those demographic characteristics.

**Approve/approval**-The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

**Assent**- Participant not of legal age (i.e., child); affirmative agreement to participate in research. Mere failure to object should not be construed as assent.

**Autonomy**-Self-rule that is free from both controlling interference by others and from limitations that prevent meaningful choice. See also respect for persons.

**Basic research-**Research with the primary purpose of advancing scientific knowledge about the health and physiology of animals

**Belmont Report**-Statement of ethical principles and guidelines for the protection of human participants of research. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research published this report in 1979. The three principles are respect for persons, beneficence, and justice. See:https://www.hhs.gov/orhp[/humansubjects/guidance/belmont.htm

**Beneficence**- principle of ethical precept asserting an obligation to prevent harm, to remove harm, or to do or promote good; two-part rule: (1) do not harm and (2) maximize possible benefits and minimize possible harms.

**Benefit**-A potential advantage or gain.

**Breach of protocol**-Material departure from approved procedures of the study, such as the consent process, violations of data confidentiality, or complaints by participants; may be a reportable incident.

**Breeding**- the mating and production of offspring by animals

**Biodiversity**-short for biological diversity—means the diversity of life in all its forms—the diversity of species, of genetic variations within one species, and of ecosystems. The importance of biological diversity to human society is hard to overstate. An estimated 40 per cent of the global economy is based on biological products and processes. Poor people, especially those living in areas of low agricultural productivity, depend especially heavily on the genetic diversity of the environment.

**Biotechnology-** Any technology that is applied to living organisms to make them more valuable to people.

**Child/children**-Person who has not attained the legal age for consent to treatments or procedures involved in the research, under the Ethiopian law

**Clinical trial**-A prospective research study in human participants that is designed to answer specific questions about health-related interventions (such as medications, herbal supplements, nutritional strategies, physical interventions, behavioral interventions, prevention trials, or diagnostic tools), particularly to determine whether these interventions are safe, efficacious, and effective.

**Close/closure**-Proactively and permanently end both research-related intervention or interaction with participants and collection and use of identifiable private research information when study objectives have been met as specified in the protocol.

**Coded**-Replacement of identifying information (such as name or social security number that would enable one to readily ascertain the identity of the individual to whom the private information or specimens pertain) with a number, letter, symbol, or combination thereof where a key to decipher the code exists and links the identifying information to the private information or specimens. In contrast with linked, coded often means that the link exists but is unavailable, as through a nondisclosure arrangement.

**Collaborative research-** Research conducted by research/academic institutions in partnership with more than one research/ academic institutions (local and/or international)

**Compensation**-Payment to cover actual research-related harm. Where understandability is an issue, use a simpler word like "payment". Contrast with incentive, reimbursement.

**Completion of study**-Point at which data analysis has ended or identifying information is removed from the data and biological specimens.

**Comprehension**–in this context, understanding what the study is about.

**Complementary medicine (CM):** The terms “complementary medicine” or “alternative medicine” refer to a broad set of health care practices that are not part of that country’s own tradition or conventional medicine and are not fully integrated into the dominant health-care system.

**Conduct**-To be engaged (in research) by obtaining data about living individuals through intervention or interaction with them for research purposes or by obtaining individually identifiable private information about living individuals for research purposes.

**Conflict of interest**-A situation where the goals or obligations of an investigator or reviewer conflict with an obligation to uphold another party's interest, thereby compromising objectivity and impartiality.

**Confidential/confidentiality-**The condition of honoring a request or expectation that information will be protected from disclosure.

**Convened-**A formal, joint meeting or action of a quorum of the IRB.

**Collaborative research-**Research that involves more than one institution.

**Council for International Organizations of Medical Sciences (CIOMS)**-An international, non-governmental, non-profit organization established in 1949 whose membership represents many of the biomedical disciplines and national academies of sciences and medical research councils. A main objective of CIOMS is to facilitate and promote international activities in the field of biomedical sciences, especially when the participation of several international associations and national institutions is deemed necessary.

**Data and safety monitoring**-Structured, ongoing monitoring of specified characteristics of a research protocol, generally by a small, independent body of experts appointed by the study sponsor. Sometimes incorrectly called "data safety and monitoring". Monitoring may pertain to study performance (such as rate of accrual), safety (such as occurrence of AEs), and efficacy (such as achievement of primary endpoints). A body that monitors all three characteristics is usually called a data monitoring committee (DMC) or a data and safety monitoring board (DSMB).

**Declaration of Helsinki-**A statement of ethical principles to provide guidance to physicians and other participants in medical research involving human participants; adopted by the World Medical Assembly in 1964 and last updated in 2004. See <http://www.wma.net/e/policy/b3.htm>.

**Disapprove/disapproval**-The determination by the IRB that the research may not be conducted at an institution.

**Documentation of consent**-Consent that is documented by the use of a written consent form approved by the IRB and signed by the participant or the participant's legally authorized representative.

**Endpoint**- The stage in an experiment or test where the procedure is terminated. Where experiments increase suffering, animals should be killed as early as possible.

**Emergency response**-A public health activity undertaken in an urgent or emergency situation, usually because of an identified or suspected imminent health threat to the population, but sometimes because the public or government authorities perceive an imminent threat that demands immediate action. The primary purpose of the activity is to document the existence and magnitude of a public health problem in the community and to implement appropriate measures to address the problem (Langmuir, 1980).

**Engineering**- Engineering is a systematic and iterative approach to design and develop objects, processes, and systems using scientific and mathematical principles to meet human needs and wants.

**Engineering research**- Research in engineering and technology.

**Euthanasia-** Literally: ‘good death’. The act of killing a human or other animal in as painless way as possible.

**Exemption/exempt research**-Categories of research to which the Federal regulations for human research protections do not apply. Research involving prisoners and some research involving children are not exempt.

**Expected-**Pertaining to an AE, the event has been previously observed or documented in humans under the research intervention (or one substantially similar), and the nature or severity of the event is consistent with information in the relevant source documents (e.g., investigator's brochure, package insert, or non-reportable events [NRE] list).

**Expedited review**-Review performed by the IRB Chair or a designated experienced member for research that involves no more than minimal risk and meets the criteria for expedited review or represents minor changes in approved research.

**Experiment-**Part of a methodological research project with the aim of answering a particular theoretical question

**Experienced reviewer** -A member of an IRB who is designated by the Chair as authorized to conduct expedited reviews.

**Expert reviewer**-A member of an IRB who is designated by the Chair as authorized to conduct expedited reviews.

**Expiration date-**The expiration date is the day before the anniversary of the approval date – unless the IRB approves it for less than one year. For instance, a protocol approved on 12/4 has approval date of 12/4/06 and an expiration date of 12/3/07 midnight (which means research may be conducted on 12/3).

**Fetus**-The product of conception from the time of implantation until delivery.

**Focus group**-Group of individuals brought together to discuss an issue within a structured environment, often for formative or qualitative research purposes.

**Gene-** The functional unit of heredity; the part of the DNA molecule that encodes a single enzyme or structural protein unit.

**Gene bank**- A facility established for the ex situ conservation of individuals (seeds), tissues, or reproductive cells of plants or animals.

**Genetic diversity**- the variety of genes within a particular population, species, variety, or breed.

**Generalizable knowledge**- New information that has relevance beyond the population or program from which it was collected.

**Generalizable knowledge**- New information that has relevance beyond the population or program from which it was collected.

**Genetic Testing**: A procedure to detect the presence or absence of, or change in, a particular gene or chromosome, including an indirect test for a gene product or other specific metabolite that is primarily indicative of a specific genetic change.

**Genetic Screening**: Large-scale systematic genetic testing offered in a program to a population or subsection thereof intended to detect genetic characteristics in asymp­tomatic people.

**Good Clinical Practice (GCP)**-An international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human participants. See also <http://www.fda.gov/oc/gcp/default.htm>.

**Guardian-** An individual who is authorized under applicable local law to consent on behalf of a child to general medical care.

**Harm-**Injury, damage, or hurt; an experience in which one's interests are thwarted, defeated, or set back, especially one's physical or psychological interests.

**Human subject/human participant-**A living person about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information (e.g., medical records, employment records, or school records).

**Identifiable private information-**Information (data or biological specimens) such that the identity of a participant is or may readily be ascertained by the investigator or associated with the information, and either the information concerns behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or the information has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.

**Incentive**-Payment or other goods or services offered to motivate study participation.

**Incident**-An instance of one of the following: an unanticipated problem involving risks to participants or others, serious or continuing noncompliance, or suspension or termination (for reasons other than expiration).

**Indigenous people**- People whose ancestors inhabited a place or country when persons from another culture or ethnic background arrived on the scene and dominated them through conquest, settlement, or other means and who today live more in conformity with their own social, economic, and cultural customs and traditions than with those of the country of which they now form a part. (also: ‘native peoples’ or ‘tribal peoples’)

**Industry research -** This is research conducted within the premises of research institutes or industries. Like projects, these researches are usually conducted to solve existing problems using known approaches so that scientist novelty is less.

**Informed consent**-The free and informed decision by a prospective participant or participant's legally authorized representative to participate in research. The consent process should ensure that the participant has been provided full information regarding the research, the participant comprehends the research, and the participant is volunteering free of coercion and undue influence.

**Injury**-Physical harm to a participant in a research study.

**Institutional Review Board (IRB)**-The formally appointed ethics review committee established to ensure that research involving human participants conforms to ethical principles.

**Intervention**-Physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes.

**Justice, principle of**-Ethical precept asserting an obligation to treat persons fairly and give to each person what she is due; two-part rule: (1) exhibit fairness and (2) distinguish between classes of participants that ought, and ought not, to participate in any particular kind of research.

**Legally Authorized Representative (LAR)**-An individual or judicial or other body authorized under applicable State law who may consent on behalf of another individual to participate in the procedure(s) involved in the research.

**Local IRB**-IRB located in the institution where the research is to be conducted.

**Medical device**-Any instrument, apparatus, or other similar or related article, including component, part, or accessory, which is (a) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; (b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals; or (c) intended to affect the structure or any function of the human body or in animals; and does not achieve any of its principal intended purposes through chemical action within or on the human body or in animals and is not dependent upon being metabolized for the achievement of its principal intended purposes.

**Minimal risk**-(a) Risk such that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**Minor changes**-Changes to a research protocol that do not result in a net increase in risk, a change in the harm-benefit balance, or provide minor clarification or correction. Minor changes may be reviewed under expedited review, even if the protocol has been deemed to pose more than minimal risk to participants.

**Noncompliance**- Failure by investigators, research staff, IRB members, or IRB staff to follow regulations for human research protections.

**Oral consent**-Consent obtained only through speaking, generally in the absence of documentation of consent. See also [documentation of consent](http://intranet.cdc.gov/od/ocso/osrs/hrpo/guides/hrpo-glossary.htm#documentation of consent#documentation of consent), [informed consent](http://intranet.cdc.gov/od/ocso/osrs/hrpo/guides/hrpo-glossary.htm#informed consent#informed consent), [verbal consent](http://intranet.cdc.gov/od/ocso/osrs/hrpo/guides/hrpo-glossary.htm#verbal consent#verbal consent).

**Parental permission**-The agreement of a parent or guardian to the participation of their child in research.

**Personal identifier**-Information obtained and recorded in such a manner that human participants can be recognized, directly or through links to the participants. Examples include names, social security numbers, and codes.

**Pilot study**-Preliminary study to determine the feasibility of a larger study, use of a test instrument, or other activity.

**Pregnancy**-The period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

**Principal Investigator (PI)**-Lead scientist who is working on the design of a research study, development of methods and procedures for the study, collection of data or specimens, analysis of data or specimens, or interpretation of data.

**Prisoner**-Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

**Private information**-information about individually identifiable behavior that occurs in a context in which the individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record).

**Private/privacy**-Individual person's interest in preventing disclosure of information about himself or herself.

**Procedure-** A combination of one or more technical acts carried out on an animal for an experimental or other scientific purpose which may cause that animal pain, suffering, distress or lasting harm.

**Project**-A planned activity or collection of activities conducted for a particular purpose; may encompass more than one protocol on the same subject matter.

**Protocol**-The formal design or plan of a data collection activity; specifically, the plan submitted to a reviewing authority such as an IRB. The protocol includes a description of the design or methods for conducting the data collection, description of the study population, methods for data handling and analysis, procedures for handling incidents, and methods for notification and dissemination of results.

**Quorum**-The number of IRB members required to be present at a convened meeting in order for the IRB to transact business.

**Reimbursement**-Repayment for costs incurred by virtue or participation in research, such as for lost earnings or travel costs.

**Related/relation**-Pertaining to an AE, the likelihood that the event was caused by research procedures, usually relative to the likelihood it was caused by something other than research procedures.

**Research**-defined as the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies and understandings. This could include synthesis and analysis of previous research to the extent that it leads to new and creative outcomes.

**Research fund**- Research fund is the resource earmarked to conduct a research. The fund could come from the home institution, other academic institutions (local or global) as part of partnership, or funding entities (local or global).

**Report**-A written account of the IRB's findings, conditions for approval, or reasons for disapproval regarding human research protections in a research protocol.

**Repository**-An entity that collects, stores and manages, and distributes data or human tissue materials to recipient investigators for research and other purposes. See also <http://www.hhs.gov/ohrp/humansubjects/guidance/reposit.htm>.

**Research**-Systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

**Research fund-**Research fund is the resource earmarked to conduct a research. The fund could come from the home institution, other academic institutions (local or global) as part of partnership, or funding entities (local or global).

**Respect for persons,** principle of the requirement to treat individuals as autonomous agents and to provide additional protections to persons with diminished autonomy. Respect for persons requires that participants, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them.

**Response**-An investigator's written reply to an IRB report.

**Responsible conduct of research (RCR)**-A collection of core areas for conducting scientific research with integrity: data acquisition, management, sharing and ownership; conflict of interest and commitment; human participants; animal welfare; research misconduct; publication practices and responsible authorship; mentor/trainee responsibilities; peer review; and collaborative science.

**Risk**-Exposure to injury, loss, or harm, expressed in terms of the probability and magnitude of that harm. Risks to participants must be minimized and must be reasonable in relation to anticipated benefits to participants and the importance the knowledge that may reasonably be expected to result.

**Serious adverse event (SAE)**-An [AE](http://intranet.cdc.gov/od/ocso/osrs/hrpo/guides/hrpo-glossary.htm#adverse event#adverse event) that results in death, is life-threatening (at the time of the event), requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect. An AE may also be considered serious if it jeopardizes the participant or requires intervention to prevent one of the other outcomes listed.

**Serious noncompliance**-Noncompliance that results in increased risk to participants or reflects a failure to apply substantial portions of governing regulations. Serious noncompliance must be reported promptly.

**Severe/severity**-The graded level of intensity of an AE and its interference with usual social and functional activities, often standardized in toxicity tables. Grade levels generally include normal, mild, moderate, severe, life-threatening, and fatal.

**Social and behavioral research**- refers to studies involving human participants that are not primarily seeking to understand or observe purely physical processes related to health, or to test devices or drugs in order to improve measurable health outcomes by means of biomarkers. More ositively, social and behavioral research seeks through a wide variety of methodologies to understand human behavior, including psychological processes (cognition, emotion, temperament, and motivation), biosocial interactions, and social influences on individual and group behaviors. Terms such as ‘qualitative research’ and ‘social and behavioral studies’ are also used interchangeably to describe the same domain, though some social and behavioral studies can also incorporate quantitative approaches and involve direct interventions. While many social and behavioral studies are health related, they commonly use approaches standard and distinctive for the disciplines of, for example, anthropology, sociology, or psychology

**Species**- A group of organisms capable of interbreeding freely with each other but not with members of other species.

**Sponsor-** a person or other entity that initiates a clinical investigation, but that does not actually conduct the investigation.

**Suspend/suspension**-Temporary cessation of research-related intervention or interaction with participants and obtaining or using identifiable private research information. Partial suspension halts some but not all such activities, for example when enrollment is stopped but follow-up continues with enrolled participants. A suspension must be reported promptly unless the suspension results from expiration of IRB approval.

**Technology**- Technology is deﬁned as any modiﬁcation of the natural or designed world developed to fulﬁll human needs or desires.

**Terminate/termination**-Permanent cessation of research-related intervention or interaction with participants and obtaining and use of identifiable private research information. A termination must be reported promptly unless the termination results from expiration of IRB approval or withdrawal or closure for reasons other than research risks.

**Traditional medicine (TM**): It is the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.

**Understandable language**-generally 8th grade reading level or lower/higher depending on targeted population.

**Undue influence**-An excessive, unwarranted, inappropriate, or improper reward intended to motivate study participation.

**Unexpected**-Pertaining to an AE, the event is previously unobserved or undocumented in humans under the research intervention (or one substantially similar), the nature or severity of the event is not consistent with information in the relevant source documents (e.g., investigator's brochure, package insert, or non-reportable events [NRE] list), or the event is observed with higher frequency than previously observed or documented. Expectedness does not entail the ability to predict results from in vitro, animal, or other pharmacological models.

**Unlinked**-The condition of data or specimens which had been coded but for which the key linking the code to direct personal identifiers has been destroyed.

**Unrelated**-Pertaining to an AE, the condition in which the event is due to a documented cause other than research procedures.

**Verbal consent**-Consent obtained by communication in words; this may include spoken or written format.

**Voluntary/voluntariness**-Freedom from coercion and undue influence.

**Vulnerable**-Having reduced capacity to offer free and informed consent due to possible coercion, undue influence, or other diminished autonomy, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons as vulnerable. Vulnerability may be associated with other characteristics such as age, health status, or social standing. The IRB must ensure additional safeguards protect the rights and welfare of vulnerable persons.

**Vulnerable population**-A group identified by one or more common characteristics associated with reduced capacity to offer free and informed consent.

**Waive/waiver**-Temporarily set aside the requirement of a particular rule, regulation, or condition in a protocol or consent document.

**Withdraw/withdrawal**-Permanently halt a research study after submission for IRB review but before human participants become involved, whether or not the study has been reviewed by an IRB. This term has been replaced by the term close/closure.

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# SECTION I. HUMAN HEALTH RESEARCH ETHICS REVIEW GUIDELINE (6TH EDITION)

# General

## Background

Research involving human participants may have existed on Earth for several millennia, albeit the research may have been unscientific, uncoordinated, unmonitored, and largely unethical. Some of these experiments have survived the test of time and are still used wholly or in part, in modern healthcare and services. The development and safety of health-related services and practices evolved from experiments on self, other animals, and people in the community, although the ethics were far from acceptable in most cases.

On the other hand, the moral principles of ancient philosophers and practitioners are still used in modern day medicine, as well as in the field of ethics. One such example is the use of the Hippocratic Oath taken by physicians and health practitioners, though recently, the Oath has been challenged by contemporary philosophers and ethicists.

In Ethiopia, health research has been and is still being carried out by various sectors including government and private organizations, pharmaceutical agencies, civil societies, nongovernmental organizations bilateral and multilateral agencies including United Nations (UN) agencies, and faith-based organizations. These organizations have been conducting research of their interest independently or through collaborations with institutions such as medical and paramedical schools, research institutes, drug control agencies, and others.

To disseminate these research findings, the grounds for formal peer-reviewed health research publication was laid by the Ethiopian Medical Journal in 1962. Other peer-reviewed scientific journals followed suit.

Commitment of the government towards research, research ethics and innovation has been expressed in various undertakings throughout the years. These undertakings include:

Endorsement of a constitution and legal codes that protect the well-being, welfare, and autonomy of its citizens, while also protecting the right to intellectual and academic freedom, as well as the pursuit of knowledge

Establishment of medical and public health colleges since 1952, the Central Research Laboratory in 1942 which is currently named as EPHI, the Institute of Pathobiology in 1966, the Armauer Hansen Research Institute in 1969, the Demographic Training and Research Center in 1982, the Ethiopian Academy of Sciences and recently, the Ethiopian Biotechnology Institute.

Introduction of Ethics Review Committees (ERC) at the university level in the 1970s to protect the rights, safety, and welfare of research participants and to ensure independent review of protocols before commencement of research activities.

Establishment of the Ethiopian Science and Technology Commission (ESTC) in 1975, with the mandate to guide, coordinate, and facilitate all Science and Technology-related activities including health-related activities. ESTC was later changed to the Ethiopian Science and Technology Agency (ESTA) to lead the development and application of science, technology and innovation in Ethiopia, and further coordinate, regulate, and oversee research. On October 24, 2008, under proclamation No. 603/2008’, ESTA was formally renamed as the Ministry of Science and Technology (MoST) by the Federal Democratic Republic of Ethiopia (FDRE). On 29th November, 2018, under Proclamation No.1097/2018the Ministry of Science and higher education was established.

Development of a National Research Ethics Review Committee and the now dissolved, National Health Research Council, were formed to lay the foundation for standardized protection of human participants in research. National Health Research Ethics Review Guidelines were first developed in 1995 by the former ESTC. The guidelines were revised four times since its first release in 1995. At the institutional level, standard operative procedures (SOPs) for research ethics review came into practice by organizations that include, MoSHE, the Addis Ababa University Medical Faculty Institutional Review Board (AAUMFIRB), Armauer Hansen Research Institute (AHRI), Ethiopian Health and Nutrition Research Institute (EHNRI), and the Ethiopian Public Health Association (EPHA).

Launching a Health Science and Technology Policy in which the country’s health research priority areas were explicitly listed as policy directives. The Health Science and Technology Policy in article 2.2.2.2 states the need *“to enhance the monitoring and coordination of Health Science and Technology activities and the practical implementation of research outputs*.” This Health Science and Technology Policy in article 4.3.5 further stresses the need to *“Organize an ethical committee to review the ethical aspects and procedures of research undertakings as required”* as one strategy. In addition, article 4.3.6 emphasizes the need to “encourage institutional peer reviews….”,

Founding the Drug Administration and Control Authority in 1999 which was renamed the Food, Medicine and Health Care Administration and Control Authority (FMHACA) and recently named the Ethiopian Food and Drug Authority.

Declaration of the potential allocation of 1.5% of the gross national income or gross domestic product (GNI/GDP) to research in various disciplines.

To regulate and provide oversight for health research in light of its increasing landscape, complexity, and sophistication, MoSHE established a committee of professionals with expertise in the field of bioethics to review the existing guidelines. The experts reviewed local and international standards, guidelines, instruments, and procedures related to bioethics. Furthermore, opinions and suggestions were solicited from a dozen highly educated, ethically experienced, reputable professionals in the country. The shortcomings and strengths of the existing guidelines, extent of decentralization of protocol review, mandates of the National Health Research Ethics Committee (NHREC) and Institutional Review Boards (IRB), terminology, operative procedures, and general suggestions from these dozen professionals, was sought using a semi-structured tool. All efforts were made to strike a balance in accommodating the experts’ sometimes differing opinions and suggestions for these guidelines.

Moreover, the draft guidelines were discussed with a wider group of experts and representatives drawn from MoSHE, HRERC, Ministry of Health, EFDA**,** IRBs of universities and research institutions, international and UN agencies, and other relevant stakeholders. The comments and recommendations from this nationwide consultative meeting were analyzed and incorporated before this guideline was endorsed and released for use to safeguard the rights, safety and welfare of research participants and for oversight of research in Ethiopia.

## 1.2. Introduction

*“Research is a systematic investigation including research development, testing, and evaluation designed to contribute to generalizable knowledge.”* Nevertheless, as a matter of principle, in research involving human participants, the well-being of the participants takes precedence over the interests of society and the knowledge to be gained.

*“Human subject [research participant] is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information.”* Besides, research participants may include pregnant women where fetuses, fetal material, or abortuses as the primary subjects of interest. Similarly, research involving autopsy materials shall also be included as sources of data.

The main purpose of health research involving human participants is for better understanding of the epidemiology, etiology, pathogenesis, and pathophysiology of disease and the related diagnostic, preventive, promotive, and therapeutic procedures and measures. Moreover, evidence-based practice has become necessary at the turn of the 21st century, and quite understandably, existing procedures and practices are challenged continuously for their effectiveness, efficiency, quality, accessibility, and acceptability by the community.

However, in the quest to ensure better health and knowledge, the rights, safety and welfare of research participants must be protected at all times. Participation must be voluntary and free of coercion, persuasion, manipulation, deception, undue influence or inducement, and threat or intimidation. The information shall be obtained in a private setting whenever necessary and confidentiality maintained throughout the lifetime of the research. This is even more important when research involves participants whose comprehension and decision making is compromised because of age, lack of knowledge on medical concepts and technological terms, or severe mental or behavioral disorders.

For all research involving human participants and human biological materials/specimens, investigators should be aware of, and are obligated to, respect and adhere to all ethical, legal, and regulatory requirements applicable in Ethiopia.

In this rapidly advancing, complex, and sophisticated era of genetic studies, preventive, diagnostic, and therapeutic clinical trials, as well as collaborative research and human biological material transfer being common place, oversight and regulation is imperative to properly safeguard the rights, safety and welfare of human research subjects.

For research to be ethical, all of the following eight criteria must be met:

**Ethical justification and scientific validity:** The research must be rigorous in its methodology. For research to be ethical, the methods must be valid and practically feasible, the research must have a clear objective, be designed using sound scientific principles, have sufficient statistical power, and be based on adequate knowledge of the scientific literature.

**Science and social value:** The proposed protocol should demonstrate valid scientific basis/ground, enhance health or generalizable knowledge, and benefit individuals and the community where the research is conducted. However, the research participants’ rights and welfare outweigh any benefit to the society or gain in knowledge.

**Favorable risk-benefit ratio to research participants and their communities:** Risks to subjects shall be minimized through using procedures that are consistent with acceptable research design and potential benefits enhanced. The maximum benefit should be provided at the lowest possible risk, and risks to research participants shall be reasonable in relation to anticipated benefits.

**Fair selection and enrollment of human participants:***“Scientific objectives, not vulnerability or privilege, and the potential for and distribution of risks and benefits, should determine communities selected as study sites and the inclusion criteria for individuals…”* The justification for selection and the equitable nature of selection of research subjects should be described.

**Privacy and confidentiality:** Privacy should be respected, confidentiality maintained, the opportunity to withdraw at anytime or refuse any component(s) of the research should be available, and the well-being of research participants should be monitored, while information related to research participants should be kept confidential.

**Independent/IRB review:** “*Individuals that are not affiliated with the research must review the research and approve, amend, or terminate the research.*” However, individuals involved in independent review with any conflicts of interest may be summoned to provide information to the IRB.

**Informed consent process:** The information provided to research participants should be complete and appropriate to the participants’ level of understanding. The participant should be competent to give or refuse consent and research participants should provide their entirely voluntary informed consent without coercion, manipulation, undue influence, or intimidation.

**Community engagement:** Research is quite often generalized to the community from which individual participants are drawn from. Such generalization can result in different positive or negative impacts to the community in terms of stigma, resource drainage, health outcomes, and more. Hence, researchers are encouraged to involve the community in decision making about the design and conduct of the study. Besides, investigators should consider the local customs, traditions, culture and religious practices of the community where the research is proposed to be conducted.

## 1.3. Preamble

MoSHE attaches the highest priority to maintaining high standards of integrity, responsibility, and accountability in all research conducted in Ethiopia.

In addition, MoSHE obligates that *‘Research with human subjects should be carried out only by or strictly supervised by, suitably qualified and experienced investigators and in accordance with a protocol that clearly states the aim of the research, the reasons for proposing that it involves human subjects, the nature and degree of any known risks to the subjects, the sources from which it is proposed to recruit subjects, and the means proposed for ensuring that subjects' consent will be adequately informed and voluntary. The protocol should be scientifically and ethically appraised by one or more suitably constituted review bodies, independent of the investigators.’*

MoSHE ensures that these guidelines basically operate within the legal framework of Ethiopia and that the IRBs operate independently and without influence and coercion. Furthermore, MoSHE demands that membership of IRBs/ERCs should be large enough to ensure a robust discussion of protocols. Additionally, IRB/ERC membership should have a healthy mix of representation by different genders, disciplines, sectors, and laypersons.

While this document focuses primarily on guidelines for IRBs/ERCs, it emphasizes that attention shall be given to the wider system of human research participants’ protections of which IRBs are a part. These guidelines empower IRBs to perform effectively and efficiently with best intentions. The review guidelines are developed to operate in the existing research systems with the following objective realities**:**

Constitutional and legal rights, relevant policies related to health and science research exist.

These guidelines are executed under the Law of Ethiopia. IRBs operate under explicit legal authority.

All research with human participants is subject to the oversight of an IRB/ERC.

MoSHE has the primary responsibility for ensuring that IRBs/ERCs are subject to adequate oversight.

Mechanisms are in place to ensure IRBs/ERCs work effectively and efficiently. IRBs/ERCs are part of a larger research participant protection programs that also include training of IRB/ERC members and investigators.

Procedures exist to ensure clear and efficient communication, harmonization of standards, networking, and cooperation among the EFDAand other IRBs/ERCs, and between different levels of review and publication committees in departments/units of institutions. In addition, procedures exist for the coordinated review of multi-site research within Ethiopia or international collaborative research.

Mechanisms exist to ensure that IRB/ERC activities are coordinated with national regulatory authorities’ oversight of drugs, vaccines and medical devices.

Mechanisms are created for obtaining community input into the ethics review system.

A system exists for registration and accreditation of IRBs that operate in Ethiopia.

MoSHE attaches emphasis that this guideline is part of an effort to establish, facilitate and strengthen an effective health research system in Ethiopia. The aim of the health research system is to advance and use scientific knowledge to improve health and health equity. The key functions of this health system research are stewardship, of which research ethics is a part, finance of the systems, creation of and sustaining resources, and production and use of knowledge. Hence,

**Understanding and considering**

The shortcomings of the existing guidelines in the face of the widening landscape of research areas, complexity of research procedures, and evolvement of genetic studies, genomics and biobanks

The critical importance of establishing a strong health research system,

The relevance and responsibility of ensuring standardized research ethics review all over Ethiopia,

The need to ensure independence of IRB/ERC operations and decision-making from influence by anyone who sponsors, conducts, or hoststhe research it reviews,

The need for ensuring networking and collaboration of IRBs/ERC, both local and international,

The increasing number of health teaching institutions and with them the number and quality of research,

Evidence-based practice is the order of the day, and

**Cognizant of**

The rapidly advancing and complex research related to genetic, biomedical science, and transfer of human biological materials,

The increasing number and scope of collaborative studies by numerous investigators and institutions within and outside of Ethiopia, and with the existing policy, academic and administrative environment, the increasing interest of donors to sponsor research in Ethiopia,

Research participants’ protection, that should involve not only research protocol review, but also ethically sound research participant-investigator interactions, continuous safety monitoring, adherence to approved protocol, and quality improvement in research,

The duty to ensure mechanisms to make IRB/ERC operations transparent, accountable,consistent, and of high quality; establishing mechanisms for IRBs/ERCs to employ reliable means to evaluate whether the staff and members routinely follow the IRB/ERC policies, rules and guidelines; the need for both internal and external evaluation; the demand to address complaints and grievances from all parties involved in research (researchers, research participants, communities, sponsors, and others),

The need for extra protection of research participants in humanitarian emergencies, marginalized and vulnerable populations including aging or geriatric people

The absence of guidelines for research conducted from clinical records, alternative and traditional medicine,

The emerging issues of data sharing e-research, e-health and controlled human infection models,

That research should be carried out in full compliance with, and awareness of, standards, laws, regulations of the country, as well as local customs, community, and the mix of social, traditional, and cultural diversity,

MoSHE developed this National Health Research Ethics Review Guidelines to safeguard the rights, safety and welfare of all human participants in all research proposed to be conducted in Ethiopia, based upon the Health Science and Technology Policy and the responsibilities assigned to MoSHE.

No other guidelines and requirements are allowed to diminish or remove any of the human research participants’ protections set forth in this National Health Research Ethics Review Guidelines.

## 1.4. Scope of Application

These Guidelines are applicable to all types of research that involves human participants, including but not limited to:

Studies of a physiological, biomedical, biochemical, or pathological processes

Genetic research, clinical trials, pharmaceutical, and other investigational products

Research studies involving clinical records or other personal information

Public health and epidemiological research

Health systems and implementation research

Quality improvement research

Human health related social-behavioral research, research on medical and paramedical education, and research related to traditional healing.

Technology based health research

It also includes research that may include one or a combination of observations; interviews, internet-based, mail-based, and telephone research; focus group research; survey and research with biological samples. Furthermore, the guidelines are applicable in research proposed to be conducted by all sectors and organizations. These include, but are not limited to, public, private, faith-based, indigenous and international non-governmental organizations (NGOs), bilateral, multilateral, and United Nations’ agencies.

# 2. Objectives

## 2.1 General Objective

To safeguard the rights, safety and welfare of research participants through respecting the participants’ autonomy, protecting the participants from risk related to research, and ensuring that individual and/or community benefits and fairness are maintained.

## 2.2 Specific Objectives

2.2.1 To ensure the rights and autonomy of research participants are respected and that participation or otherwise in research, is entirely voluntary

2.2.2 To safeguard research participants from unnecessary/unjustifiable risk

2.2.3 To ensure fair selection of research participants and fair distribution of benefits and risks

2.2.4 To create awareness among investigators, sponsors, reviewers, decision and policy makers, and individuals/communities on basic ethics principles

2.2.5 To ensure that research holds/embraces/possesses/considers social and cultural responsiveness/sensitivities for participating individuals and communities

2.2.6 To ensure the scientific integrity, ethical standards, and appropriate procedures for the conduct of research involving human participants

2.2.7 To monitor and evaluate ongoing and post-research ethical implications and benefits to the participants and the community at large

2.2.8 To provide extra protection to research participants in humanitarian crisis,

vulnerable and marginalized populations including aging people

2.2.9 To address ethical issues related to controlled human infection models, data

sharing, e-research and e-health, clinical records, alternative and traditional

medicine

2.2.10 To put in place legal considerations against research investigators/ studies undertaken prior to appropriate ethics review or unethical implementation of studies.

# 3. Ethical Principles

High ethical standards in health research can be achieved only when investigators aspire to such standards in their research activities. To safeguard the rights, safety and welfare of human subjects in research, all Ethics Review Committees (ERCs) and Institutional review committees (IRBs), shall promote three basic ethical principles: 1) respect for persons 2) beneficence/non-maleficence and 3) justice. In general, HRERCshall ensure that investigators have thought of ethical issues, specifically that no ethically acceptable harm will be done, and no resources are wasted in the name of research, regardless of the research question planned for exploration. However, in certain circumstances, the weight given to each of these three basic ethical principles may differ in accordance with the type of the research and the setting where the research is conducted. Nevertheless, the IRB/ERC should ensure that the following basic ethics principles are met.

## 3.1. Respect for Persons

Out of respect,participants must be informed about the research and allowed to decide about participation. Research participants unable to make decisions independently deserve extra protection.

3.1.1 Autonomy - This principle aspires to protect the interests of human research participants from physical, psychological, and cultural harm. It refers to the obligation on the part of the investigator to respect each research participant as a person capable of making an informed decision regarding participation in the research study. It obligates investigators to respect the rights of human subjects to hold their views, make choices and take actions without controlling influences. For human subjects who are not capable of making an informed decision because of age, mental, or medical capacity, the next of kin or guardian shall make the decision in the best interest of the research participant.

3.1.2 Informed Consent – The importance of informed consent of research participants is unquestionable and the informed consent should be analyzed in terms of containing the basic elements of information, comprehension, competence, disclosure, and voluntarism. Information shall be given in writing and signed or verbally approved by the research participant. The information to be provided should be written or verbal in a way that considers the local culture and values, as well as the level of understanding of the research participant. The information provided should weigh the research participants’ competence. When informed consent is that of a third party (proxy; parent, next-of-kin, legally authorized representative (LAR)), the reasons for the indirect approach shall be stated and become part of the protocol.

Research participants or persons giving proxy consent cannot give full informed consent unless the consent process/form contains adequate information. All such information shall be expressed in a language that is understandable to the participant. Generally, the study information sheet (SIS) and consent form should explicitly indicate the points mentioned in **Section 6.13**below**.**

## 3.2. Beneficence/Non-maleficence

The principle of beneficence refers to the obligation on the part of the investigator to attempt to maximize benefits for the individual participant and/or community, while minimizing risk or harm to the individual/community. As much as possible, beneficence also considers inflicting no harm and removing harm. An honest and thorough risk/benefit assessment must be performed. Balancing the risk and benefit of the research is indispensable in the design and conduct of the research.

Risk is the probability and magnitude of some future occurrence of harm. Harm is injury and setback to interests as a result of being a research participant. Risks and harm can be known or presumed. And, although no specific regulations exist, risks and harm may include physical, psychological, emotional, economic, educational, legal, and social.

In addition, beneficence includes whether the usual care is changed or manipulated to inflict no harm, minimize harm, remove harm, and maximize the benefit to research participants and to the community, or both.

Researchers should always abide by maleficence and no intentional harm should be inflicted on participants.

## 3.3. Justice

Justice connotes fairness and equity in the distribution of the benefits and burdens of research to participants.

3.3.1 Justice demands equitable selection of participants, i.e., avoiding populations that may be unfairly coerced into participating, including but not limited to, prisoners, pregnant women, fetuses, newborns, children people with mental and physical disabilities, immigrants, refugees, ethnic minorities, marginalized groups and institutionalized persons. There must be a justification for inclusion of these vulnerable groups in the research. There should be no disproportionate use of vulnerable populations. The same recruitment approach should be used in all populations. Injustice may arise when selecting participants from a specific socio-economic class, age, sex, racial, cultural, religious, creed, and institutional make up.

3.3.2 The principle of justice requires equality in the distribution of benefits and burdens among the population groups likely to benefit from the research. Distributive justice means that no segment of the population should be unfairly burdened with the harms of research. It thus imposes obligations toward individuals who are vulnerable and unable to protect their own interests. Conversely, distributive justice imposes duties neither to neglect nor discriminate against individuals and groups who may benefit from advances in research.

3.3.3 Justice also demands balancing the benefits and burdens to the community where the research is undertaken.

3.3.4 In addition, the investigators shall assure that information obtained in the course of the investigation remains confidential to protect participants from possible harm. Data unlinked from individuals or groups does not jeopardize confidentiality. The privacy of individual participants also needs to be protected throughout the investigation by the investigators.

# 4. Institutional Authority and Purpose

## 4.1. Institutional authority

HRERC and IRBs are established under the authority of the Ministry of Science and Higher Education (MoSHE), but function independently.

The MoSHE requires all research involving human participants or human biological materials to be reviewed and approved by HRERC or one of the MoSHE registered and accredited IRBs prior to initiation of any research-related activities, including recruitment and screening of participants.

## 4.2. Purpose of HRERC, IRBs/ERCs

The HRERCand IRB’s/ERC’s objective is to protect the rights, safety and welfare of human participants in biomedical and social-behavioral research. The IRB/ERC reviews and oversees human participant research to ensure that it meets the ethical principles cited in these guidelines, EFDA regulations, and that it complies with legal requirements and other pertinent regulations, guidance, and local laws.

4.2.1 The HRERCand IRB’s/ERC’s duty is to inform and assist the investigators and advisors on ethical and procedural standards related to the use of human participants in research, to facilitate compliance with this guidelines, Ethiopian law, and international regulations.

However, the primary responsibility for assuring that the rights and welfare of individuals are protected rests upon the investigators conducting the research. Others engaged in the conduct of the research including host institutions and sponsors share this responsibility. Faculty advisors serving as Principal Investigators (PIs) to students who conduct research have an obligation to carefully consider whether the students are qualified to safeguard adequately the rights and welfare of participants.

4.2.2 The HRERCand IRB/ERC have the authority to ensure that research studies conducted under its jurisdiction are designed and conducted in a manner that protects the rights, welfare and privacy of research participants. Specifically:

The HRERCand IRB/ERC reviews, and has the authority to approve, require modification in, or disapprove all research activities that fall within its jurisdiction.

The HRERCand IRB/ERC have the authority to conduct continuing review as it deems necessary to protect the rights, welfare, and privacy of research participants, including requiring progress reports from investigators.

The HRERCand IRB/ERC may suspend or terminate approval of a study not being conducted in accordance with the HRERCand IRB’s/ERC’s requirements or that has been associated with unexpected serious harm to participants or others.

The HRERCand IRB/ERC have the authority to observe or have a third party observe the informed consent process and/or audit the progress of any study in its jurisdiction as it deems necessary to protect the rights and welfare of human participants.

The HRERCand IRB/ERC may place restrictions on a study.

## 4.3. Use of Policies and Procedures

The HRERCand IRB/ERC members and its Secretariat staff must maintain and follow all written policies and procedures consistent with Ethiopian regulations, good clinical practices, good manufacturing practices, and biomedical ethics when reviewing proposed research.

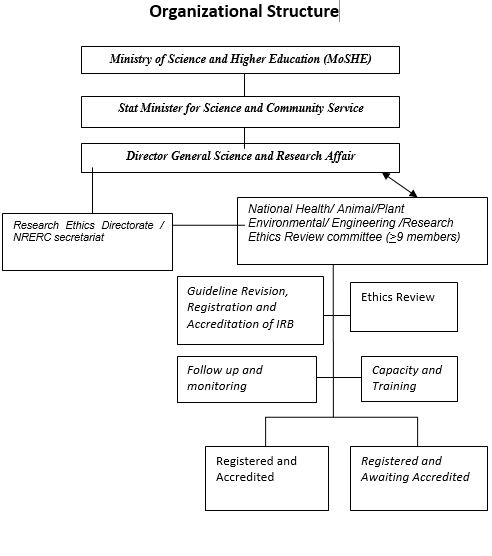
# 5. Ethics Review System

The MoSHE through the Attorney General shall ensure that health research ethics review is supported by an adequate legal framework.MoSHEshall strive to put in place an appropriate and sustainable system to monitor the quality and effectiveness of research ethics review. In addition, MoSHE is responsible to ensure existence of mechanisms for networking and cooperation among IRBs/ERCs at different levels, as well as IRBs/REC of international standing in collaborative research.

All health research involving human participants must undergo review by the HRERCor an independent IRB. In Ethiopia, IRB/ERC are established at three levels: National Health Research Ethics Review Committee (HRERC), Institutional (registered and accredited and registered and awaiting accreditation). The composition and mandates of these ERCs are stated below. It is important to note that decentralization of the activities of the NHRECand subsequent establishment of new and empowerment of already existing IRBs/ERCs shall be realized.

## 5.1. Organizational Structure

To effectively and efficiently deliver research ethics review services, functional and structural arrangements are established at the National, and Institutional levels as depicted in the Organogram below.



## 5.2. Health Research Ethics Review Committee (HRERC)

The purpose of the HRERCis to safeguard the dignity, rights, safety, and welfare of all actual or potential research participants and/or communities. The HRERCis mandated to review research protocols and the supporting documents on their scientific and ethical merit. Furthermore, the HRERCis mandated to assure that proposed research complies with the health research directives as stipulated on the Health Science and Technology Policy.

5.2.1 Composition

Shall have members with professional competence and mix of varying backgrounds, gender representation, balanced age , a community representative, research ethics training and experience.

Minimum number of members is nine(9).

The details are described in **Section 6.3** below.

5.2.2 Mandates and Functions of HRERC

5.2.2.1 Regularly update research review guidelines and SOPs

5.2.2.2 Recommend registration and accreditation of IRBs/ERCsby MoSHE

5.2.2.3 Solicit funds to build its capacity and other IRBs/ERCs

5.2.2.4 Organize and deliver research ethics training to IRBs and develop standardized training materials for countrywide use

5.2.2.5 HRERCProtocol Review - The HRERCis responsible for giving final ethical decisions on:

Experimental research which is carried out by a national agency or agencies with international collaboration.

Review emergency / humanitarian crisis research projects that are of national interest and priority

5.2.2.6 Umpire complaints, disputes, appeals and grievances on functions and review processes of IRBs submitted by researchers or institutions.

5.2.2.7 Monitor and evaluate all IRBs/ERC

5.2.2.8 Facilitate experience sharing among local and international IRBs/ERC.

5.2.2.9 Facilitate international registration of accredited IRBs/ERCs such that their reviews are accepted by funding agencies.

5.2.2.10Policy-advocacy and creating community awareness on ethical principles in research, and legal and regulatory reforms, and changes related to research involving human participants.

## 5.3. AccreditedIRBs/ERCs

These are IRBs that are registered and accredited by HRERC (MoSHE), and have the capacity to review, monitor, document research protocols and undertakings involving humans in institution where they are based, or other institutions that do not have their own IRBs and beyond. Similarly, IRBs shall be capable of safeguarding the rights, safety, and welfare of human research participants.

5.3.1 Composition

Shall have members with professional competence and a mix of varying backgrounds, gender representation, balanced age, a community representative, research ethics training, and experience similar to or equivalent with the HRERC.

Minimum number of members is seven (7).

5.3.2 Mandates and Functions

5.3.2.1 Organize and deliver research ethics training.

5.3.2.2 Regularlyupdate their SOPs

5.3.2.3 Submit bi-annual report to HRERC

5.3.2.4Once a proposal is reviewed and approved by an IRBs/ERCs that is accredited, there is no need for multiple review

5.3.2.5 Review and approve all research protocols including :

All clinical trials involving new drugs, or new combinations of drugs, vaccines, new therapeutic regimens, and cells and other biological products as well as invasive diagnostic procedures. For all research that involves investigational products, authorization and monitoring by EFDA is a requirement before submitting a protocol for review and approval.

Multi-center collaborative research, including student theses (MSc, PhD, specialization studies) that inherently exhibit more than minimal risk,

Review SAEs and Unexpected events

Genetic research, stem cell research

Projects that require transfer of human biological materials (samples/specimens).HRERC/MoSHE will write a letter to Customs commission at the time of shipment of samples abroad

Investigation of new devices, drugs or vaccines not registered for use in Ethiopia

5.3.2.6 Solicit funds to build its own capacity

## 5.4. Registered IRBs/ERCs

These are IRBs that have the capacity to review, monitor, and document research protocols and undertakings involving humans from the institution where they are based or other institutions that do not have their own IRBs, according to the mandates and functions stated below. Similarly, theseIRBs shall be capable of safeguarding the rights, safety, and welfare of human research participants. These IRBs/ERCs are not accredited. These IRBs may not have the expertise and experience of accredited IRBs, in which case the protocols can be reviewed by HRERC.

5.4.1 Composition

Shall have members with professional competence and a mixof backgrounds, gender representation, balanced age, a community representative, research ethics training, and experience,which may not be similar to or equivalent with HRERCor accredited IRBs.

Minimum number of members is five (5)

5.4.2 Mandates and Functions

5.4.2.1 Organize and facilitate research ethics training

5.4.2.2 Develop SOPs that govern the IRB’s/ERC’s research review procedures.

5.4.2.3 Submit progress report of the IRB’s functions annually to the HRERC.

5.4.2.4 Manage the AE related with research reviewed and approved by the IRB/ERC.

5.4.2.5 Review and approve research protocols, except protocols that are stated under5.3.2.5.

5.4.2.6 Solicit funds to build itsown capacity

## 5.5. Private/ Civil Societies IRBs/ERCs

These are IRBs that have the capacity to review, monitor, and document research protocols and undertakings involving humans from the institution where they are based or other institutions that do not have their own IRBs, according to the mandates and functions stated below. Similarly, these IRBs shall be capable of safeguarding the rights, autonomy, rights, safety, and welfare of human research participants. These IRBs may not have the expertise and experience of accredited IRBs, in which case the protocols can be reviewed by HRERC.

### 5.5.1. Composition

Shall have members with professional competence and a mix of gender representation, a community representative, research ethics training, and experience, which may not be similar to or equivalent with NHERECor accredited IRBs.

Minimum number of members is five (5)

### 5.5.2 Mandates and Functions

5.1.2.1 Organize and facilitate research ethics training

5.1.2.2 Develop SOPs that govern the IRB’s/ERC research review procedures.

5.1.2.3 Submit progress report of the IRB’s functions annually to the HRERC.

5.1.2.4 Manage the SAEs related with research reviewed and approved by the IRB/ERC.

5.1.2.5 Review and approve research protocols that are not mandated to accredited IRB/ERC and HRERC.

5.1.2.6 Solicit funds to build its own capacity

## 5.6. Secretariat of the HRERC

The Director of research ethics Directorate of MoSHEis the Head of the Secretariat and is thesecretary and voting member of the HRERC.

**Responsibilities of the Secretariat:**

Receive research protocol applications from IRBs/ERCs, Institutions, organizations.

Ensure the completeness of application documents for ethical review.

Distribute protocols to its SOP

Facilitate regular and extraordinary meetings in consultation with the Chairperson of the HRERC.

Communicate decisions of the HRERCto the applying institution with a copy to the PI.

Archive all project-related protocols, correspondence, decisions and minutes of the NHREC.

Send reminders and receive periodic progress reports from investigators’ Institution

Receive annual and bi-annual reports from IRB/ERCs

Organize bi-annual meetings with accredited IRBs/ERCs and HRERC

Organize annual research ethics conference

Facilitate the accreditation and registration of IRBs based on the recommendation of the HRERC

Propose revision criteria for registration and accreditation of IRBs/ERCs.

Support networking among the HRERCand other IRBs/ERCs.

Facilitate the monitoring and evaluation of the ethical implementation of research.

Organize, support,and facilitate the conduct of research ethics training at National and Institutional levels.

Manage and facilitate all official correspondence of the HRERC.

Facilitate collection of review fees from research review applicants

Solicit funds for realization of the duties of the HRERC.

Request for renewal of approval date will be managedaccording to the SOP

Register and maintain database of all ongoing and completed health research under the oversight of IRBS/ERCs that are registered

## 5.7. HRERCOffice

5.7.1 Physical Location and Security - The HRERCshould have a dedicated office located in the premises of MoSHE

5.7.2 Only the HRERCSecretariat should be authorized to have access to the HRERCdocuments unless ordered by a court of law.

5.7.3 HRERCdocuments should be kept in locked cabinets and secured electronic copies which will only be accessed by authorized personnel.

## 5.8. HRERCOperations

5.8.1 The HRERCoperations office should be spearheaded by the HRERCSecretariat as per instructions from the HRERCthrough the Chairperson or his/her designate.

5.8.2 The HRERCoperations office should be separate and independent of the administration of MoSHE

5.8.3 Applications to the HRERCmust be channeled through the HRERCSecretariat.

5.8.4 All decisions and communication from the HRERCto the applicant must be conveyed through the Secretariat.

## 5.9. Registration and Accreditation of IRBs/ERCs

5.9.1 All IRBs/ERCs in Ethiopia have to be registered by HRERC secretariat

5.9.2 IRBs/ERCs which fulfill the requirement set by HRERC will be accredited by HRERC secretariat

5.9.3 Renewal of registration of all IRBs shall be done every twoyears from the date

of registration or renewal of the IRB.

5.9.4 Re-accreditation of IRB/ERC shall be done every three years

5.9.5 Following registration, a letter of registration shall be issued by the secretariat

5.9.6 Following accreditation, a letter of accreditation shall be issued by the Secretariat When IRB members are replaced for any reason, these outgoing members shall benotified in writing. The reason for replacement ofmembership shall be clearly described in the letter.

5.9.7 Review procedures, TORs, and the review forms should be standardized.

5.9.8 The minimum acceptable number of members on any IRB is five. No IRB can

have even numbered members for the sake of decisions, particularly when there is a need

to vote.

5.9.9 IRBs shall have members with a varied professional mix, gender and age

balancedand community representation. No IRB can be composedentirely of asingle

profession, similar gender, or without a community representative.

# 6. Establishment, Functions, Review Procedures

## 6.1. Definition

Institutional Review Boards(IRBs)/Ethics review committees (ERCs) are independent committees established in an institution to conduct initial and continuing review of research projects with the primary goal of protecting the rights, safetyand welfare of research participants. All institutions in Ethiopia that conduct research involving humans as research participants should set up IRBs/ERCs in accordance with these guidelines. Where an institution cannot set up an IRB, that institution may rely on an IRB of another institution to review their research projects, provided the IRB is registered by the HRERC

## 6.2. Establishment

6.2.1 Appointing Authority

The Head of the Institution is the authority responsible for the appointment of IRB/ERC members. In cases where members come from diverse institutions, the appointment should be upon the recommendation of the institution where the potential IRB/ ERCmember is based.

Members are selected in their personal capacities based on their scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and efforts for the Board’s/Committee’s function.

Appointments should consider age and gender distribution, and relevant but diverse professional representation.

The appointing authority should write an appointment letter to the prospective member inviting him/her to be a member of the IRB. The appointment letter should indicate the term of service

Members will sign a confidentiality agreement and conflict of interest (CoI) form.

6.2.2 Applying forregistration of an IRB/ERC

An institution that needs to get an IRB/ERCregistered shall apply in writing for approval and registration at the National Secretariat at MoSHE, and include the following requirements: -

Statement that the IRB will follow the guidelines as stipulated in this document, law, relevant regulations.

A list of IRB members identified by name, qualifications, profession, updated CV, representative capacity; any changes, in due process or in IRB membership must be reported to the secretariat.

Written SOPs for the activities of the IRB: composition of IRB members; conducting initial and continuing review of research, and for reporting its suggestions/opinion and decisions to the investigator and the institution; expedited review process; follow-up and monitoring of approvedstudies.

The HRERCSecretariat presents the application to the HRERCwho shall examine the institution’s application, and if satisfied, will approve the registration.

## 6.3. Composition

The IRB should consist of a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed research.

Each IRB shall be composed of at least five (5) members, with varying backgrounds to ensure complete and robust review of research activities commonly conducted by the institution. It must be multidisciplinary and multi-sectoral in composition, including persons with relevant but diverse scientific expertise, balanced age and gender distribution, and who have the qualifications and experience to review and evaluate the scientific and medical ethics aspects of research protocols.

All IRBs/ERCs shall have at least one member whose main area of expertise is in the scientific field and at least one member whose primary area of expertise is in a non-scientific field.

Each IRB/ERC shall include at least one member who is not otherwise affiliated with the institution or have a close family member working in the institution**.**

The IRB/ERC should have at least one community representative, who does not necessarily have to have any scientific expertise, but may be a layperson that represents the interests and concerns of members of the community and is familiar with the community’s values, customs, traditions, and culture.

If an IRB/ERC regularly reviews research that involves vulnerable populations,or which require special expertise the IRB shall involve or co-opt one or more individuals who are knowledgeable about and experienced in working with these research participants.

All IRB members should at the minimum take one basic training on bioethics within one year of appointment.

## 6.4. External Reviewers

If a protocol requires expertise that is beyond the competence of the IRB members or the IRB need additional opinion in the review process, the IRB may engage independent experts to review and give their opinion.

The Secretariat should keep an updated list of experts along with their CVs, which should be reviewed annually by the IRB.

Independent experts must sign privacy and confidentiality agreements and conflict of interest (COI) forms to ensure that the information in the protocol is protected and that consultants do not have any conflicts.

The IRB may ask questions that could guide the review of the experts.

The expert may be invited to attend or consult by telephone an IRB meeting, but he/she cannot vote in the meeting.

## 6.5. Independence of IRB

6.5.1 The IRB must be independent from the appointing authority, hosting institution, investigators, sponsors and any other stakeholders in its review and decision-making processes.

6.5.2 If there is any conflict of interest, COI, regarding a particular protocol, IRB members must declare their COI and excuse themselves from the review process of that particular research protocol. This is critical to ensure an objective assessment of the protocol.

COI can be declared at the time research protocols are submitted, upon receiving the IRB agenda prior to the meeting and at the beginning of each meeting.

IRB members who have a COI related to any research protocol must not participate in any initial or continuing review of that specific protocol or related matters except to provide relevant, factual information which may be requested by the IRB. The conflicted IRB member cannot deliberate or vote on those protocols or related matters.

The IRB member or invited expert with a COI will be required to excuse himself/herself from the meeting during discussion and decision.

The conflict of interest and action taken should be included in the minutes of the meeting of IRB/ERC

An IRB member or invited expert assigned to carry out an expedited review on a protocol (or related matter) for which a conflict has been identified must notify the IRB Chairperson or Secretary so that the protocol may be reassigned to another person.

## 6.6. Terms of Office

6.6.1 Membership should be for a period of three years

6.2.2 Membership may be renewed for two terms, however at least one-third of the

former members should be retained at every point in time. Thus, the maximum tenure of

IRB members is six years.

6.2.3 For a permanently employed secretariat, tenure is not limited provided he/she is

still under the employment of the IRB/ERC. If, in the event of additional qualified

personnel being hired/trained, this time limit may need to be reviewed.

## 6.7. Roles and responsibilities of IRB Members

6.7.1 Chairperson

In order to enhance independence of the HRERC, the Chairperson should not be affiliated with MoSHE. In other IRBs/ERCS, the Chairperson can be a member of the institution.

The Chairperson should be selected by the IRB/ERC members through a process of nominations followed by secret ballot voting; the committee is obliged to inform the appointing authority.

The Chairperson should have the authority to sign official IRB/ERC documents such as approval certificates.

Should the Chairperson decide to step down as Chairperson of the IRB/ERC, he/she should inform the board in writing at least one month in advance; the committee is obliged to inform the appointing authority.

6.7.2 Vice Chairperson

The Vice Chairperson should be selected using the same process as for the Chairperson.

The Vice Chairperson shouldchair meetings and sign official IRB/ERC documents when the Chairperson is not available.

The Vice Chairperson may sign official IRB/ERC documents such as approval certificates if the Chairperson is not available.

In the absence of both the Chairperson and Vice Chairperson, the IRB/ERC members should select an Acting Chairperson to chair the current meeting provided a quorum is satisfied.

The selected Acting Chairperson should sign minutes of previous meetings confirmed during his/her Chairpersonship.

The Acting Chairperson should not have authority to sign official IRB/ERC documents such as approval certificates but may sign minutes confirmed during his/her Chairpersonship.

The process of resignation should be the same as that for the Chairperson.

6.7.3 Members

Membership becomes effective upon accepting an invitation from the appointing authority. Acceptance must be indicated by the member’s dated signature.

A member should be willing to have his/her full name, profession and affiliation(s) published in the public domain.

Members are responsible for reviewing protocols to safeguard the rights, safety and welfare of study participants.

Members are responsible for reviewing progress reports.

Members are responsible for oversight visits in order to monitor ongoing studies approved by the IRB.

Members are obliged to read protocols, including ancillary documents (e.g., patient brochures, informed consent forms, project reports and SAE reports given to them by the IRB/ERC Secretariat in advance preparation of IRB meetings.

Members are obliged to keep IRB/ERC documents secure, private, and confidential.

Members should attend IRB/ERC meetings regularly and participate fully and actively in deliberations.

Members should participate in continuing education activities in health research ethics, HRE.

Members must declare any COI for any protocol and withdraw from the review of that protocol.

Members must maintain privacy and confidentiality of documents and deliberations of IRB meetings.

## 6.8. Orientation and Education of Members

New members should undergo orientation training upon joining the IRB/ERC in order to familiarize them with basic human research ethics. Such training should be organized by the IRB/ERC Secretariat, the host institutions and/or any other players involved in such training.

Continuous training of IRB/ERC members on health research ethics and other relevant areas such as Good Clinical Practice (GCP) and experimental designs should be conducted as necessary.

Updated CVs and records of training of all members should be kept on file by the IRB/ERC Secretariat in the IRB/ERC office.

## 6.9. Termination of Membership

Membership may be terminated voluntarily. The member should write a resignation letter to the appointing authority through the IRB/ERC Chairperson giving at least a one-month notice.

The Chairperson may resign by sending his/her resignation letter to the appointing authority after informing the committee at its next meeting.

Membership should be terminated by the appointing authority on the advice of the IRB/ERC if a member is going to be away for more than six months.

Membership could be terminated by the appointing authority upon advice of the IRB/ERC if the member has been absent from five consecutive meetings without offering an explanation.

Membership should be terminated by the appointing authority for misconduct that tarnishes the credibility of the IRB/ERC as determined by the IRB/ERC.

Membership should be terminated if a member is convicted of a criminal offence.

Membership should be terminated by the appointing authority in consultation with the IRB/ERC if a member is suffering from a chronic incapacitating illness that significantly reduces the ability to process information and make rational independent decisions.

## 6.10. Dissolution of IRB/ERC

The IRB/ERC should automatically cease to exist when the institution at which it is based ceases to exist.

## 6.11. Committee Meetings

### 6.11.1. Scheduled Full (Convened) IRB/ERC Meetings

6.11.1.1The calendar dates and time of scheduled full (convened) IRB/ERC meetings should be agreed upon and confirmed by the committee and made public.

6.11.1.2The frequency of the scheduled full (convened) IRB/ERC meetings should depend on the workload in terms of volume of applications submitted as well as the availability of IRB members who have other duties at their places of employment.

6.11.1.3A quorum is more than 50% of the total number of IRB members.

6.11.1.4The quorum should include members with the relevant expertise to effectively review the protocols on that day’s agenda. The presence of a non-scientist is required.The community representative’s presence is essential.

6.11.1.5The quorum should be present before a full (convened) IRB/ERC meeting is held.

6.11.1.6The IRB/ERC Secretary should send an agenda; minutes of the previous meeting; notice about the date, venue and time of the next scheduled meeting; and other relevant documents to all IRB/ERC members at least ten working days before the meeting.

6.11.1.7Applications should be submitted to the IRB/ERC Secretariat at least three (3) weeks prior to the next scheduled meeting that the applicant wants his/her applications reviewed.

6.11.1.8The Secretariat should prepare and distribute a tentative agenda based on the applications received, matters arising from the previous meeting, SAEs, expedited reviews performed, continuing review applications, exemptions, and amendments.

6.11.1.9The general conduct of the meeting should be as follows:

Meeting called to order by the Chairperson/vice Chairperson /delegate

Adoption of the agenda, with or without changes

Call for a vote to approve the minutes of the previous meeting

Declaration of COI

New business (new protocols)

Other business

Adjournment of the meeting by the Chairperson /vice Chairperson /delegate

### 6.11.2. Ad Hoc /Extraordinary IRB Meeting

6.11.2.1Ad hoc/Extraordinary IRB/ERC meetings should be held if there is an urgent issue or issues that do not qualify for expedited review but require a full (convened) IRB/ERC meeting.

6.11.2.2The Secretariat should circulate a notice giving the date, venue, time, and agenda of the ad hoc/extraordinary meeting at least 48 hours before the meeting.

6.11.2.3The general conduct of the meeting should be as follows:

Call meeting to order by the Chairperson

Adoption of the agenda

The issues for which the ad hoc meeting was convened

6.11.2.4Relevant documents should be made available to IRB/ERC members at least 24 hours before the meeting.

6.11.2.5A quorum must be present for the ad hoc meeting to conduct business.

6.11.2.6Adjournment of the ad hoc meeting by the Chairperson

6.11.2.7Minutes of the ad hoc meeting should be circulated at the next scheduled IRB/ERC meeting. A vote to approve or request modifications should be made.

## 6.12. Mandates and Functions of IRBs/ERCs

The purpose of IRBs/ERCsis to contribute to safeguarding the, rights, safety, and well-being of all actual or potential research participants, by making an independent scientific and ethical review of research before commencement of research activities.Therefore, the major responsibility of IRBs/ERC is to safeguard the rights, safety, and well-being of research participants. The goals of research, while important, should never be permitted to override the health, well-being, and care of research participants.

IRBs/ERCs should provide independent, competent, and timely review of the ethics of proposed studies. In their composition, procedures, and decision-making, IRBs/ERCs need to have independence from political, institutional, professional, and market influences. They need similarly to demonstrate competence and efficiency in their work. They also need to ensure that there is regular evaluation of the ethics of ongoing studies that received a positive decision. Therefore, the functions of the IRB are the following:

### 6.12.1. Initial review

The IRB must determine that the following requirements are satisfied before it approves a research protocol:

Risks to participants are minimized. Risk to subjects are reasonable in relation to anticipated benefit (if any) and the knowledge that is expected to result

Selection of study participants is equitable

Determine that informed consent will be sought from each prospectivestudy participant, or the participants’ parent or guardian as appropriate

Determine that assent is sought where appropriate

Determine that informed consent will be appropriately documented

Determine that there are adequate provisions to protect privacy of study participants and maintain confidentiality of all study related data

Determine that there are additional safeguards included in the study to protect the safety and welfare of study subjects who are likely to be vulnerable to coercion or undue influence such as such as children, prisoners, mentally disabled people, etc.

## 6.13. Study information sheet (SIS) and Informed Consent form (ICF)

6.13.1 The IRB/ERC must determine that the SIS and ICF is documented using a written or verbal form,

The SIS and ICF should be approved by the IRB/ERC.

The ICF must be signed by the participant, or a parent, or next-of-kin or a guardian and by the individual that conducted the informed consent process.

In case the participant cannot read or write, a witness should sign that the consent process was carried out appropriately.

Should be translated to relevant local language where the study is going to be conducted

A copy of the SIS and signed ICF form should be given to the study participant.

6.13.2 Research participants or persons giving proxy consent cannot give full informed consent unless the consent process/form contains adequate information. All such information shall be expressed in a language that is understandable to the participant. Generally, the SIS should explicitly indicate the following:

A statement that the study involves research, the purpose of the research, the expected duration of participants’ involvement

Identification of any study procedures

Foreseeable risks and discomforts

Reasonably expected benefits to the participants as well as the community.

Disclosure of appropriate alternatives procedures or treatments.

Extent to which confidentiality will be maintained.

Compensation for possible injury if the research is greater than minimal risk; if so, an explanation is needed as to whether any medical treatments are available if injury occurs and what they consist of, or where further information may be obtained.

An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant.

A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled. The consent form should also clearly indicate that research participants are free to withdraw from the study at any time and that the participant may discontinue participation at any time without penalty or loss of benefits. Research participants also are not obliged to respond to all questions in a study questionnaire.

**6.13.3 E-consent for internet-based research**

Informed consent (e-consent): after participants are given information, it can include "I agree" or "I do not agree" buttons

If the IRB requires documented Informed consent, the researcher may email the consent form to participants, who may then type their name and date and send it back to the researcher

## 6.14. Assent

Assent will be sought from a study participant from 8 up to 18 years old. The minor child should be given appropriate information based on the child’s level of comprehension whatever the complexity of the research procedures, in addition to the consent of a parent, next-of-kin, or guardian.

## 6.15. Waiver of Informed Consent

Waiver of informed consent should be approved by the IRB/ERC. The investigator must secure an explicit waiver of consent from the IRB/ERC. The IRB/ERC may waive some or all of the elements of an informed consent, if the IRB determines that:

The research project carries no more than minimal risk, If the research or demonstration project is to be conducted or approved and is designed to study, evaluate, or otherwise explore public benefit or service programs; possible changes in or alternatives to those programs; possible changes in methods or levels of payment for benefits or services under those programs.

The research project could not practically be carried out without the waiver or alteration (whenever appropriate the research participants will be provided with additional pertinent information after participation); In emergency/acute conditions where a new drug (or new combination of drugs) or a new procedure(s) potentially holds a direct benefit but, the research participant cannot give or refuse informed consent because of the acute condition, the IRB/ERC may waive need for informed consent. However, it is the responsibility of the investigator and the sponsor to publicize such a study to the community before commencement of any research activity. The IRB/ERC should monitor such publicity to ascertain the community’s awareness.

In emergency conditions of national or regional importance, for example epidemics, where a participant cannot refuse informed consent.

The only record linking the research participant and the research project would be the consent document and the principal risk to the research participant would be potential harm resulting from a breach of confidentiality.

## 6.16. Continuing Review

The IRB/ERCconducts continuing review of all approved studies at intervals appropriate to the degree of risk that the study participants are exposed, at least once a year.

The IRB/ERCwill require continuing progress reports annually, unless it designates otherwise.

All amendments (all changes in approved research projects) should be reported and approved by the IRB/ERCbefore implementation, except where necessary to eliminate immediate apparent risks.

## 6.17. Suspension or Termination of Approval

The IRB/ERC has the authority to terminate or suspend its approval for research projects if it considers is appropriate such as:

The research is not being conducted according to the approved protocol, or according to applicable guidelines,

The research has been associated with serious harm to subjects

The research creates a potential threat to the safety and welfare of research participants or the community.

The termination or suspension of approval should include a statement of the reasons verifying the IRBs/ERCs decision and be reported to the investigator, the sponsor of the research and appropriate institutional officials.

Upon notification of the suspension or termination of the research, the investigator must promptly inform the research participants about the status of the research with assurance of continuing care and treatment when applicable.

# 7. Review Mechanisms

Each IRB must have written standard operating procedures (SOPs), including procedures to be followed in their review mechanism. The following are the minimum requirements for an IRB/ERC review mechanism.

## 7.1. General Requirement

The IRB/ERC shall review proposed research at convened meetings at which more than 50% of the members of the IRB/ERC are present, including at least one member who represents the interests of the community.

In order for the research project to be approved, it shall receive the approval of a simple majority of those members present at the meeting. The exceptions to this procedure include expedited review as outlined in **Section 7.3** and exempted **in Section 7.2**

Each IRB shall decide the frequency of its meetings, which should be announced.

An IRB/ERC shall require that information given to research participants as part of informed consent complies with the general requirements for informed consent as prescribed by the guidelines.

An IRB/ERC shall notify investigators in writing the outcome of the review of the research project. Such notice shall be provided to the investigator within 15 days from the date of IRB/ERC meeting on the research protocol. In case the IRB/ERC does not approve a research activity, it shall include in its written notification a detailed statement of the reasons for its decision.

An accredited IRB/ERC shall notify the outcome of the review of the research protocol immediately after approval of clinical trials, genetic studies, stem cell research, multi-center collaborative studies and send all copies of review documents and minutes to HRERC Secretariat.

An accredited IRB/ERC Chair or its secretary or its delegate shall attend a biannual meeting with HRERC and submit all activity reports

## 7.2. Exempted Review Procedures

Research activities in which the only involvement of human participants will be in one or more of the specific categories stated below can be considered as exempt:

Education: Research conducted in established or commonly accepted educational settings, involving normal educational practices.

Education: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observation of public behavior, provided the research participants cannot be identified.

Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or recorded without identifiers.

Evaluation or examination of government projects or programs designed to explore public benefit or service programs; procedures for obtaining benefits or services under those projects or programs; possible changes in or alternatives to those programs or procedures.

Taste and food quality evaluation and consumer acceptance studies where the foods are free of additives and where the ingredients are known to be safe.

Quality assurance activities.

All research including that in the exempt categories must meet, at a minimum, the principles of respect for persons, beneficence and justice. The exemption determination other than mentioned above will be based on regulatory and institutional criteria and documented.

7.2.1 Exempt Study Submission Requirements - Research activities that meet the requirements for one or more exempt research categories must be endorsed by the IRB/ERC.

7.2.2 The investigator must complete the appropriate Exempt Application and submit the application along with (if appropriate):

Questionnaires, surveys, assessments, interview questions, and tools.

Consent statements, informed consent forms/scripts, and assent forms/scripts.

Advertisements and letters of permission.

7.2.3 Exemption Categories and Determinations - Research activities, in which the only involvement of human participants will be in one or more of the exempt categories, can be approved as exempt. The Chair or the Chair’s designee, the IRB Secretary/Administrator, will complete the appropriate Exempt Category Form to review the protocol and make a determination.

7.2.4 Assessment of the research - The review of the research will also include:

Whether the research has a sound research design

Assuring there is minimal risk to participants

Ensuring that the investigator has the resources, time, and expertise to conduct the study

The reviewer may require additional protections to meet the principles, including a level of informed consent appropriate to the research, or review by the full (convened) IRB/ERC.

7.2.5 Policies do not allow exemption of research involving video or digital recordings, and surveys or interviews that are extremely sensitive or personal. Allowance of audio recording is dependent on the research, is determined on a case-by-case basis, and must be documented.

7.2.6 Approval Period - At the one-year anniversary of the approval, an email is sent to the investigator requesting an update on the status of the study. During the approval period, the investigator needs to keep the IRB informed of any changes in the study, so that the IRB can ensure that the study continues to meet the exempt criteria. The investigator may close the study when data collection has ended or contact with the subject is complete.

7.2.7 Documentation of Exempt Review - If the study qualifies for exempt review, the reviewer will complete the appropriate Exempt Category Form which will be used as documentation.

7.2.8 Investigator and IRB members notification

The investigator will be notified by appropriate medium of the exempt determination.

Each month claims of exemptions will be listed on the IRB meeting agenda.

## 7.3. Expedited Review Procedures

Expedited review is review of a protocol that need not be seen by the full (convened) IRB, but by one or two IRB members assigned by the chairperson.

**7.3.1 Eligibility Criteria**

For the review to be expedited the proposed research must:

Involve minimal risk, meaning that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Appropriately protect privacy/confidentiality.

Fall into one of the following categories:

Research employing survey, interview, oral history, focus group, or human factors

evaluation.

Research involving materials (data, document, records, or specimens) that were

originally collected for non-research purposes.

Collection of data from voice, video, digital or image recordings previously made

for research purposes.

Research on individual or group characteristics or behavior (including, but not

limited to, research on perception, cognition, motivation, identity, language,

communication, cultural beliefs or practices, and social behavior).

Follow-up on changes, amendments and annual renewals:

Follow-up on changes or information requested by the Review Committee as a condition of approval.

Minor amendments to previously approved research.

Annual renewals, if the original approval was through expedited review.

The only remaining activities involve long-term follow-up of previously enrolled participants.

The only remaining activities involve data analysis.

The review committee has determined and documented at a convened meeting that the research involves no greater than minimal risk (and there are no proposed changes that involve additional risk).

**7.3.2 Applying for an Expedited Review**

Requests for an expedited review can be submitted at any time to the Secretariat.

An investigator who wishes to apply for an expedited review should submit an application indicating the reason(s) for the eligibility of the study for expedited review.

Upon receiving an application for expedited review, the IRB Secretary/Administrator in consultation with the Chairperson/Vice Chair makes the initial assessment to determine if it qualifies for expedited review.

If the study qualifies for expedited review, IRB chairperson or by one or more experienced reviewers designated by the chairperson from among the members of the IRBshould be assigned to review the protocol. If the review involves a study amendment, the selected member should be a member who reviewed the previous version of the protocol.

When the protocol is approved, the investigator(s) will be notified immediately through the Secretariat.

7.3.2.1 A summary of the protocols reviewed through the expedited process should be submitted to the full (convened) IRB at its next meeting.

7.3.2.2 A decision arising from an expedited review will be provisional pending approval from the IRB. Such decisions should be communicated to the investigator in writing.

7.3.2.3 Should a protocol be disapproved by the expedited review, it should be submitted for a full (convened) IRB review.

7.3.2.4 The full (convened) IRB has the authority to confirm, modify or reverse a decision of the expedited reviewer. If the decision of the full (convened) IRB is contrary to the decision of the expedited review, detailed reasons and explanations should be recorded in the minutes.

7.3.2.5 The applicant should be informed of any modifications that the full (convened) IRBrecommends and the ethical justification for such a decision.

**7.3.3 Review Procedure**

An expedited review covers the same issues as a full (convened) review. The reviewer has the same options as the full (convened) review committee, i.e., to approve, or request modifications of a protocol. If the protocol is not approved, it will be referred to the full board.

Expedited and exempt research: The chairperson should notify the IRB members about decisions made pertaining to such research using a suitable medium (full board meeting, internet, post, telephone). At that time, any member or the committee may request a re-review of the approved protocol at the full (convened) committee meeting. If this were to occur, the investigator would be notified and asked to suspend the study pending full review. Expedited reviewers refer the issue to the full committee if there is any question about the level of risk or the applicability of the activity categories before approving the protocol.

## 7.4. Decision Making Procedures

7.4.1 The IRB can only make decisions if a quorum is met.

7.4.2 A member with conflict must excuse himself/herself from the review process and voting.

7.4.3 Non-members such as project PIs and independent experts may be consulted as part of the review process, but do not vote.

7.4.4 Only IRB members who participated in the review process and deliberations should take part in the decision-making process.

7.4.5 IRB decisions shall be either unanimous or by consensus where there is a majority decision. If the decision is by voting the number for and against should be recorded in the minutes.

## 7.5. IRB Decisions

The IRB may reach the following decisions after reviewing the research protocol:

7.5.1 **Approved:** if a protocol fulfills all requirements as stipulated in this guideline

7.5.2 **Minor revision:** if a protocol needs minor modifications.

7.5.3 **Major revision**: if a protocol needs major modifications

7.5.4 **Not approved:** if a protocol is found to be unscientific and/or unethical.

## 7.6. Communicating Decisions to Applicants

7.6.1 Decisions regarding protocols should be officially communicated, in writing, to the applicant within 10 working days of the meeting where the decision was made.

7.6.2 Communication of the IRB decision shall include but not be limited to the following:

7.6.2.1 The name, title, and address of the applicant.

7.6.2.2 The exact title of the protocol.

7.6.2.3 The name of the study site(s) or study area.

7.6.2.4 The names and identification numbers (versions numbers/dates) of the reviewed documents.

7.6.2.5 A clear statement of the decision reached by the IRB.

7.6.2.6 The name of the IRB making the decision (letterhead of the IRB suffices),

7.6.2.7 The date of the decision and the signature of the Secretary/Administrator

or Chairperson/Vice Chairperson.

7.6.2.8 In case of a conditional decision (approved on condition), any requirements by the IRB, including suggestions for revisions, should be clearly explained in writing to the applicant.

7.6.2.9 In case of a positive decision (approval), a statement of responsibilities of

the applicant and any requirements as stipulated in the decision by the ERC.

7.6.2.10 The validity period of the approval.

7.6.2.11 The final approval certificate/letter shall be countersigned by the

Chairperson/Vice Chairperson.

## 7.7. IRB Records

### 7.7.1. Documentation

The IRB should maintain adequate documentation of all its activities, and maintain the following:

File of detailed written procedures for the IRB.

File of each protocol, containing all versions of protocol submitted and accompanying documents such as informed consent, approved versions, approval letters, progress reports submitted by investigators, reports of injuries to research participants, and other relevant documents.

Agenda of IRB meetings, minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution.

Records of continuing review activities.

Updated member files with CVs, training documents, etc.

SAE reports submitted by investigators.

Final reports from investigators.

### 7.7.2. Archiving

All closed files shall be retained for, at least, five (5) years after completion of the research project. All documents should be kept under a proper system that ensures confidentiality. All records shall be accessible for inspection by authorized personnel.

## 7.8. Research Ethics review fee

HRERC/MoSHE and IRBs/ERCs will develop guidelines based on local situations, types of study and available budget for conducting the study to determine the amount of review fee for protocols.

# 8.Requirements for Submission to an IRB

There are requirements that must be fulfilled in order for the research protocol to be accepted by the IRB Secretariat for IRB review and approval. The requirements are administrative and research protocol related issues. Special categories of research entail fulfillment of particular requirements inherent in the type of research.

## 8.1. Administrative Requirements

8.1.1 The applicant must be the Principal Investigator (PI) or co-PI of the proposed research study.

8.1.2 A Protocol Application Form should be completed, signed, and dated by the PI/co-PI or his/her designee.

8.1.3 A signed cover letter from the PI or co-PI and the institutionaldetails where the investigator is based (which should include a physical address, fax number, telephone number, mobile number and email address) also must be submitted.

8.1.4 The applicant should submit hard copies of the full research protocol and/or an electronic version.

8.1.5 All materials to be used in “advertising” the research study (e.g., campaign materials, brochures etc.) should be submitted along with the protocol.

8.1.6 Up-to-date signed and dated CVs of the PI and/or co-PI should be submitted. Also, bio-sketches of co-investigators should be submitted although full CVs may be requested by the IRB.

8.1.7 All applications should be submitted to the IRBs depending on the location of the research site.

8.1.8 The accredited IRBs shall give final official approval for studies under their mandate.

8.1.9 The awaiting accreditation IRBs shall also review studies beyond their mandate and send protocols, relevant documents, minutes with recommendations and remarks to HRERC for final approval.

8.1.10 All IRBs,accredited,or awaiting accreditation, shall review all studies under their mandate and report to HRERC biannually or annually respectively.

8.1.11 The HRERC Secretariat receives applications submitted using the application form from all awaiting accreditation IRBs for ethics review and final decision as stated under HRERC mandates.

8.1.12 Upon receipt of complete applications, preliminary screening shall be done by the HRERC Secretariat.

## 8.2. Protocol Requirements

All research protocol and related documents submitted to the IRB for review and approval must at the least include the following information:

Research protocol: title of the study, purpose of the study, sponsor of the study, background of the project, a rationale with full justification of the study and that there is no other alternative and less risky way of obtaining the data, description of the study population, participants inclusion /exclusion criteria, precise description of all proposed procedures and interventions, including the duration of the study, provisions for protecting privacy and confidentiality, provisions for managing adverse events, plans for data management including plan for statistical analysis and publication, and budget,

Vulnerable population involvement requires further explanation to justify that without these vulnerable populations involvement there is no other way of obtaining the relevant data.

All materials to be used (including advertisements) for the recruitment of research participants must be attached to the protocol.

Data collection tools such as questionnaires, interviews /discussion guides, checklists and case report forms must also be submitted.

Documents to be submitted for review include: Study protocol, protocol amendments, study/participant information sheet and informed consent form, current investigators’ CV, investigator’s brochure, and other materials to be used. The study informed consent process/form and information sheet, in both the official language and, when necessary, its translation into the local language is required. A back translation into the official language may be requested by the IRB. In addition contact addresses of the PI, people to contact and the IRB that approved the research protocol must be included in the study information sheet.

If the proposed study is a clinical trial, the investigator’s brochure which provides an adequate summary of all safety, pharmacological, pharmaceutical and toxicological data available on the study product, together with a summary of the clinical experience of the study product (e.g. recent investigator’s brochure, published data, summary of the product’s characteristics etc.), must also be submitted. Information on payment and compensation available for research participants for time lost and injury or harm as a result of participating in the study.

If the proposed study is a clinical trial, a certificate of Human Participant Protection , Good Clinical Practice, of at least one of the investigators, and a certificate of Good Manufacturing Practice based on the nature of the research, must be attached.

In studies that need transport of human biological substances, a request for a material transfer agreement, the type of biological material, how it is going to be processed and stored, how the material is intended to be analyzed, intent for possible future analysis, if there is one, as well as how and when it will be disposed , must be included in the study protocol

A dissemination and community involvement plan should be developed.

## 8.3. Types of Research with Special Consideration

There are special categories of research that possess particular characteristics and demand special emphasis in ethical considerations. This type of research includes clinical/experimental trials, genetic, socio-behavioral, and collaborative research.

### 8.3.1. Clinical Trials

***8.3.1.1 Submission requirements***

An investigator’s brochure which provides an adequate summary of all safety, pharmacological, pharmaceutical, and toxicological data available on the study product, together with a summary of the clinical experience of the study product (e.g. recent investigator’s brochure, published data, summary of the product’s characteristics, etc.), must also be submitted.

If the trial involves an investigational product, prior approval and permission to import the investigational product must be obtained from EFDA.

Information on payment and compensation available for research participants for time lost and injury or harm as a result of participating in the research

Insurance certificate covering research-related injuries of participants and errors in protocol implementation,

The PIs should attach a certificate of Good Clinical Practice (GCP), and a certificate of Good Manufacturing Practice (GMP),based on the nature of the research. The investigator must assure that the clinical monitor and the IRB will have access to the participant’s file to verify trial procedures and data are kept in accordance with the approved protocol. This should be stated in the participant information sheet. Additionally, the research participant should be told that by signing the informed consent, the participant is permitting access to the file by the clinical monitor and the IRB.

SOPs for the trial; AE reporting format

The investigator should affirm that he/she has sufficient time to conduct and monitor the trial, as well as to submit progress reports on time

If the study involves a new intervention, investigators need to give an assurance, when applicable, the post-trial benefit of the community where the study in conducted and the country at large.

***8.3.1.2 Investigator’s File***

The investigator must prepare a file containing documents related to the trial. During the study, the investigator is responsible for updating the file and regularly adding trial-related documents. Identification codes of subjects shall be kept for 10 years.

The Investigator's File should contain, at the minimum:

Local regulatory requirements

IRB and other authorities’ written approval for all documents

IRB and other authorities’ written approval for protocol amendments

Correspondence with the IRB

Approved protocol and amendments

All signed and dated informed consent forms

Investigator’s and Co-investigators’ CVs

Copy of the insurance certificate/other insurance

Investigator’s SOPs

Notification and documentation of serious adverse events

Specimen management procedures, trial supplies/equipment

Participant identification list

Investigator interim and final report/summary of the trial

***8.3.1.3 Participant File***

The participant file should, at the minimum, contain the following original information:

Subject identification: family name, given name, date of birth, sex, and identification number in the trial

Protocol identification number/study reference

Dates of first screening and/or enrolment in the trial

Name of drug or investigational product or procedure on test

Dates of product administration and dosage, and procedure(s)

Dates of assessment visit and name of individual responsible for making the assessment

Serious adverse event and related treatment or medication

Dates of laboratory specimen/sample collection

***8.3.1.4 Monitoring***

Compliance to approved protocol must be followed during the course of the research.

Deviation from the protocol is acceptable only to manage/treat a serious adverse event that endangers the participant’s life or is presumed to result into serious or permanent disability. In such acceptable cases of protocol deviation, the IRB, clinical monitor and the sponsor must be notified immediately. The protocol deviation must be appended to the approved protocol. And, the investigator should subsequently make a request for protocol amendment while applying for renewal of the research.

The investigator should regularly submit a progress report; the progress report should include reports of the DSMB.

***8.3.1.5 Medical Care for Trial Subjects***

The highest available standard of care in the country shall be provided to trial participants

In international collaborative research, the care should be equivalent to the care provided in the country where the sponsor or the collaborating institution is based.

Adequate/standard medical care should be offered to participants for adverse events.

***8.3.1.6 In case the trial is terminated or suspended prematurely, for any reason:***

The research participants must be informed with assurance of continuing care and treatment.

The IRB and the sponsor should be informed as soon as possible.

***8.3.1.7 In randomized, double-blinded trials, premature unblinding:***

The code may be broken because of serious adverse event, if deemed necessary by the DSMB during interim report,

Must be documented in the file and reported to the clinical monitor immediately

### 8.3.2. Genetic Research

Genetic Research: is as research conducted for the purpose of generating scientific knowledge about genes and/or the genetic basis of disease.

Genomics Research: the study of the genome, its action, and related techniques to understand the inter- relationships of all genes in order to identify their combined influence on the organisms, in contrast to geneticswhich investigates the functioning and composition of a single gene*.* However, the term Genetic research in this guideline encompasses both genomic and genetic investigations.

Genetic Counseling: A procedure to explain the possible implications of the findings of genetic testing or screening, its advantages and risks and where applicable to assist the individual in the long-term handling of the consequences; It takes place before and after genetic testing and screening:

**8.3.2.1 Collection, storage, handling of Genomic data**

In genetic studies involving acquisition of biological samples, the procedure to be used to obtain samples, the type and amount/size should be clearly stated.

The collection, processing, handling, storage, transfer, and destruction of human biological materials and data should be conducted in a manner that protects the privacy of the participants and the confidentiality of their specimens and data.

**8.3.2.2 Privacy and Confidentiality**

The protocol must state the use of appropriate coding techniques as well as security and access procedures at each step of sample collection, transport, analysis, and storage.

The institute/organization where the data will be generated must have appropriate data protection and confidentiality guideline. Providing access should consider the risk of compromising the privacy of individual study participants as well as risks of compromising data quality and interpretation. Data protection should be guaranteed in terms of secured physical or computational infrastructure.

**8.3.2.3 Informed Consent**

During the informed consent process, there should be a clear statement that the study is for genetic research purposes. Informed consent should describe, in simple language, the type and quantity of biological material to be collected, the collection procedures, and the plan on returning genomic data.

The informed consent process should cover the human biological materials and data to be collected, data anticipated to be derived from the analysis of sam­ples (including the possibility of incidental findings that were not initially intended to explore), and the health and other records to be accessed, their intended uses, storage, and duration of storage.

The participants must be informed that specific information resulting from the study will not be available to participants and their families unless there are existing standard medical interventions or locally acceptable social/legal norms. Explanation should be given if the samples will be shared with third parties and that in these cases the samples will be anonymous.

If there are opportunities to obtain genetic counseling, it is desirable to include the information in the informed consent form.

The consents should clearly state the use of broad or specific consent. If broad consent is sought, the protocol should clearly indicate relevance, risk and benefit and other issues. It must disclose the data will be stripped of identifiable data or clearly indicate that the identity of those with access to secondary use will remain unspecified. Either of these consent options could be used depending the study nature and context.

**Broad consent:** is a consent where participants are given an option to consent to very broadly described research possibilities with no further consent required.

**tiered consent:** is a consent where Participants are given an option to consent to circumscribed research possibilities with an additional option to be recontacted for research proposed in the future or in a form of waiver of consent, where ethics committees decide on their behalf for other research.

**Opt-out consent:** is a consent where participants will be given an option to consent to circumscribed research but specifically decline to research beyond described purposes or timelines.

When subsequent use of human biological materials or data is envisaged that would not be consistent with the original informed consent, ethical approval should be sought. a new consent should be obtained from the participant/guardian/LAR or request for waiver of consent from IRB.

**8.3.2.4 Communication of Findings**

Research institutions/sponsors who generate genomic data in a study are encouraged to adopt mechanisms regarding return of data to subjects, as appropriate. The protocol should clearly state the possibility of discovering ‘incidental finding’ and must ensure participants have proper understanding of this concept.

Offering genetic results depends on ethical and local issues including the clinical significance. The potential lack of accuracy and understanding of results obtained in the research should be reviewed. Thus, assessment of analytic and clinical validity is necessary, which includes evaluation of the strength of genotype-phenotype data association.

The protocol should describe the timing of such communication, by whom (e.g., researcher, physician, or genetic counselor), and to whom (subjects, or the primary caregiver or legal guardian). A valid justification must be given for each of the above-mentioned points.

Ethics review boards have to be consulted when communicating clinically justifiable findings. The committee will decide whether communication is needed or not after reviewing the clinical utility of the finding and cost-effectiveness of the available medical intervention.

### 8.3.3. Biorepository/Biobanks

Bio-repositories/Biobanks: A systematic collections of human biological samples and linked associated personal health information used for any possible future research. Unlike a standard biological research, research based on biobanks could involve a large number of researchers, who might not have direct contact with participants and may encompass a large range of research questions of which some are undefined at point of sample collection.

All principles described above in the genetic research section will apply when reviewing studies involving biorepository samples/biobanks.

Ownership of specimen and linked data primarily belongs to the research participant. However, institutions could take responsibility and custodianship over collected specimens or linked data for appropriate and controlled use, safe keeping, responsible sharing and eventual disposal of the specimens or linked data.

When storing biological materials with related data institutions or researchers must have a governance system to obtain authorization for future use of these materials in research, on how the quality of the material is controlled, on how confidentiality of the link between biological specimens and personal identifiers is maintained.

### 8.3.4. Biotechnology and stem cell research

Medical biotechnology is a branch of medicine that uses living cells and cell materials to research with the aim of producing pharmaceutical and diagnostic products. It comprises various techniques that exploit the application of biological organisms, systems or processes for the benefit of human being. Some of the most recent uses of medical biotechnology include genetic testing, and development of therapeutics such as biosimilars, gene editing and artificial tissue growth.

Such products help to diagnose and treat or prevent diseases, making huge advancements and helping millions of people around the world. However, with the many advancements in this technology, there are medical and ethical issues that need to be considered.

When conducting clinical trials on biotech products where safety issue is a concern, the information sheet should clearly indicate the likely hood that ‘unknown risk’ might occur because the effect of genetically modified/manipulated products (such as stem cell, gene editing etc) might not be determined within a short period of time or during the trial period. In such cases insurance to trial participants shall be covered accordingly

Stem cell research (tissue engineering) especially embryonic stem cell should not be allowed but somatic/adult stem cell research may be considered, given that all fundamental research ethics principles are observed.

### 8.3.5. Research on the dead

Research on the dead, heart beating cadavers and cadavers should receive scientific and ethical review and oversight. The following ethical concerns should be addressed:

* use procedures respectful of the dead
* Protect confidentiality
* proxy consent for body or organ donation
* Authorization from legal authorities where applicable
* Possibility of waiver of consent
* plans for disclosure of findings
* clearly explain ultimate disposition of the body
* should take into account the religious and cultural beliefs of the community where the research shall be conducted

### 8.3.6. Social and Behavioral Research

Social and behavioral science researchers encounter unique ethical challenges that warrant serious consideration. One of the key criteria used to review and approve protocols is to determine a satisfactory risk/benefit ratio, to ensure that the risks borne by participants are balanced by adequate benefits – both in relation to the knowledge that the study hopes to generate. Social science research may cause non-physical harm in the form of emotional distress, stigma and other social harm such as destabilization of social and relational systems, violation of privacy and confidentiality.

**8.3.6.1 Generalizability and societal benefit**

Since social and behavioral research is often context dependent and not easily generalizable. This draws doubt on the societal benefit of this kind of research.

**8.3.6.2 Informed consent**

Social and behavioral research can involve most-at-risk or hard-to-reach and legally unprotected communities. Permission can be obtained from gatekeepers such as community leaders, government authorities or heads of households.

IRBs/RECs need to be vigilant about the use of deception by ensuring that the debriefing includes adequate disclosure of the rationale for deception and be aware of the expected risks/harm that the participants may face from the deception process.

Depending on the nature of the study waiver of consent or waiver of documentation of consent can be given by IRB/RECs.

Engaging communities in research can also facilitate the conduct of a given study in safeguarding and empowering vulnerable groups, fair distribution of benefits and burdens, minimizing the potential conflicts of interest.

Considering obtaining consent as a process that should be subject to negotiation during and even after the end of the interview; the informed consent process should include authorization of recording (audio, video) of interviews, focus group discussions, and observations.

In situations where deception needs to be applied to achieve the objectives of the study, while assuring that there will be debriefing at the end of the study.

**8.3.6.3.Privacy and confidentiality**

Depending on the nature of the study, the use of pseudonyms was also suggested to hide the participant’s identifiers or study site location. But anonymity is not only ethically appropriate for research with those who are better-off and better known.

Confidentiality should be maintained on sensitive topics that involve discussion of private matters through interviews, phone calls, and home visits.

**8.3.6.4 Psychosocial harm and interventions**

Social and behavioral studies are usually perceived to pose minimal risk. However, in social and behavioral research, the following are potential risks that all stakeholders should be aware of:

*Anxiety and distress*: Responses are intimately dependent upon the context of the participants’ beliefs, values, behaviors and actions. The differing experience of the participants largely makes predicting who may experience the anxiety and distress difficult/problematic.

*Intrusion in life:* exploring behavior related to health may require observation of participants at various places including the household, and sometimes, for a prolonged period of time.

*Exploitation:* Power imbalance between the researcher and the study participants, or exerting undue influence.

*Misrepresentation:* Participants’ opinion are taken out of context or interpreted in the researcher’s perspective, dynamics of the qualitative interviews and the nature of data collected can be affected by the professional background of the researcher.

*Identification of participant*: (by self or others) in published papers due to clues provided to describe the participant’s age, gender, educational and economic status, place of residence, profession, etc.

Hence, to minimize these risks of harm, the following ethical issues should be given special emphasis during protocol review, conduct, and monitoring of qualitative research:

Ensuring scientific soundness

Providing counseling and rehabilitation support where appropriate

Ensuring confidentiality through securing storage of audio and video tapes and transcripts

Making ‘respondent validation’ of the researcher’s analysis before dissemination of the research findings

Publicizing the research before commencement such that the community is aware of the observation that can be in public domains: at market places, sport events, brothels, theatres, etc. In such cases, the IRB may decide waiver of consent and documentation of consent

### 8.3.7. Collaborative Research

Collaborative research is research that is conducted by investigators from more than one institution. If one of the collaborating institutions or investigators is based outside of Ethiopia, then, the research is termed “international collaborative research”.

There are different potential reasons for conducting collaborative research. The reasons may include greater prevalence, convenience of or familiarity with the setting and the researchers, scientific or public health justification, and the research question or intervention is only relevant to the type of health problem in Ethiopia. Hence, the reason for choosing to conduct the research in Ethiopia should be explicitly stated.

8.3.7.1 Requirements

International collaborative research should be in line with the health research priorities of Ethiopia.

The research must be consistent with the Health Science and Technology Policy and must be responsive to the health needs of Ethiopians.

The research should contribute towards strengthening national research capacity to carry out similar research independently, including providing research ethics training to members of the investigation team.

The sponsor/donor should agree in advance that products will be made reasonably available after completion of the study, and the community must have access to the fruits of research.

All collaborative research must have a Principal Investigator or a Co-PI actively working in Ethiopia. Also, the PI or Co-PI must be employed or affiliated to a recognized institution or organization in Ethiopia. The research procedure should consider, to the extent possible, socio-cultural conditions in the community where the research is presumed to be conducted.

In all collaborative research, all involved institutions are required to review and write a recommendation of approval before submission to IRBs/ERCs mandated to review and approve such collaborative research. In the event the involved institutions do not have a functioning IRB, the research protocol and other documents can be submitted directly to any of the IRBs mandated to review and approve collaborative research.

However, to avoid duplication of review efforts by IRBs/ERCs, the NHRECmay choose to conduct joint reviews in part or in whole, accept the review of another qualified IRB, or make other arrangements to establish oversight responsibilities.

Adoption of a paternalistic approach by research sponsors/donors towards institutions in Ethiopia or the research priorities of the government, is unacceptable.

8.3.7.2 Monitoring

When conducting collaborative research studies, each institution is responsible for safeguarding the safety, rights and welfare of human participants and for complying with all applicable regulations. The IRB that reviewed and approved the collaborative research is primarily responsible for monitoring the ethical conduct of the research procedures. However, the National IRB can monitor the proper conduct of the research whenever it deems further oversight is necessary. Any modification, amendment, or change in the approved collaborative research protocol should be made at each collaborating institution. Material transfer agreements must be obtained whenever applicable.

### 8.3.8. Community Engagement

Community engagement is a component of scientific research, policy-making, ethical review, and technology design. Effective community engagement is essential for ensuring both instrumental objectives and moral ideals of scientific research. Engagement has the potential to redress past harms; dissolve long-standing mistrust and suspicion; minimize the risk of further exploitation; compensate for or resolve existing differences in power, privilege, and positionality; allow for marginalized voices and experiences to be represented in the production of scientific knowledge; and ensure that research is relevant and impactful. Engagement activities must aim to create meaningful partnerships between researchers and the local community. Ongoing dialogue and collaboration is important in shaping study design and implementation.

Researchers are encouraged to involve the community in decision-making about the design and conduct of the study. Investigators should consider the local customs, traditions, culture and religious practices of the community where the research is proposed to be conducted. Involvement of community stakeholders shall not override the rights of individuals to consent voluntarily for participation in a research project. Community engagement is to be treated as an ongoing process until completion of research. Community dialogues shall be effected to promote understanding, research participation and ownership. Researchers should develop plans for providing feedback on the research results and outcomes of the research process.

### 8.3.9. Internet based research

Data collection takes place over the Internet using methods such as email, listservs, electronic bulletin boards and web surveys. IRB approval or Certification of Exemption from IRB review is necessary whenever conducting research involving human participants. Researchers should identify and manage risks during data collection, processing and dissemination.The existence of data and information already online does not relieve the researcher from the obligation to respect privacy and mitigate risks that could result from combining data from multiple sources and their subsequent use and publication.Researchers should identify and manage risks during data collection, processing and dissemination

IRB/ERC shall review that:-

* Risks such as violation of privacy, legal risks, and psychosocial stress are minimized
* Provision of similar levels of protection to research activities that pose similar privacy risks
* Participants' participation is voluntary
* Informed consent requirements are met (refer to section 6.14)
* Information obtained from or about human participants is kept confidential
* the method and procedures for data collection and security
* all materials used for posting recruitment materials on the internet, e.g. through a website, a banner advertisement, or an email solicitation

### 8.3.10. Vulnerable Population

Vulnerable populations are those segments of the population whose capacity to safeguard their welfare, demand their rights and satisfy their interests, is compromised. Because of these limitations, they cannot provide or refuse consent. Vulnerable populations are particularly subject to undue influence, manipulation, coercion, and intimidation. Hence, vulnerable populations deserve special protection from IRBs and other regulatory authorities.

8.3.10.1 Pregnant women and Fetuses

To conduct research on pregnant women, the following must be fulfilled:

There is evidence from studies on pregnant animals and non-pregnant women thatstudies need to be done on risks related to pregnant women and fetuses.

If the research holds the prospect of direct benefit to the pregnant woman and the fetus, and the knowledge cannot be obtained through other means.

There should be no inducement to terminate a pregnancy.

If the prospect of benefit is both to the pregnant woman and the fetus, an informed consent form from the mother alone suffices to enroll the woman into the research.

If the prospect of benefit is solely to the fetus, informed consent should be obtained from both parents, provided they are competent to give or refuse the consent.

In both conditions, the foreseeable risks of the research on the fetus or the neonate must be thoroughly explained.

Viability of the fetus should be determined by a health care provider who is not a member of the investigation team.

8.3.10.2 Newborns/Neonates

In research involving neonates with uncertain viability, the following must be met:

Previous research provides data to assess potential risks to neonates.

Viability of the newborn/neonate should be determined by a health care provider who is not a member of the investigator team.

There should be no other means of obtaining the knowledge to be derived from the research.

There should be no added risk to the neonate due to the research.

The research is likely to enhance viability and survival.

Informed consent should be obtained from either of the parents.

For, research involving dead fetuses or organs or tissues of the dead fetus:

There should be a prospect of important knowledge that can be possibly used in the prevention and treatment of similar or related conditions.

Informed consent should be obtained from either of the parents of the dead fetus.

8.3.10.3 Children

Children are persons who have not attained the legal age of 18 years (Ethiopian Law) for consent for prevention, treatments or procedures involved in health research. The following apply in research involving children.

The child should provide assent ( 8 years upto18 years) in addition to the informed consent by a parent or guardian as stated in **Section 6.15** above.

The research presents a realistic opportunity and clearly justified to further understanding, prevention, or alleviation of problems affecting the health or welfare of children.

Clinical trials that recruit children should justify that these trails had been conducted in animals and adult conditions.

In disease condition specific to children clinical trials can be allowed based on risk-benefit analysis, public health issues, etc…

Emancipated minors – working or earn their living, married, parenting – may be allowed to give an informed consent or an IRB may decide a waiver of consent.

In research related to sensitive topics like drug use and abuse, sexuality, reproduction, STIs, where obtaining consent from a parent, next-of-kin, or guardian is challenging and may be problematic to the minor because of the nature of the research, assent with waiver of consent may be applicable.

In institutional children, a legally approved guardian may give consent.

8.3.10.4 Prisoners

Prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and decision which is not coerced, whether or not to participate as subjects in research. Therefore, additional safeguards should be included in the study to protect the rights and welfare of these subjects, as follows:

If an IRB regularly reviews research that involves these vulnerable populations, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

Where possible, a prisoner or an ex-prisoner co-opted in to the IRB reviewing the proposed research project should be included.

Only research on conditions particularly affecting prisoners as a class and with reasonable probability of improving the health and well-being of the research participants should be permissible.

The IRB shall determine that the informed consent process is properly applied with adequate assurance that a prisoner’s participation or refusal to participate will not be considered in decisions regarding his or her release or further detention and each prisoner is clearly informed in advance that his or her participation in the research project will have no affect on his or her release.

8.3.10.5 Mental and Physical Disability

Persons with disability need special attention because they are prone to being socially marginalized. Therefore, their dignity, rights and well-being in research must be respected. Careful consideration should be made where proxy consent is to be used, and where the use of signed consent forms is not feasible, alternative viable methods should be employed.

Persons with disabilities (mental or physical) should not be unfairly excluded from participating in research. Researchers should make an effort to address communication, disability and comprehension constraints are often the excuse for exclusion.

People with mental disabilities or substance abuse related disorders include those people with psychiatric, cognitive, or developmental disorders. These groups of people are usually institutionalized, and institutionalization may further compromise their ability to make voluntary decisions to participate in a research project. Therefore, research on people with cognitive disabilities or with substance abuse related disorders should:

Provide sufficient justification for involving such people;

Have appropriate evaluation procedures adapted to Ethiopian situation or context for ascertaining research participants’ ability to give informed consent. If research participants are deemed unable to understand and to make an informed decision, then an appropriate proxy should be identified.

Have an informed consent process that is free from coercion.

Be of no more than minimal risk, or if minimal risk is involved, the risk is outweighed by the anticipated benefits of the research project to the research participant.

**8.3.10.6 The Older people**

The older people (age over 65 years) which accounts about 5 % of the population in 2019 in Ethiopia. It is imperative to adapt a healthy ageing approach in health research to better understand and recommend interventions for Healthy Ageing.

It is therefore necessary to look into the following while doing research in the older people:

Ensure that the basic ethical principles are applied

Use all available mechanisms to collect gender and age differentiated health data on older persons.

Disorders that usually come with old age like problems in vision, hearing, orthopedic and joints should be addressed with provision of supporting instruments as applicable.

**8.3.10.7 Marginalized groups and ethnic minorities**

These groups tend to be marginalized so special care should be taken to ensure research does not further disadvantage these groups-Expectation that research conducted in such communities directly benefits these communities

**8.3.10.8 Rural and remote populations**

Due to limited health care resources in such regions, special care needs to be taken to ensure the provision of health care services for research participants does not serve as undue inducement to volunteer for the study. The burdens and benefits of research should be fairly distributed between rural and urban populations

### 8.3.11. Traditional, complementary medicine (alternative medicine) (T&CM)

Traditional and complementary medicine (T&CM): T&CM merges the terms TM and CM, encompassing products, practices and practitioners

In principle, traditional and complementary medicines research is subject to the same ethical standards as conventional research practices.

The research should follow scientifically sound procedures and observe the fundamental ethical principles of autonomy, beneficence and justice and the ethical review process outlined in these guidelines.

It is important to balance the need to protect the intellectual property rights of indigenous peoples and local communities and their health care heritage while ensuring access to T&CM and fostering research, development and innovation

All herbal processing must be carried out in accordance with applicable legal and environmental requirements and with the ethical codes or norms of the community and the country.

To ensure safety and efficacy of herbal medicines, proper science needs to be applied in the research studies

Unique characteristics in these areas of research must be given due consideration such as inclusion/exclusion criteria, use of placebos

The general principles and requirements for a clinical trial should be very similar to those which apply to conventional drugs

### 8.3.12. Research in public health emergencies (emergencies, outbreaks, pandemics) and disasters

Research conducted in the contexts of public health emergencies include but are not limited to outbreaks,Tsunami, displacements, infectious disease outbreaks, natural disasters, and human-made disasters such as conflict, bioterrorism, and industrial accidents etc. Types of research conducted during emergencies fall in the ranges of Epidemiologic, behavioral, qualitative, action research, ethnographic, clinical, trials etc.

Research can play an essential role in improving the effectiveness of the health response to those affected by such emergencies but is often ethically contested because of the highly challenging environment in which it takes place. The contexts in which global health emergency research takes place are diverse, complex, dynamic, and time-pressured

**Ethical issues:**

Vulnerability and power influences: how are the voices of those who are most affected by emergencies meaningfully included in deciding what research takes place, where and how? Affected populations include those whose lives, health, and livelihoods are threatened by the emergency, people within those populations who take part in research; and front-line research workers.

Finding ways to ensure front-line research workers are better supported in addressing the ethical dilemmas they face

Significantly raised risks to physical or mental well-being at both individual and population level

Pressures of time, creating tensions between research and response timescales, and exacerbating the challenges of multidisciplinary working;

Uncertainty, making decision-making in these time-limited contexts particularly difficult for all concerned;

Fear, distress, and sometimes panic, potentially undermining populations’ ability or desire to engage with research

Appropriateness of study designs and flexible review systems that are sensitive to the difficult contexts in which research is taking place.

Achieving meaningful consent processes within a wider ethical system of governance, to ensure people’s interests are respected

**Recommendations to IRBs /ERCs**

Research should be conducted only if it does not impede emergency response efforts*.*

This means that research should not be conducted if it can be expected to take away personnel, equipment, facilities, and other resources from those required for outbreak response.

All research conducted during a public health emergency must have scientific validity and social value. Proceeding otherwise exposes participants and researchers to unnecessary risk and is ethically unacceptable. The appropriateness of any research design should be informed by the context in which the research is to be conducted.

Research projects should be coordinated to avoid wasteful duplication and underpowered studies, and to ensure that priorities and activities are consistent with response efforts.

Independent ethical review (both in the country affected and, where relevant, in other countries) provides an important safeguard for research participants, and the *standard* of review should not be compromised in any way by the emergency context.

Flexibility and adjustments made by IRBs/ERCs to be able review multiple studies in short timeframes

Emergency Ethics Committees: Ethics committees may consider establishment of sub-committees to focus specifically on the review of protocols related to the disaster under considerations

Public Health Emergency research would require accelerated review within an average of 10-15 working days. Similarly, quick turnaround times, including an urgent amendment agreed in 12-24 hours.

Such responsiveness might include the use of phone or online meetings, willingness to discuss protocols with researchers at development stage and provide informal feedback, and the ability to respond quickly to protocol modifications, for example in response to community feedback.

IRBs/ERCs would have to develop SOPs for running remote meetings virtually

IRBs/ECCs should be careful that urgency and flexibility should not lead to compromises in the quality of the review.

A triage system could be introduced whereby expediting some protocols may mean that other protocols may have to wait. IRBs/ERCs to include SOPs on the same.

Depending on the nature of the issues some such as national interest and national security, some of the protocols would require national review by NHREC such as Clinical Trials and international sample transportations.

Communications: IRBs/ERCs should clearly communicate any emergency procedures for researchers and stakeholders.

Rapid sharing of information generated during research—subject to ethical requirements such as maintaining the confidentiality and privacy of personal information—with those participating in response efforts can also help strike an effective and mutually beneficial balance between research and response.

To better ensure that research is responsive and sensitive to local realities, needs, values, and cultures, it is imperative that communities and researchers from local contexts be engaged at all stages of research, if feasible.

Developing community engagement networks in advance to facilitate relationships is a key part of emergency preparedness. Research during an emergency requires fair and meaningful community engagement and inclusive decision-making. The most inclusive level of engagement is one in which local stakeholders are not only consulted but also take part in decision-making processes with respect to research design, implementation, and evaluation. This involves inclusive and accountable decision-making. It requires that all reasonable steps are taken to ensure that all those concerned—including those who are the most vulnerable and marginalized—are included.

Research involving human participants requires independent ethics review. Routine public health activities not constituting research do not require independent ethics review, but should still proceed with due attention to ethical considerations, as outlined in part in the WHO’s Guidelines on Ethical Issues in Public Health Surveillance.

To minimize duplication of ethics review and oversight, in most cases independent ethics review should proceed collaboratively between one local and one international review body, with at least one being well-versed in research ethics.

To facilitate expeditious ethical review in emergency situations without compromising human participants’ protection, generic advance protocols (which can be rapidly adapted and reviewed), templates, and other tools for the ethical review of research can be employed.

Pregnant women, minorities, children, and other groups considered to be ‘vulnerable’ should not be routinely excluded from research participation without a reasonable scientific and ethical justification. Any exclusion from participation in research should be justified by robust and current scientific evidence, such as an unfavourable benefit-risk ratio.

Informed Consent: Cultural and linguistic differences, as well as confusions about the dual role of the clinician/researcher, may be heightened for research conducted in this context, and so processes for obtaining informed consent, including the wording of documents and methods of obtaining and recording consent, should be developed in consultation with local communities. Finally, researchers should inform potential participants about the circumstances under which their data or samples might be shared.

Participants and stakeholders should be fully informed about the collection, storage, future use, bio-banking and export of human biological material. Researchers generating information that has the potential to aid response efforts have an ethical obligation to share that information as soon as it is quality-controlled for release (e.g., peer-reviewed).

To ensure the greatest impact of the research, information should be shared with those involved in response efforts in addition to research participants, affected populations, and the global community. Researchers should share this information without waiting for publication in scientific journals. Journals can facilitate this by ensuring that data or preprints shared ahead of submission will not pre-empt publication in their journals.

Any exclusion criteria from studies should be clearly justified with reference to the risks and benefits for the group in question, in this context, rather than an automatic exclusion of ‘vulnerable groups’.

Ongoing research which may increase risks to the participants and/or the research team (e.g. COVID 19) may have to be stopped and amendments sought on how to continue ensuring protective mechanism or in a modified approach (e.g. Phone or web based interview instead of face to face encounters)

### 8.3.13. Health Systems Research

**Synonyms:** Health Systems Research, Operations Research, Implementations Research, Health Systems and Policy Research (HSPR)

**Introduction**

Health Systems and Policy Research (HSPR)is recognized as a hybrid, or ‘trans-disciplinary’ field, drawing on different ‘disciplinary traditions and methodological approaches. It is an applied research that is undertaken with an orientation towards influencing policy and wider action to improve the performance of health systems.

Health systems research (HSR) is a subset of public health and is defined by the World Health Organization (WHO) as “the purposeful generation of knowledge that enables societies to organize themselves to improve health outcomes and health services” (World Health Organization 2009). HSR is necessary to ensure health systems strengthening, quality of care, and evidence-informed public policy creation. HSR researchers must carefully define their intent and goals and openly clarify the values that may influence the premises and design of their protocols.

IR addresses different aspects of implementation including social and contextual factors (poverty, environment, and culture), the process of implementation (which approach best answers the implementation issue?) or the outcomes of implementation (clinical/process end points). IR questions cover a broad range of topics that focus on improving health system functioning and improving equitable and just access to effective health care interventions. As such, IR designs are flexible and often innovative, and ethical principles cannot simply be extrapolated from their applications in clinical research.

In short, HPSR has close interconnections with health policy with social and political implications and employ a range of study designs.

**Ethical Issues**

As HSR and IR involve a range of particular ethical considerations that have not yet been comprehensively covered in international guidelines on health research ethics, the fundamental ethical principles governing clinical research apply equally in HSR and IR, but the application of these principles may differ depending on the research question, context, and the nature of the proposed intervention.

**Identification**: The definition of HSR varies depending on the type of research, location, or source considered and these often leave gray zone between research and non-research and that can be considered part of the HSR agenda in LMIC.

**Distinction of research**: A clear operational definition of what counts as health research and therefore is subjected to ethical review and what does not count as health research or counts merely as quality improvement, monitoring and evaluation exercises.

**Community engagement**: Meaningful engagement with all stakeholders including communities and research participants is a fundamental ethical requirement that cuts across all study phases of IR

**Study design:** different study designs, often with multidisciplinary involvement, have been used in IR, each raising particular ethical concerns careful consideration at the planning stage, engagement with all stakeholders is crucial to develop the most effective and fair study design.

**The balance between the risks and benefits:** The benefits of IR may not accrue to the same groups who participate in the research, therefore justifying the risks versus benefits of IR may be ethically challenging and should aim to balance.

**Autonomy and informed consent:** Challenges in operationalizing informed consent in the context of IR include whether the beneficiaries are individuals or populations, and appropriate identification of who the actual research participants are. The informed consent process in IR therefore may be quite different from that in clinical research and requires thorough consideration to ensure optimal ethical conduct of IR.

**Ancillary care:** Ancillary care refers to the identification of problems that may contribute to ill-health that are beyond the scope of the study in question which may occur at design stage, during the conduct of the IR.

**Data ownership and sharing:** In case of donor or sponsor-driven IR, data is often owned by the donor, who may regulate and restrict further handling of the data.

**Recommendations to Ethics review committee (ERC) or institution review board (IRB)**

**Introduction**: HSR may pose ethical issues to human participants, the ethical review processes of research ethics committees (RECs) and institutional review boards (IRBs) the following are recommendations to reviewers, committees / boards.

Realize that the ethical concerns differ from other types of research; therefore, its ethical review should arguably be tailored to address the features and unique ethical challenges that are particularly salient (though not exclusive) to HSR.

RECs need to distinguish program and quality monitoring and evaluation exercises from implementation and health research. Health research which are merely as quality improvement, monitoring and evaluation exercises are organised as programmatic interventions and may require classical ethical review assessment.

RECs need to have an SOP and checklist to review HSR Suggestions in the guidelines /SOP, including a review checklist to SOP for this type of research.

Health systems research is reviewed not by the same ethical standards as clinical research if it does not impose the same risks to study participants as other types of clinical or public health research.

HPSR need to go through ethics review (like clinical research) depending on the design and population under consideration. Yet additional systems considerations also need to be put in place such as:

Institutional engagements and permissions

levels of consent appropriate to the groups and the settings

**Justification and responsiveness: Research p**roblems addressed by IR must be of high local priority in order to justify the research. Engagement with local health experts and communities is therefore essential in the planning stages of IR to determine whether a health problem is indeed perceived to be a local priority.

**Equipoise: I**t is required to justify any potential risk to research particpant i.e., whether there remains genuine doubt whether a new and untested package of interventions will work in a specific context [18]. To ethically justify IR, therefore, equipoise regarding the effectiveness of the implementation processes must be preserved.

**Stakeholder and community engagement:** Key stakeholders in IR may include the government, policy-makers, public health functionaries, health care providers, health care managers, financing mechanisms, health care industry, and the community (community representative).

**Privacy and confidentiality:** Where such consent is not possible, it is the responsibility of the researcher to obtain a waiver of consent from the respective ethics review committee or institutional review board, and put in place mechanisms to ensure that the confidentiality of the patient information is respected. A proactive strategy of informing patients about potential data collection for research and quality improvement purposes up-front, but reassuring them about privacy and confidentiality could also serve strengthen the patient-researcher partnership and build trust.

**Standard of care or prevention:** There are two approaches to decide on standard of care or prevention to be given to a control group either *de facto* or *de jure*. *De facto* standard refers to allocate the local de facto existing standard, which in some situations may be grossly insufficient, making it ethically unacceptable based on justice and fairness principles. For example, having a placebo control arm is not acceptable in spite of the local de facto care being no treatment, if effective treatment is available. *De jure* standard refers to provide the local de jure standard of care or prevention, which is agreed upon by public health experts of that region and is acceptable to the community.

**Ancillary care:** ancillary care need to be agree upon which needs may realistically fall within the scope of responsibility of the researchers, local government or non-governmental organizations during the planning and conduct phases of IR.

**Research capacity and health system strengthening:** Research capacity strengthening and provision of infrastructure need to be assessed if IR is being conducted.

**Dissemination of research findings:** Given the important public health impact of IR, there is an ethical obligation to disseminate the research findings (both positive and negative) widely, including feeding back to the communities and stakeholders who participated in the research

**Data ownership and sharing:**  an ethical oversight of the data ownership process is required to ensure appropriate access to the research findings by the relevant stake-holders post-study, including the local researchers and communities when appropriate, to maximize the utility of the knowledge generated.

**Translating findings into public health action:** there should be an ethical obligation for IR findings to be used to inform effective and equitable public health action. Prompt communication of findings by researchers to policy-makers, and work to establish and support a culture of evidence-based decision-making.

### 8.3.14. Digital Health

*Synonyms*: Electronic Health, M Health, Artificial Intelligence (AI), Big Data

**Introduction**

With the increasing use of mobile and wearable devices, new opportunities have been created for personalized health (tailored care to the needs of an individual), crowd sourcing, participatory surveillance, and movement of individuals pledging to become ‘‘data donors’’ and the ‘‘quantified self’’ initiative (where citizens share data through mobile device-connected technologies). These initiatives created large volumes of data with considerable potential for research through open data initiatives. The range of data sources include Electronic Health Records (EHRs), data from mobile health (mHealth) applications, medical blogs and web-networks, healthcare robotics, medical internet of things, as well as direct-to-consumer genetic, and screening tests. Additionally, health-related information can be derived not only from digital health applications, but also from non-strictly medical data sources such as online personal dietary programs, fitness club memberships and Twitter hashtags. Health-related big data is the umbrella term used to describe extremely large and heterogeneous data sets that may be analyzed computationally to reveal patterns, trends, and correlations, that have relevance for human health.

Digital Health research is a broad area of research, which encompasses electronic health records, mobile health applications, social-media, medical artificial intelligence and health related big data. The mainstay being use of interrelated and interconnected online data sources for generation of knowledge and medical application. Digital health is a rapidly expanding medical field premised on the availability of ever-increasing amounts of data about people’s lifestyles, habits, clinical histories and pathophysiological characteristics.

Digital health, entails connecting health-related data, including data generated by patients themselves, and harnessing the medical potential of technological tools of common usage, such as smart-phones, wellness bands, apps, social media and sensing devices disseminated in our dwelling environment. It generates a “seamless flow of critical medical data between patients, their families and their physicians”. Given their volume, complexity, variety and propensity to be analyzed through data-mining techniques, such data qualify as big data or, more precisely, as biomedical big data.

**Ethical Issues**

The methodological novelty and computational complexity of big data health research raises novel challenges for ethics review. For digital health to materialize several ethical and policy challenges need to be overcome.

Ownership of personal data, privacy and confidentiality breaches with increased likelihood of privacy threats to data sets that are not readily identifiable. The clinical development of digital health applications is premised on the creation of very large data collections recording sensitive personal data.

There is increased risk of (re)identification of individuals and/or a weakening of the security that data masking techniques appear to provide. The privacy model should ensure that the privacy of data contributors is adequately protected while at the same time ensuring that data is not rendered useless as a result of privacy protection efforts.

Open data movement and commercial exploitation: a balance must be struck between an individual’s desire for privacy and their desire for good evidence to drive healthcare, which may sometimes be in conflict. Moreover, bodies with a commercial interest in selling health-related goods and services may be able to use shared data to pressure people into purchasing them.

Risk to compromise privacy, personal autonomy, and the solidarity-based approach to healthcare funding, as well as effects on public demand for transparency, trust, and fairness while using big data.

Lack of appropriate infrastructures for data storage as critical technical and infrastructural issues that might endanger a big-data-driven healthcare.

Informed consent: Heavy reliance on consent is becoming increasingly impracticable in the big data context because data might be linked and used within and across ecosystems that are far removed from the original source of information. While individuals might be re-contactable in some cases, it might still not be possible to inform them fully of the range of uses to which their data might be put by multiple users across countless ecosystems. It is important to explore alternative ethically acceptable approaches and mechanisms which provide appropriate protections for individuals whose data may be used.

Data security, personal, institutional and national: some of the data collected and stored electronically may pose data security threats at all levels from individual to the nation.

Levels of Vulnerability which may (a**)** The big data divide, which is a term describing the situation in which the benefits arising from the collection and use of big data are not evenly shared; (b) Group harms, which is a term that describes the possible harms to the collective interests of a community arising from the use and misuse of big data.

Issues of fairness and the risk of discrimination misuse of big data resulting in various forms of ethnic, gender and class discrimination (group-level harms)

**Recommendations to IRBs/ERCs**

Due to the existing and emergent critical ethical issues mentioned above, all digital health research need to be reviewed by research ethics committees, there is no implicit exemption of such research.

Issues of data ownership, group-level ethical harms, and the distinction between academic and commercial uses of big data, need to taken into considerations in the review of digital health research.

In particular, it should scrutinize more carefully

whether and how each project attempts to address the social benefits, if any, of research;

how data subjects involved in the study can exercise control over their data (data control problem);

which measures of accountability are being employed by the researchers,

whether the collected data can be reused for secondary, including malevolent, purposes (dual use problem) and what measures are implemented to prevent that.

Ethics committees need new expert profiles are needed during the review process. Data scientists, security experts, bio-informaticians should complement the expertise of clinicians, ethicists and other traditional IRB/ERC members.

Adequacy of privacy models should take into account the attributes of a dataset and specify the conditions that the data must satisfy in order for the disclosure risk to be minimized to an acceptable risk level, such as

a. data likability (the ability for anonymized data to remain relatively linkable so the value of the data is not significantly diminished)

b. composability (the privacy guarantees that can be given when data from multiple sources to which the same or different privacy models have been applied is integrated into one data-rich source)

c. low computation (algorithmic efficiency, i.e. the algorithm uses a low number of computational resources, such as time or space)

The researchers need to demonstrate and present (attach/annex) clearly written data sharing policies for Data Repositories and Electronics Medical Records and Online Data Platforms

Data security: Researchers should refer and cite comprehensive regulatory policies and safeguards to address public concerns, such as the protection of individually identifiable information. However, in absence of specific guidelines and comprehensive evaluation studies, ERCs might be facing uncertainty on how to review health-related big data projects and according to which evaluative criteria.

Informed consent: depending on data type, data source and context, there should be a mechanism to seek informed consent for collecting and sharing data. The researchers need to explain in what terms data were collected from the originators of the data.

Anonymity and confidentiality: Informed consent is often not practical to obtain for studies involving a retrospective access to data from millions of individuals.

Open access data and Licensure of digital technologies and products

Accountability**:** Data generators and data managers take responsibility for the proper and ethical use of data. In addition in the areas of AI, there should always be human supervision and monitoring.

Co-governance, (to address issues of big data vulnerability by ensuring that all stakeholders have a say in decision-making over how data are gathered, stored, and distributed.

# 9. Human Biological Materials

## 9.1. Definition

Human biological materials include any substance obtained from a human research participant including, but not limited to, blood, urine, stool, saliva, hair, nail clip­pings, skin, and microorganisms, and other associated bio-products obtained from human research participants.

## 9.2. Acquisition, Storage, Secondary Use

The acquisition, storage, and future use of human biological samples from research participants in Ethiopia shall be guided by the following procedures:

Collection of samples should follow acceptable standard procedures by adequately trained personnel.

There should be a separate informed consent process for obtaining human bio­logical samples for storage and for future use.

Research participants should know the purpose of sample storage, quantities of samples to be stored, place where samples will be stored, duration of storage, measures to protect confidentiality, policies that will govern use of the samples in future research, potential risks and benefits of storing samples for future re­search and any other information deemed necessary by the Investigators, IRBs.

After explaining the need to store the samples, the research participant should be offered to choose whether their samples should or should not be stored for future studies.

The host institution in Ethiopia should hold the samples in trust on behalf of the research participant.

Research participants should reserve the right to withdraw their samples from storage if the samples are linked.

Where samples have not been obtained as part of research (for example as part of routine surveillance, emergency procedures, laboratory quality control, notifi­able diseases, routine counseling and testing, etc), the institution that collected the samples takes custodianship of the samples. Any future research study on such samples must be reviewed by an IRB.

Stored samples may be used to address research questions not included in the approved protocol after getting an IRB approval.

## 9.3. Procedure for Material Transfer

In order to justify transfer of human materials to overseas, investigators should demonstrate that in-country capacity to perform investigations/tests doesn’t exit or inadequate. However, samples may be transferred for quality control and laboratory reference purpose.

When it is necessary to transfer samples to overseas, the host institution shall negotiate an appropriate contract with the recipient institution. This con­tract shall be in the form of a Materials Transfer Agreement (MTA). The specific details of the MTA should include, among other things, purpose for the transfer/ export, clear arrangements for collaboration and benefit sharing, a framework for accessing and sharing data, restrictions to third party transfer, date for termination of the use of the material, disposal plan and annual reports to the host institution on the status of the samples.

It is required that Ethiopian institutions retain ownership of the materials and an Ethiopian scientist must be included as co-investigator in all future studies using the human biological materials collected from Ethiopia.

The IRB/ERC in Ethiopia shall review all research studies on stored human biological samples.

# 10. Open data access, data ownership, sharing, and result dissemination

Ethiopia has clear policy and guideline on data in general and the use of open data in particular. All researchers who receive public funding must submit their Data Management Plans for approval, to confirm that data will be handled according to international FAIR data principles. (FAIR data are data that meet standards of Findability, Accessibility, Interoperability and Reusability.)

**10.1 Data Ownership**

Data ownership and associated intellectual property rights shall be discussed and agreed upon by collaborating partners at the inception of a research project while respecting the law of the country. Collaborating research partners shall negotiate data ownership and use in accordance with the host organization’s data use and ownership policies. The National Ownership of data shall be clearly stated in the research protocol or collaborative research agreements, which shall be reviewed by HRERC and accredited IRBs/ERCs.

**10.2 Data Sharing**

a. Collaborating research partners shall agree on appropriate data access and use rights before commencement of the study. Researchers shall have in place mechanisms for maintaining confidentiality of research participants and their communities.

b. A collaborating research partner shall not transfer data to a third party without the written consent of the other partner.

c. Local researchers shall have unrestricted access rights to data sets collected through a collaborative research project and that has to be clearly indicated in the research proposal.

d. Researchers shall ensure that research records from which the data has been obtained are available at the research site for at least five years after completion of the research project. Electronic records are acceptable.

e. Data sharing request requires IRBs/ERCs approval

**10.3 Results Dissemination**

a. Researchers shall, as appropriate, make all reasonable efforts to share findings (following the open data policy of the country) of research with the host organization, research participants, key stakeholders and communities in which research was done.

b. Researchers shall describe in the protocol plans for research results dissemination and ensure its execution.

c. Researchers shall be sensitive about the ethical implications of the research results, and take appropriate measures to protect research participants and their communities.

# 11. Regulatory Oversight of Research

Regulatory oversight of research involving human participants is exercised at two levels. At the country level, the NHREC, which is established by MoSHE, is the primary responsible organ for oversight. At the institutional level, the organization’s IRB, accredited by MoSHE, oversees all research being conducted under its jurisdiction. For research involving experimental/clinical trials, an additional approval to import and use the drug or investigational product should be solicited from EFDA.

The legal obligations in research shall be overseen by MoSHE and EFDA. IRBs, and DSMBs and are primarily responsible for safeguarding research participantsafety. The Institutional Biosafety Committee (IBC) and Community Advisory Board (CAB) shall ensure public/community wellbeing.

## 11.1. MoSHE

MoSHE is established by Proclamation No.1097/2018on 29th November 2018.is bestowed with the powers and duties to:

Forward recommendations based on studies for adopting and revising policies, strategies, laws and directives on the development of science, technology and innovation activities.

Prepare science, technology and innovation master plans; provide guidelines for…, programs and projects; monitor and evaluate their implementation.

Set priorities for the country’s research activities.

Direct, coordinate and support science, technology and innovative activities, and countrywide research programs

Support and strengthen institutions that undertake research and development activities.

## 11.2. EFDA

The Ethiopian Food and drug Authority was established by ‘Council of Ministers Regulation No. 189/2010’ on August 23, 2010. Under the Proclamation FMHACA took over the rights and obligations of the Drug Administration and Control Authority (DACA) and, under Article 5, its ‘…objectives shall be to protect the health of consumers by ensuring: 1) food safety and quality 2) the safety, efficacy, quality, and proper use of medicines 3) competence and ethics of health professionals, medical practitioners and pharmacy professionals.

The ‘…authority is responsible to protect the safety and rights of the subjects participating in a trial and to ensure that trials are adequately designed to meet scientifically sound objectives.’ ‘The mandate of the Authority is to review protocols, and where necessary to protect the safety of subjects, to require protocol revisions and/or termination of trials. The Authority also has a right for on-site inspection of the quality of the data obtained…’

‘Any clinical trial conducted in the country on human beings and/or on animals other than laboratory animals should have received prior permission before the commencement of the trial.’ Furthermore, the Authority demands that findings from a clinical trial need its approval before publishing. Besides, the responsibilities of the investigator, the sponsor, and the monitor should be stated clearly in the research protocol.

The authority also requires that a specific application form for clinical trials shall be completed and submitted for review and approval of a research.

## 11.3. IRBs/ERC

IRBs/ERCs are established by institutions whose mandate includes carrying out research. The primary function of IRBs/ERCs is initial and continuing review, monitoring research to ensure adherence to the approved protocol in order to safeguard the rights and welfare of research participants, train faculty on research ethics, accredit, register, and monitor other IRBs/ERCs, and develop guidelines applicable to all research in Ethiopia.

## 11.4. DSMB

11.4.1 Definition

A Data and Safety Monitoring Board (DSMB) is an independent committee composed of a multidisciplinary group of experts established by the research sponsors to assess and report the ongoing scientific and ethical integrity of a study by reviewing and evaluating (unblinded as necessary) data at regular intervals.

The DSMB should ensure that the study is conducted and the data are handled in accordance with the provisions of the research protocol and monitors adverse events and safety data.

A DSMB should be established before the commencement of a clinical trial and its composition submitted to the IRB.

All Phase I, Phase II, and Phase III, including drug efficacy and clinical trials proposed to be conducted in Ethiopia should have a safety monitoring plan, and a DSMB as recommended by an IRB.

DSMBs should be established in studies where interim data analysis is required to ensure the safety of research participants. Other interventional studies, such as community trials, may be required to set up DSMBs on a case by case basis.

Sponsors should consider the need for establishing a DSMB prior to undertaking a particular study. An ethics committee may also suggest to the sponsor that a DSMB be established for a particular study.

Recommendations of a DSMB are communicated directly to the sponsor, but the sponsor should notify other relevant parties and ensure that the recommendations are communicated to, and acted upon by, the various parties involved in the research.

11.4.2 Composition

A Data Safety and Monitoring Board is composed of people external to the research team. The members of the Board:

Should be independent of the sponsor and the manufacturer of the investigational drug or product.

Have no conflict of interest in the research they are monitoring.

Receive no scientific recognition in the form of publications or promotions from the results.

Have relevant expertise (clinician with relevant specialization, clinical pharmacology and/or toxicology, epidemiology, statistics, ethics and additional types of expertise depending on the type of the research, e.g., anthropologists or community members for research which involve assessing cultural sensitivities).

Have fair representation from participating countries in multi-center studies.

Consist of at least three members and the size and necessary expertise of the DSMB will depend upon the research design.

11.4.3 Constituting a DSMB

When required by the nature of a study, a sponsor should ensure the establishment of DSMB to ensure the broadest possible coverage of potential research participants, and the validity and scientific integrity of the data. In order to generate competent reviews and sound recommendations, the DSMB should be multidisciplinary and includeas appropriate, expertise in medicine (physicians with relevant backgrounds), clinical pharmacology and/or toxicology, epidemiology, statistics, clinical trial process, and ethics. The suitability of members of a board should be determined according to the nature of the study to be monitored.

The sponsor is responsible for establishing the DSMB’s charter that defines the relationship between the sponsor and the DSMB, which should be included (or referred to) in the research protocol.

Members should not be affiliated with the sponsor, investigators, ethics committees, regulatory authorities, sites, or study staff. Members should also not have vested interest (e.g. a financial or other interest in an intervention or product similar to the intervention being studied).

A procedure should be established concerning the requirements for candidacy, including an outline of the duties and responsibilities of DSMB members

Procedures for reporting and addressing potential or real conflicts of interest for members and independent consultants should be clearly defined in the charter.

11.4.4 Responsibilities

Review research protocol, informed consent documents and plans for data safety and monitoring.

Evaluate the progress of the trial, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of the trial site, and other factors that can affect the study outcome.

Consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the trial.

Review clinical center performance, make recommendations and assist in the resolution of problems reported by the PI.

Protect the safety of the study participants.

Conduct interim analysis of efficacy in accordance with stopping rules which are clearly defined in advance of data analysis.

Ensure the confidentiality of the trial data and the results of monitoring.

Assist the sponsor through remarking on any problems related with study conduct, enrollment, sample size, and/or data collection.

Report on the safety and progress of the trial and make recommendations to the IRB and the sponsor regarding continuation, termination, or other modifications of the trial based on the observed benefits or adverse effects.

Report the decisions to investigators who must submit those reports to the IRBs, which shall further report to the National IRB.

## 11.5. Institutional Bio-Safety Committee

11.5.1 Establishment

The IBC evaluates research projects that use recombinant DNA, agents that are infectious to humans, animals and plants, other potentially infectious materials, select agents and biological toxins. Institutional Bio-safety Committees (IBC) are established by institutions that undertake research on potentially hazardous substances of a physical, chemical, biological, or any other nature. Any institution involved in or planning to conduct research with potentially hazardous substances is required to set up or designate a competent IBC. Each IBC once formed shall consist of a bio-safety officer and at least three other officers with appropriate expertise in DNA, biological safety and physical containment. The IBC shall be certified by the MoST.

It is the responsibility of the Principal Investigator to notify and provide the IBC with the research proposal involving potentially hazardous substances of a physical, chemical, biological, or any other nature. The Principal Investigator is ultimately responsible for the registration, training, and safe handling of research materials handled by their personnel.

Members of the IBC shall protect confidentiality of all information given to them in the course of their work, and shall sign confidentiality agreements with their institutions.

11.5.2 Functions of an IBC

The IBC’s function is to minimize potential human and environmental harm that may be associated with research on or with potentially hazardous substances such as pathogens, biological toxins, radioactive material and applications of bio-technology, especially recombinant DNA techniques and processes.

The purpose of an IBC is to ensure adequate containment of potentially hazardous biological agents, add a level of expert review and monitoring of potentially hazardous experiments, and provide a means of communication among researchers and healthcare providers about potentially hazardous protocols.

IBCs shall**:**

Notify FHRECand other IRBs of any research with potentially hazardous substances in their institutions.

Conduct bio-safety review and approval of research proposals involving recombinant DNA and potentially hazardous substances.

Continued review of approved research projects.

Ensure the provision of suitable and safe storage and disposal facilities for all materials involved in work with potentially hazardous substances.

Ensure that all appropriate technical personnel of the institution have adequate training in bio-safety.

Establish a health-monitoring plan for all high-risk personnel involved in application, use and production of potentially hazardous substances.

## 11.6. Community Advisory Boards

11.6.1 Establishment

Community Advisory Boards (CABs) are established by the investigator team. They are indispensable in orienting the investigator team about the local customs, traditions, terminologies, culture, and attitude towards research and development. Besides, CABs are important bridges to liaise the researchers with the community. CABs are critical forums to facilitate dialogue between community members, research participants and investigators.

CAB members shall be selected from the community where research is to be undertaken through a stakeholder consultative process. The CAB’s role and expectations should be explicitly described in their terms of reference. Members of the CAB may include but are not limited to the following:

Individuals familiar with local laws, customs, cultural values and gender issues

Elders, opinion leaders, local chiefs

Peer leaders,women leaders

Religious leaders

Representatives of the study population

Media personnel

Professionals who understand research or science issues

11.6.2 Functions

The main function of a CAB is to assist investigators with understanding and incorporating community concerns into their research procedures. The functions are expressed through different ways like advising on issues central to the informed consent process, achieving successful volunteer recruitment and retention, and other related issues.

The responsibilities of the CABs may vary according to the study location, size, complexity, familiarity of the investigators with the local setting, to mention but few. CABs functions are to:

Provide information on traditional beliefs and needs of the study population and their concerns regarding the research project

Provide input into the design of the research protocol as appropriate especially in the recruitment and the informed consent process

Advise investigators on acceptable and effective methods for disseminating information about the research project and its outcomes

Provide advice and support regarding retention of research participants including gender equity

# 12. Monitoring Reporting

Monitoring essentially encompass four activities: continuing review, review of the consent process, review for adherence to an approved protocol and review to identify unapproved activities. Continuing review is the most common, conventional, and fundamental aspect of monitoring of an IRB.

The primary function of monitoring is ensuring participant safety through assuring compliance with regulations and adherence to approved research protocols. In clinical trials, data monitoring is conducted to ensure data quality and safety. The DSMB is designated by the sponsor upon the recommendation of the IRBprimarily to periodically monitor data quality and participant safety. Moreover, interim analysis of risks and benefits should be a component of monitoring to ensure safety, whenever applicable.

In multi-center research, monitoring at each of the research centers should primarily be carried out by the local IRBs. However, the FHRECis also responsible for oversight at selected, representative research centers, as deemed necessary.

In international collaborative research, periodic progress report must be submitted, and all adverse events must be notified to the NEC.

The investigator bears the major responsibility of regular monitoring and reporting of adverse events to the IRB. The sponsor is also obligated to report, or otherwise, ascertain the adverse events are reported to the IRB.

Based on monitoring and reporting that includes Adverse Events (AEs) as applicable, the IRB may allow continuation, suspension, or termination of the research or recommend an amendment (a change) in the research procedure. Besides, if the research involves a drug or investigational product, the investigator must notify FMHACA.

## 12.1. Adverse Events: Definition, Grading, Follow-up, Reporting

### 12.1.1. DefinitionGradingof an Adverse Event

Adverse eventsare considered to be serious when theyare fatal, life threatening, cause serious or permanent disability, cause or protract hospitalization, cause congenital anomaly, or lead to death.

An AE is considered to be related with the research procedure, drug and/or an investigational product based on temporal association with and response pattern to the procedure, drug or product, and the relationship, or otherwise, to the research participant’s clinical state, other interventions unrelated to the research or concomitant therapy.

An AE shall be considered unexpected if the event has not been observed or documented in a similar research involving humans; the characteristics or severity of the event is inconsistent with information in the investigators brochure; or the event is observed with higher frequency or severity than previously documented.

An adverse event is graded as:

**Mild**: if the event does not interfere with day-to-day activities and does not require treatment.

**Moderate**: if the event marginally affect the day-to-day activities but can be tolerated by the participant or require out-patient treatment.

**Severe**: if the event significantly interferes with daily activities and demands hospitalization or procedures for relief.

### 12.1.2. Follow-Up on an Adverse Event

Oncean AE has occurred, the investigator shall:

Monitor the AE closely

Provide a standard care to manage the AE and follow the AE until complete resolution of the AE.

Thoroughly investigate the likelihood and extent of relationship of the AE with the research procedure, drug and/or investigational product.

The details of the AE, from occurrence to complete resolution, must be recorded and attached to the participant’s file.

### 12.1.3. AE Reporting

A serious adverse event and the measures taken to manage the SAE must be reported by the investigator, in writing, to the IRB Secretariat and to the clinical monitor, if one is assigned by the sponsor, within 48 hours of occurrence of the event, even if the SAE is considered not to be related to the research procedures. Other adverse events should be reported with the progress report and submission of a renewal or an extension of an approval.

The IRB examines the AE report and the appropriateness, or otherwise, of the measures taken, and whether the measuresare in accordance with the approved protocol. Measures beyond the approved protocol shall be documented in the participant’s file and reported to the IRB. The IRB ultimately decides the need for additional action.

The medium for reporting should be according to the communication means/channel described in the approved protocol.

Anonymity of the research participant shall be respected when all information are sent/reported.

## 12.2. Compliance Monitoring

Progress reports - PIs should submit progress reports at regular intervals stipulated by the IRB as a condition for renewal of ongoing research. Periodic progress reports enable the IRB to determine whether the research is progressing according to the approved protocol. In clinical trials, the progress report should include reports of the DSMB.

The IRB shall establish a follow-up mechanism to monitor the progress of all ethically approved research. The follow-up review shall be done in the following manner:

Ethics approval is valid for one year. For research that takes more than a year to complete, a renewal (continuation) application should be submitted to the Secretariat with a full progress report and justification for IRB approval.

Any amendment in the protocol at any time should be reported to the Secretariat and approval secured from the IRB.

Serious and unexpected AEs shall be reported to the Secretariat as stated above in **11.1.3**

In case of a premature suspension or termination of a research, the investigator should notify the Secretariat including the reasons for the premature suspension or termination of the research and summary of the research findings.

## 12.3. Types of Monitoring Oversight visits

12.3.1 Types of Monitoring

**Passive monitoring**–The IRB receives information about the research that it approved and uses that information to assess the study’s progress.

**Active monitoring**–IRB members should physically visit the research site(s) in order to assess the conduct of the studies.

Approved research should be actively monitored to ensure adherence to ethics principles, as considered necessary by the IRB.

IRB members should use the IRB’s oversight checklist in order to ensure appropriate issues are assessed during the visit.

Should research exist that has not received ethical clearance, the presence of such research should be proved through a site-visit, witnesses, and appropriate and prompt actions should be taken (see **Section 12.2**).

The number of IRB members needed to conduct an oversight visit depends on the workload of the monitoring team. To maximize objectivity, at least two (2) members of the ERC or delegated persons with diverse expertise and drawn from different institutions should make up the monitoring team. A monitoring team may include the community representative in the IRB.

12.3.2 Types of Oversight Visits

The type and frequency of oversight visits should depend on the level of risk and complexity of the research. The IRB can make the monitoring visit announced or unannounced.

**IRB –initiated announced oversight visit**: the IRB informs the PI the date of the visit in advance.

**IRB-initiated unannounced oversight visit**: the IRB does not inform the PI in advance of the visit.

* Additional monitoring visits may be made for the following reasons:
* Response to reports made directly to the IRB or circulating in the community.
* Increased frequency of SAE reports.
* Failure to submit progress reports or a final report in time.
* Reports of suspected research misconduct.
* Investigators who extend their research beyond the approved time frame without formal approval from the IRB.
* Investigators that are suspected of having changed their objectives and study design without the IRB’s approval.
* Any other reason that the IRB feels warrants further follow-up.

# 13.Research Misconduct

All researchers are obliged to respect the requirements set in these guidelines and the law and regulations related to research. Misconduct in health research is one of the aspects that make research unethical.

## 13.1. Research Misconduct

Research Misconduct includes but is not limited to:

Conducting health research involving human participants or that which potentially affects humans without first obtaining ethical approval.

Collecting samples or information from human participants without first obtaining valid, voluntary informed consent except in conditions where waiver of informed consent is applicable.

Sharing with other investigators samples collected from human participants or institutions without ethical approval and without a signed Material Transfer Agreement.

Sharing samples collected prospectively from human participants with other investigators or institutions without the informed consent of the participant. The IRB may waive the requirement for informed consent in the case of archived and anonymized samples if the justifications are considered to be ethically and scientifically sound by the IRB.

Failure to submit mandatory reports such as SAE reports, progress reports and final reports to the IRB.

Failure to uphold the confidentiality of research participants’ information including informed consent documents.

Failure to report deviations from the approved protocol procedure(s) in time. Deviation from approved protocol procedure(s) should not be made without the agreement of the IRB that approved the protocol except when it is necessary to avoid immediate danger to a research participant.

Unjustifiable deviations.

Fabricating or falsifying data, or knowingly plagiarizing others’ work.

Misuse of research funds.

Forgery of IRB documents (e.g., alteration of approval letter/certificate; Material Transfer Agreement, etc).

## 13.2. Possible Actions AgainstResearch Misconduct

The IRB may receive reports of cases of misconduct via investigators, community members, voluntary whistle-blowers, research participants, or through its oversight activities. Upon receiving such reports, the IRB should confirm the validity of the alleged misconduct before deciding on an appropriate course of action. The actions that the IRB may take after confirming the misconduct include:

A letter of warning written to the PI by the IRB Chair with instructions for the misconduct to be stopped and/or rectified. The head of the institution, partners, and sponsors should be copied.

Corrective or educational measures.

Frequent monitoring of research activities.

Recommended and more frequent reporting by the investigator of his/her research activities.

Suspension of eligibility to receive research grants. The IRB may blacklist the investigator for a period of time to be determined by the IRB. During that period the IRB should not approve any research protocol submitted by the blacklisted investigators. The list should be copied to the relevant authorities.

In the event that serious harm/injury was caused to participants as a result of the misconduct, compensation for the harm/injury should be made by the investigators, or the host institution, or both. All research-related harm or injury as a result of ethically unapproved research shall be compensated by the investigator, the host institution, or both. The compensation package should be determined by qualified and relevant authorities.

Temporary or permanent suspension of the PI and other investigators from research and/or professional practice.

Suspension of all research being conducted by the investigator.

Termination of the research.

The host institution may also be temporarily suspended from research activities.

Editors of journals should refuse publication of manuscripts from unethically

conducted research and retract articles that are already published but eventually found to be conducted unethically.

In the case of criminal misconduct inform legal authorities.

# 14.Responsibilities of Investigators, Host Institutions, Sponsors

Responsible conduct of research requires that all stakeholders discharge the duties expected from them according to this guidelines and the law and regulations of Ethiopia.

## 14.1. Investigators

The investigator is responsible for overall conduct of the research according to the approved research protocol/procedures. More specifically, the investigator:

14.1.1 Shall maintain adherence to basic ethics principles,

14.1.2 Shall possess appropriate scientific and human ethics standards,

14.1.3 Shall ensure the highest possible standard of health care and follow-up, within the limit of the investigator’s and the sponsor’s capacity, is available to research participants;the available care shall be provided for a variable period even after the completion of the research based on the researched disease, condition or instrument; shall open an investigator’s file where all documents related to the research are kept.

Shall keep records of informed consent document confidentially (in a locked cabinet).

14.1.5Shall ensure privacy and confidentiality is maintained for research participants. The investigator shall ensure that hard data is kept in locked cabinets and electronic data is password protected accessible only to appropriate personnel.

14.1.6 Monitor research staff to ensure the research is done according to the approved research protocol/procedures.

14.1.7 Periodically submit a progress report to the IRB. The frequency of the report is to be determined according to the level of risk inherent in the research, i.e., the higher the risk the shorter the reporting interval.

14.1.8 Shall promptly investigate serious adverse events and take appropriate measures to safeguard the safety of human subjects. The investigator shall inform such adverse events and measures taken, if any, to the IRB, clinical monitor and the sponsor.

14.1.9 Shall inform the IRB and obtain approval for any changes or amendments in the approved protocol/procedures except in circumstances where an apparent immediate hazard or danger to the research participants. Any amendment shall be appended to the approved research protocol.

14.1.10 Shall inform the IRB, clinical monitor, the sponsor and the participants if the study is terminated or suspended at any time during the research process.

14.1.11 Shall be responsible for periodic assessment of the quality of data management as well as reporting on interim analysis whenever appropriate.

14.1.12 In case of clinical/experimental trials, shall ensure, at least, one of the investigators have a certificate on good clinical practice and/or good manufacturing practice or both or whichever is appropriate.

14.1.13 Shall ensure beneficial investigational products are available to the community after the research is completed.

Shall report to the DSMB, as applicable.

In collaborative research, shall consider the cultures and ethnic diversities and should make the research objectives particularly clear and remain aware of the concerns and welfare of the individuals or communities to be studied.

14.1.16 Shall provide adequate information in all publications to the reader, and to colleagues to permit the methods and findings to be properly assessed. Limits of reliability and applicability should be made clear.

14.1.17 Shall submit final report and findings to the IRB.

14.1.18 Shall ensure the community where the research is conducted is informed about the research findings.

## 14.2. Host Institution

The institution’s culture in which research is conducted strongly influence whether ethical conduct of research is supported or valued. The host institution must work closely with the investigator. The host institution shall monitor the investigator(s)’ research activities at the institution. More specifically, the host institution shall:

14.2.1 Ensure that the study design is scientific and ethical.

14.2.2 Ensure ethical implementation of the research.

14.2.3 Comply with legal requirements and ethics regulations as stipulated in this guideline.

14.2.4 Ensure that the investigators conducting the study are scientifically qualified and competent to carry out the research at the institution.

14.2.5 Facilitate and provide support for smooth and ethical implementation of the research.

14.2.6 Make sure that the results of the study are properly and publicly disseminated.

14.2.7 Ensure that guidelines, ethical principles, and related materials reach the end users and the investigators.

14.2.8 Provide periodical reports of ethical implementation of the study to the IRB’s Secretariat.

14.2.9 Take disciplinary action on the investigators for breach of any of this guidelines, regulatory and legal requirements.

## 14.3. Sponsors

Sponsors/Donors are responsible for providing an environment that promotes integrity, objectivity and the highest ethical standards of research, including standards for design, implementation and reporting. Particularly, sponsors must commit to protect participants in all research. Besides, sponsors are expected to ensure research subjects and communities are not made worse off during or after completion of the research. Sponsors can accomplish these goals in the following ways:

14.3.1 Ensure appropriate review and approval by appropriate IRBs. If the sponsor is based outside of Ethiopia, the sponsor must in addition produce approval from an appropriate IRB where the sponsor is based. If the sponsor is an international organization, the review of protocol must maintain rigor in accordance with its own independent IRB.

14.3.2 Monitor the research according to a plan approved by the IRB.

14.3.3 Select qualified investigators and institutions as collaborators, sponsors.

14.3.4 Provide ethical guidelines to all investigators.

14.3.5 Complying with the local ethical, regulatory and legal requirements.

14.3.6 Promoting research integrity.

14.3.7 Ensuring the local relevance of the research by involving local partners in the developmental stages.

14.3.8 Financing the study.

14.3.9 Ensuring adequate safety and efficacy of investigational products, if applicable.

14.3.10 Ensuring safety and efficacy of investigational products, if applicable;the sponsor shall ensure investigational products are manufactured following good manufacturing practice,

14.3.11 Supplying and handling investigational products.

14.3.12 Updating investigators’ brochure as significant new information is made available.

14.3.13 Establishing a DSMB, if applicable.

14.3.14 Assigning clinical monitors, if applicable.

14.3.15 Providing insurance to study participants in case of injury.

14.3.16 Providing special forms for recording and reporting of serious adverse events and ensure adverse events are appropriately investigated and managed until resolution or stabilization.

14.3.17 Informing the IRB if it suspends or terminates a research with detailed explanation for the termination or suspension.

14.3.18 Ensuring the community where the research is conducted is informed about the research findings.

14.4 Donors

Donors are responsible for providing an environment that promotes integrity, objectivity and the highest ethical standards of research. Donors can accomplish these goals in the following ways:

14.4.1 Ensure appropriate review and approval by appropriate IRBs.

14.4.2 Monitor the research according to a plan approved by the IRB.

14.4.3 Complying with the local ethical, regulatory and legal requirements.

14.4.4 Promoting research integrity.

14.4.5 Ensuring the local relevance of the research by involving local partners in the developmental stages.

14.4.6 Financing the study.

14.4.7 Providing insurance to study participants in case of injury.

14.4.8 Informing the IRB if it suspends or terminates the financial support.

14.4.9 Ensuring the community where the research is conducted is informed about the research findings.

# 15. Networking

Networking and creating a dynamic relationship among IRBs is essential for:

Establishing a strong data base system to standardize and streamline set of data elements.

Facilitating coordination among IRBs.

Establishing a strong and standard ethical review system within Ethiopia and harmonize safety reporting.

Building capacity and strengthening partnership among IRBs.

Sharing of experiences among local and international IRBs.

Establishing a central web-based repository.

15.1 Networking Mechanisms/Modalities

15.1.1 Information flow should be multidirectional.

15.1.2 All IRBs/ERCs shall submit reports to NHREC.

15.1.3 Reports of the respective IRBs shall include at a minimum: activities performed, support needed, problems encountered, etc.

15.1.4 For urgent matters, IRBs/ERcs should seek information or technical help from NHRECat any time through its Secretariat.

15.1.5 The NHRECwill distribute appropriate guidelines and other related information to other IRBs and request feedback.

15.1.6 The NHRECestablishes working relations with local and international IRBs/ERCs through its Secretariat.

15.1.7 Reporting at each level should be by mail, fax or email.

# SECTION II. ANIMAL RESEARCH ETHICS REVIEW GUIDELINE (1ST EDITION)

# 

# 1. BACKGROUND

Globally, the welfare of animals used in research has gained attention that has led to the development of guidelines and in some instances national laws governing animal experimentation. In Ethiopia, there are many research and academic institutions that use animals and their genetic resources for research or teaching purposes. Although there may be a general agreement that use of animals and their genetic resources in research is not wrong in principle, it is critical that animals used in research are treated humanely. With research projects that use animals on the increase worldwide and in Africa in particular, animal research ethics should continue to be reviewed to improve the welfare of animals used in research. Many medical research institutions make use of non-human animals and their genetic resources as experiment. Animals and their genetic resources may be subject to experimentation or modified into conditions useful for gaining knowledge about human disease or for testing potential human treatments.

With animals, experimentation has made possible major contributions to biological and genetics knowledge and to the welfare of humans and animals, particularly in the treatment and prevention of diseases. Consideration for the humane treatment and well-being of the animal meant for research should be incorporated into the design and conduct of all procedures involving such animals and their genetic resources, while keeping in mind the primary goal of undertaking the specific procedures of the research project—the acquisition of sound, replicable data. Many important advances in medical science have had their origins in basic biological research not primarily directed to practical ends as well as from applied research designed to investigate specific medical or veterinary problems.

There is still an urgent need for basic and applied research that will lead to the discovery of methods for the prevention and treatment of diseases for which adequate control methods are not yet available. The use of animals for predicting the probable effects of procedures on human beings entails responsibility for their welfare. In both human and veterinary medicine animals are used for behavioral, physiological, pathological, toxicological, and therapeutic research and for experimental surgery or surgical training and for testing drugs and biological preparations. The same responsibility toward the experimental animals prevails in all of these cases.

Ethiopian researchers are encouraged to adopt the replacement of living animals by alternative methods and will continue at an increasing pace, but the need for experiments on living animals will remain, principally for the following two reasons. Firstly, it is impossible to imitate in any other way the complex system of interactions between different organs that exist in every living animal; and second, in testing for the safety of medicines and other substances used in the home or work, specific tests on simplified systems will only detect the types of toxicity for which they have been designed, while there is an unlimited number of still unknown ways in which the substance may be poisonous and which can only be tested for by the administration to a living animal. Large numbers of animals are also used for non- invasive experiments which do not involve any kind of discomfort. These experiments include studies on the biology and ecology of animals for nonhuman purposes, often for conservation. Research is also done in the agricultural production field, such as feeding trials with farm animals to improve food production and food security for the local human population. In addition to these, research involving animal genetic resources is for better understanding of the genetic diversity, phenological traits qualitative and quantitative characteristics, disease and stress reaction their physiology, storage behavior etc.… of the genetic resources. For all research involving genetic resources and biological materials/specimens, investigators should be aware of, and are obligated to, respect and adhere to all ethical, legal, and regulatory requirements applicable Ethiopian this sophisticated era of genetic studies, as well as collaborative research and genetic resource transfer being common place, oversight and regulation is imperative to properly safeguard the rights and welfare of the Agricultural biodiversity/Biological resources.

The vast benefits to both animals and humans which have arisen directly from past animal research, and the reasonable expectation that such research will be of equal or greater benefit to all forms of life in the future, serves to justify the continuation of animal experimentation in general. However, the scientific community must recognize that they have both a scientific and ethical responsibility for the humane care of animals, and all who care for and use animals in research, testing and education must assume responsibility for their general welfare. It is especially important to recognize that the intent of research is to provide data that will advance knowledge of immediate or potential benefit to humans and animals. Researchers and academicians have developed and should continue to develop scientifically valid adjunct or alternative methods to animal experimentation.

The rationally for animal health research in Ethiopia is due to the fact that animal diseases are rampant and have a wider distribution and extent throughout the country. Thus, to mitigate the ever-increasing trends of disease threats posed to the animal agriculture and public health, research in animal health and their genetic resource is critical. The main focus of animal health research is availing improved animal health technologies and knowledge to the different livestock development partners and stakeholders of the country so as to fast-track the transformation process of the country’s livestock sub-sector in particular and the nation’s economy in general.

# 2. OBJECTIVE AND PURPOSE OF THE GUIDELINE

The purpose of this guideline is to give due attention to the experimentation with animals and their genetic resources by the research, teaching and technical personnel, undergraduate and postgraduate students in Ethiopia. In animal experimentation attention should be directed to the important ethical, legal and scientific responsibilities and the guiding principles to assist individual researchers. In this guideline, when we say experimental animals, it include all live, sentient non-human vertebrates, including eggs, fetuses and embryos, fish, amphibians, reptiles, birds and mammals, and encompassing domestic animals, purpose-bred animals, farm animals, and wildlife and their genetic resources.

The following are the objectives of this guideline:-

* To harmonize animal health and their genetic resource related research activities nationally which upholds ethical principles?
* To safeguard research involving animals and non-human primates from unnecessary/ unjustifiable risk outcomes related to experimental procedure, handling, and care and housing
* To conserve and sustainably utilize the genetic resources.
* To ensure that animal health and their genetic resource related research holds/embraces/possesses/considers cultural responsiveness/sensitivities for participating communities
* To ensure animal health research should be undertaken with a clear scientific purpose and a reasonable expectation that the research shall increase knowledge of livestock development
* To ensure all procedures carried out on nonhuman animals are to be reviewed by an institutional/ national research ethics committee/ review board to ensure that the research procedures are appropriate and humane
* To delineate in vivid detail the mechanisms that lead to certifying and approving a research protocol in animal health research
* To ensure timely review and communication of decision of submitted protocol to investigators and regular reporting of reviewed research protocols to appropriate body (MoSHE)
* To facilitate cooperation and networking among IRBs at local and international levels
* To support and channelize institutional level established review boards with required technical support
* To ensure internationally accepted research protocol complying international standards and guidelines for reputability and scientific soundness
* To ensure ethical and scientific research is executed in compliance with this guidelines, Ethiopian law, and international regulations
* To create awareness among investigators, sponsors, reviewers, decision and policy makers, farmers/ pastoralists and individuals/ communities on basic ethics principles

# 3. ETHICAL PRINCIPLES USED IN RESEARCH PROTOCOL REVIEWS

## 3.1. General ethical principle

### 3.1.1. Ethical Guidelines for the Use of Animals and their Genetic Resources in Research

1. **Respect for animals' dignity and their genetic resources**

Researchers must have respect for animals' worth, regardless of their utility value, and for animals' interests as living, sentient creatures. Researchers should be concerned about the conservation and sustainable utilization of the genetic resources and benefit of the farming community who conserved the biodiversity. Researchers must be respectful when choosing their topic and methods, and when disseminating their research. Researchers must provide care that is adapted to the needs of each laboratory animal.

2. **Responsibility for considering options (Replace)**

Researchers are responsible for studying whether there are alternatives to experiments on animals. Alternative options must be prioritized if the same knowledge can be acquired without using laboratory animals. If no good options are available, researchers should consider whether the research can be postponed until alternative methods have been developed. When justifying experiments on animals, researchers therefore must be able to account for the absence of options and the need to acquire knowledge immediately.

3. **The principle of proportionality:** responsibility for considering and balancing suffering and benefit

Researchers must consider the risk that laboratory animals experience pain and other suffering and assess them in relation to the value of the research for animals, people or the environment. Researchers are responsible for considering whether the experiment may result in improvements for animals, people or the environment. The possible benefits of the study must be considered, substantiated and specified in both the short and the long term. The responsibility also entails an obligation to consider the scientific quality of the experiments and whether the experiments will have relevant scientific benefits. Access to animal genetic resources and the fair and equitable sharing of the benefits arising from their utilization is one of the objectives of the Convention on Biological Diversity (CBD).

Suffering can only be caused to animals if this is counterbalanced by a substantial and probable benefit for animals, people or the environment.

There are many different methods for analyzing harm and benefit. Research institutions should provide training on suitable models, and researchers are responsible for using such methods of analysis when planning experiments on animals.

**4. Responsibility for considering reducing the number of animals (Reduce)**

Researchers are responsible for considering whether it is possible to reduce the number of animals the experiment plans to use and must only include the number necessary to maintain the scientific quality of the experiments and the relevance of the results. This means, among other things, that researchers must conduct literature studies, consider alternative experiment designs and perform design calculations before beginning experiments.

**5. Responsibility for minimizing the risk of suffering and improving animal welfare (Refine)**

Researchers are responsible for assessing the expected effect on laboratory animals. Researchers must minimize the risk of suffering and provide good animal welfare. Suffering includes pain, hunger, thirst, malnutrition, abnormal cold or heat, fear, stress, injury, illness and restrictions on the ability to behave normally/naturally.

A researcher's assessment of what is considered acceptable suffering should be based on the animals that suffer the most. If there are any doubts regarding perceived suffering, consideration of the animals must be the deciding factor.

Researchers must not only consider the direct suffering that may be endured during the experiment itself, but also the risk of suffering before and after the experiment, including trapping, labelling, anaesthetizing, breeding, transportation, stabling and euthanizing. This means that researchers must also take account of the need for periods of adaptation before and after the experiment.

**6. Responsibility for maintaining biological diversity**

Researchers are responsible for ensuring that the use of laboratory animals and their genetic resource does not endanger biological diversity. This means that researchers must consider the consequences to the stock and to the ecosystem as a whole. The use of endangered and vulnerable species must be reduced to an absolute minimum. When there is credible, but uncertain, knowledge that the inclusion of animals in research or the use of certain methods may have ethically unacceptable consequences for the stock and the ecosystem as a whole, researchers must observe the precautionary principle.

7. **Responsibility when intervening in a habitat**

Researchers are responsible for reducing disruption and any impact on the natural behavior of individual animals, including those that are not direct subjects of research, as well as of populations and their surroundings. Certain research and technology-related projects, like those regarding environmental technology and environmental surveillance, may impact on animals and their living conditions, for example as a result of installing radar masts, antennas or other measurement instruments. In such cases, researchers must seek to observe the principle of proportionality (see guideline 3) and minimize the possible negative impact.

8. **Responsibility for openness and sharing of data and material**

Researchers are responsible for ensuring that there is transparency about research findings and facilitating the sharing of data and material from experiments on animals and genetic resources. Such transparency and sharing are important in order to avoid unnecessary repetition of experiments. Transparency is also important in order to ensure that the public are informed and is part of researchers' responsibility for dissemination.

In general, the negative results of experiments on animals should be public knowledge. Disclosing negative results may give other researchers information about which experiments are not worth pursuing, shine a light on unfortunate research design, and help reduce the use of animals in research.

9. **Requirement of expertise on animals and their genetic resources**

Researchers and other parties who handle live animals and their genetic resources must have adequately updated and documented expertise on animals and their genetic resources. This includes specific knowledge about the biology of the animal species in question, and a willingness and ability to take care of animals properly.

**10. Requirement of due care**

There are national laws and rules and international conventions and agreements regarding the use of laboratory animals, and their genetic material both researchers and research managers must comply with these. Any person who plans to use animals in experiments must familiarize themselves with the current rules (this guideline).

11. **Respect for animal life**

This principle requires that animals used in research should be of an appropriate species and health status and should involve the minimum number required to obtain valid scientific results. It also recognizes that the use of different species may raise different ethical concerns.

12. **Societal Benefit**

This principle entails that where animals are used, the assessment of the overall ethical value of such use should include consideration of the full range of potential societal good, the populations affected, and the burdens that are expected to be borne by the subjects of the research. In addition, the obligations related to access to genetic resources include the fair and equitable sharing of benefits arising out of genetic resources, as well as compliance with prior informed consent and mutually agreed terms.

13. **Non-maleficence**

This principle entails that the minimization of distress, pain, and suffering is a moral imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in humans may cause pain or distress in other sentient animals.

## 3.2. Ethical issues in research

Research ethics are the set of ethics that govern how scientific and other research is performed at research institutions and how it is disseminated. Research ethics are important for a number of reasons. They promote the aims of research, such as expanding knowledge. They support the values required for collaborative work, such as mutual respect and fairness. This is essential because scientific research depends on collaboration between researchers and groups. They mean that researchers can be held accountable for their actions. Many researchers are supported by public resource, and regulations on conflicts of interest, misconduct, and research involving humans or animals and their genetic resource are necessary to ensure that money is spent appropriately. They ensure that the public can trust research. For people to support and fund research, they have to be confident in it. They support important social and moral values, such as the principle of doing no harm to others. Many or even most ethical codes cover the following areas:

**Honesty and Integrity**

This means that you need to report your research honestly, and that this applies to your methods (what you did), your data, your results, and whether you have previously published any of it. You should not make up any data, including extrapolating unreasonably from some of your results, or do anything which could be construed as trying to mislead anyone. It is better to undersell than over-exaggerate your findings.

When working with others, you should always keep to any agreements, and act sincerely.

**Objectivity**

You should aim to avoid bias in any aspect of your research, including design, data analysis, interpretation, and peer review. For example, you should never recommend as a peer reviewer someone you know, or who you have worked with, and you should try to ensure that no groups are inadvertently excluded from your research. This also means that you need to disclose any personal or financial interests that may affect your research.

**Carefulness**

Take care in carrying out your research to avoid careless mistakes. You should also review your work carefully and critically to ensure that your results are credible. It is also important to keep full records of your research. If you are asked to act as a peer reviewer, you should take the time to do the job effectively and fully.

**Openness**

You should always be prepared to share your data and results, along with any new tools that you have developed, when you publish your findings, as this helps to further knowledge and advance science. You should also be open to criticism and new ideas.

**Respect for Intellectual Property**

You should never plagiarize, or copy, other people’s work and try to pass it off as your own. You should always ask for permission before using other people’s tools or methods, unpublished data or results. **Not doing so is plagiarism.** Obviously, you need to respect copyrights and patents, together with other forms of intellectual property, and always acknowledge contributions to your research. If in doubt, acknowledge, to avoid any risk of plagiarism.

**Confidentiality**

You should respect anything that has been provided in confidence. You should also follow guidelines on protection of sensitive information such as patient records.

**Responsible Publication**

You should publish to advance to state of research and knowledge, and not just to advance your career. This means, in essence, that you should not publish anything that is not new, or that duplicates someone else’s work.

**Legality**

You should always be aware of laws and regulations that govern your work, and be sure that you conform to them.

**Animal and Genetic Resource Care**

If you are using animals and animal genetic resource in your research, you should always be sure that your experiments are both necessary and well-designed. You should also show respect for the animals and properly keep the genetic resources you are using, and make sure that they are properly cared for.

**Human Subjects Protection**

If your research involves people, you should make sure that you reduce any possible harm to the minimum, and maximize the benefits both to participants and other people.

This means, for example, that you should not expose people to more tests than are strictly necessary to fulfil your research aims. You should always respect human rights, including the right to privacy and autonomy. You may need to take particular care with vulnerable groups, which include, but are not limited to, children, older people, and those with learning difficulties

**Research Misconduct**

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

(a) Fabrication is making up data or results and recording or reporting them.

(b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

(d) Research misconduct does not include honest error or differences of opinion.

## 3.3. Roles and responsibilities in research protocol reviews

### 3.3.1. Investigators

Responsibilities of the investigators (principal) include, but are not limited to:

Obtain IRB approval or an exemption determination before conducting research involving human subjects.

Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.

Ensure that Research Staff are qualified (e.g., including but not limited to training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study.

Protect the rights, safety, and welfare of subjects involved in the research.

When required by the IRB, ensure that consent or permission is obtained as required by the protocol and as indicated in your submission.

Do not modify the animal and genetics related Research without or implement a planned deviation from the approved protocol without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subject(s).

Report to the IRB all required reports within the required reporting timeframe.

Follow applicable federal department or agency requirements when conducting the animal and genetic related research funded or supported by that department or agency.

Regular review and reconciliation of online financial statements for research work orders to ensure that all transactions posted are accurate and are charged to the correct research work order.

### 3.3.2. Teaching and research institutions

The PI’s faculty and academic/research unit are responsible for providing assistance with the day-to-day administration of research funds. Key responsibilities include:

Provision of necessary resources required to conduct research (e.g., space).

Authorization and monitoring of interim research accounts (IRAs) in accordance with IRA guidelines.

In conjunction with the Research Finance Training and Compliance Team, pre-reviewing research transactions for eligibility and compliance with sponsor and Institutions guidelines

Ensuring that faculty and/or academic/research unit staff involved in these review processes attends regular training sessions.

Providing assistance to Research Finance during internal or external audits on research work orders.

Providing appropriate administrative support to researchers to ensure that they can effectively manage their research portfolios.

In consultation with Research Finance, requesting suspension of further expenditures on research work orders if necessary.

Resolving deficits or bad debts on research work orders if these cannot be resolved with alternate funds held by the PI.

### 3.3.3. Ministries/agencies

The MoSHE through and other responsible institutions shall ensure that animal health and genetic related research ethics review is supported by an adequate legal framework that resonates with this guideline. MoSHE shall strive to put in place an appropriate and sustainable system to monitor the quality and effectiveness of research ethics review. In addition, the ministry is responsible to ensure existence of mechanisms for networking and cooperation among IRBs at different levels, as well as IRBs of international standing in collaborative research. The MoSHE requires all research involving experimentation in animal or protocol related to animal biological and genetic materials to be reviewed and approved by national research ethics committee or one of the ministry accredited and registered IRBs prior to initiation of any research-related activities, including recruitment and screening of animals species involved in research and biological organisms (pathogenic/ non-pathogenic) recovered from any animal species.

## 3.4. Ethical principles in collaborative research related to animals health

### 3.4.1. Ethical principles for International Collaborative Research and Partnerships

We are in the midst of a new era where collaboration has become a standard of work between researchers, research centers and funders. The establishment of international collaborative research partnerships in times of infectious disease outbreaks of international importance has been considered an ethical imperative.

### 3.4.2. Ethical principles in material transfer agreement (MTA)

The global nature of modern genomic and biomedical research requires that biological materials and data are exchanged between researchers, both within and between countries. These exchanges are generally made under contractual material transfer agreement (MTA). The term material transfer agreement (MTA) describes the terms under which research institutions/universities/diagnostic laboratories can share biological materials, typically for research or further diagnosis or evaluation purposes. In case when only human derived data are being shared, a request for a data use agreement (DUA) should be submitted including the MTA.

The prepared MTA shall include MTA for outgoing to govern the transfer of material from the host organization to another organization and MTA for incoming to govern the transfer of material from outside entities to the host organization. MTAs may apply to anything from materials that are simply under the control of the originator but have no formal intellectual property rights attached to them to proprietary materials protected by patents and trade secrets. Research staff and students usually lack both the knowledge and legal authority to enter contracts, like MTAs, on behalf of their institutions. To address this lack of capacity, institutions should have offices with a dedicated staff to negotiate, draft, and execute MTA. There are some experiences globally the institutional research ethics board also review and draft institutional MTA processes.

Compliance with national and international ethical standards demands that the institution’s scientific and research ethics review board also should play a role in ensuring the adequacy of the ethical review processes relating to the bio specimens and data. There are two components to these ethical review processes where stored bio specimens and data are made available to other researchers:

1. Prior ethical approval must have been sought to collection, storage, transfer, and research use of the bio specimens and data; and

2. Further ethical approval must be sought for all proposed future research using the bio specimens and data.

### 3.4.3. Ethical principles guiding Research Ethics Committees in the Exchange of Bio specimens and Data Internationally

One significant difficulty relating to international transfers of bio specimens and data is that different countries have different governance frameworks for collection, transfer, and use. RECs should play a more active role in ensuring that legal and ethical principles for the appropriate use of bio specimens are adhered to, both nationally and in an international context.

## 3.5. Ethical principles in involving communities in Scientific Research Ethics committee

National research ethics guideline document should guide research conducted at the community level to ensure that national/international expectations and standards are followed. Educating the community representatives about their roles and responsibilities is important so that they have a stronger voice before, during, and after the research process. This is also critical to migrate in case of unexpected or undesirable results happen to the community or to animals under research. The participation of local community representatives in planning and conducting research is, therefore, important. Communities should be informed of the research, possible outcomes (positive and negative), and the results of the research. Research findings belong to participants and their communities as well as the researchers and the research community. Community representatives and researchers can work together to make sure that research is conducted in the most appropriate way.

Communities often play a role in research design as well. For example, research with human/animal subjects should be designed to protect the rights and welfare of participants, and animal experiments should be designed to minimize pain and suffering, wherever possible. Generally, in animal health research the community representative represent general community interests in proper care and treatment of animals.

The committee member, selected from the community, should give answer to the following questions: -

What are the general community’s interests?

How does the community define “proper care and treatment” of laboratory animals and genetic materials and resources?

By what process should a community member determine the substance of the community’s concerns? What measures should this individual take to represent his or her constituency in scientific and research ethics committee deliberations?

### 3.5.1. Value of Community Involvement

Involving a community in animal production, health,and genetic resource related research, especially when the involvement is in the nature of partnerships, offers many advantages. Community representatives bring different perspectives, values, and competencies, which can contribute to the research project. While investigators bring technical knowledge about the subject of study and about research methodology, representatives of the community bring knowledge of community concerns, needs, values, and priorities. They also can bring a history of activism, leadership, and coalition building and a network of community contacts. Their expertise can shape research in constructive ways by posing significant questions for study, pointing out ethical concerns, suggesting how to modify a study to reduce risks and increase acceptance of the research in the community, assuring that data collection instruments are culturally appropriate, and promoting enrollment and retention. Community input also can help researchers determine what and when compensation/incentives for participation in research are appropriate and design an informed consent process which is essential features of the research protocol.

Thus, community involvement may increase the likelihood that research results are translated into actions and changes that benefit the communities in which it is conducted. Communication between researchers and community members can help identify ways in which research results can be effectively communicated to and applied by the community.

### 3.5.2. Principles of Community Involvement

Community involvement can take many forms. The Centers for Disease Control and Prevention recommends that researchers apply and adapt with “understanding, skill, and sensitivity” concepts from literature on community participation, community mobilization, community empowerment, cultural influences, and others. Representative strategies to engage communities in research include capacity building, coalition building, and community organizing (Centers for Disease Control and Prevention, 1997c).

In the context of animal health interventions, it is recognized that efforts to Bottom of Form

involve the community should address multiple levels of the social environment. Efforts to engage residents will be advanced when they feel a sense of community, see the process as worthwhile and inclusive, and believe the benefits outweigh the costs. Active community involvement will take time: community mobilization and self-determination frequently need nurturing. The final goal of involving the community are developing and using community assets for animal health decision making and action.

**Principles of community involvement: -**

First, researchers need to recognize the community as a unit of identity and attempt to work with existing communities. Investigators can use tools of community assessment and diagnosis to learn about the community and its economic conditions, history, norms, demographic trends, and political structure.

Second, community engagement and research collaboration should build on strengths and resources within the community by explicitly recognizing and supporting social structures and processes that contribute to the ability of community to work together to improve animal health. Resources may include skills and assets of individuals, networks of trusting relationships, or existing organizations and institutions, such as places of worship.

Researchers might ask a series of questions related to the community during an initial assessment phase to help address important issues in planning a research project:

* Bottom of Form
* Have I conducted preliminary research to ascertain the concerns of the community about the research?
* Has a community needs assessment been done to inform the research agenda?
* Is the proposed research relevant to the communities of concern?
* What role should community residents play to improve the research, disseminate findings to the community, the broader public, and policy makers?
* What capacity building is necessary to achieving meaningful involvement in the community?
* How will I evaluate the effectiveness of the approach taken to community involvement?
* Do I have plans to ensure that the research staffs are culturally competent and sensitive to the issues in the community?
* Researchers should also anticipate the questions likely to be raised by community residents:-
* What is/are the exact question(s) you are attempting to answer?
* How will this research benefit the community?
* How does this research address the stated problem?
* What jobs will be available as a result of this research study and how will the community be informed about them?
* What will be your method of using animals?
* What is your proposed outcome(s)?
* How will you disseminate your research findings?
* How will you ensure your study is implemented in a culturally competent manner?
* What written materials/explanation will be given to the community about the ethical conduct of the research work?
* What does the informed consent form say?
* Is the research protocol culturally appropriate for the community?
* What has the research team done to ethically use animals for research acceptable by the community?
* How culturally diverse is the research team?

# 4. NATIONAL RESEARCH ETHICS REVIEW COMMITTEE

## 4.1. Establishment and composition

### 4.1.1. Establishment of Animal Research Ethics Review Committee (ARERC)

ARERC are established under the authority of the Ministry of Science and higher education (MOSHE), but function independently. PMGRRERC will establish its office at MoSHE.

***Authority and Responsibility of ARERC***

The MOSHE requires all animal and genetics related research or research involving biological sample collection or recovering of microorganisms from any animal species to be reviewed and approved by ARERC or one of the MOSHE accredited and registered IRBs prior to initiation of any research-related activities.

To ensure a uniform and high standard of animal welfare and ethics in animal research, MOSHE vested power to ARERC to satisfy the below outlined roles and responsibilities:

Develop research review guidelines and standards

Review applications for research projects (proposals) and approve only those projects/proposals that are ethically acceptable using the standard research review mechanism.

Conduct follow-up review of nationally approved projects and activities and allow the continuation of approval for only those projects and activities that are ethically acceptable

* Take appropriate actions regarding unexpected adverse events.
* Report on its operations to MOSHE
* Require all members to declare any conflict of interest (COI)
* Maintain a record of research proposals
* Organize and deliver research ethics training to researchers in the country.
* Develop SOPs that govern the IRB’s research review procedures.
* Support the establish of IRB
* Accredits the IRB
* Solicit funds to build capacity at all levels of IRBs

Arbiter complaints, disputes, appeals and grievances on functions and review processes of IRBs submitted by researchers or institutions.

Monitor and evaluate IRBs at all levels.

Policy-advocacy and creating community awareness on ethical principles in animal research

### 4.1.2. Composition of ARERC

The committee shall have members with professional competence and mix of varying backgrounds, gender representation, a community representative, research ethics training and experience, different age group. Minimum number of members is fifteen (15).

**Secretariat of the** **ARERC*:***

The secretariat of **ARERC** reports to the research ethics directorate of MoSHE. There shall be one individual from MoSHE’s research ethics directorate as the voting member of ARERC . **Responsibilities of the Secretariat:**

Receive applications from other IRBs

* Ensure the completeness of application documents for ethical review
* Distribute protocols to all ethics committee members and/or external reviewers, as applicable and when directed by ARERC chairman or delegate
* Facilitate regular and extraordinary meetings in consultation with the Chairperson of the ARERC
* Communicate decisions of the ARERC to the applying institution with a copy to the PI
* Archive all project-related protocols, correspondence, decisions and minutes of the ARERC
* Receive periodic progress reports from investigators and annual reports from other IRBs
* Facilitate the accreditation and registration of IRBs based on the recommendation of the ARERC and endorsement by MOSHE
* Propose revision criteria for registration and accreditation of IRBs
* Support networking among the ARERC and other IRBs
* Facilitate the monitoring and evaluation of the ethical implementation of research
* Organize, support, and facilitate the conduct of research ethics training at National and Institutional level
* Manage and facilitate all official correspondence of the ARERC
* Solicit funds for realization of the duties of the ARERC
* Keep updated CVs and records of training of all members in the ARERC office
* **Responsibilities of** ARERC **chairperson**
* Prepares, convenes, and chairs regular and ad hoc REC meetings
* Represents the ARERC before the appointing authority and to the public
* Elaborates the plans of ARERC meetings and other activities
* Ensures timely response to applications
* Signs official ARERC documents, especially the REC’s ARERC decisions on ethical acceptability of the research proposals under its review, and other documents.
* Coordinates, leads, and oversees the work and various activities of the ARERC and of its secretariat.
* Oversees and proposes educational/training activities for ARERC mem­bers and for the ARERC as a whole.
* Provides, on behalf of the REC/ARERC, specific consultations with research­ers, the management of its research institution or appointing authority.

**Responsibility of members:**

Membership becomes effective upon accepting an invitation from the appoint­ing authority. Acceptance must be indicated by the member’s dated signature. Moreover, member shall need endorsement letter from his home institution

* A member should be willing to have his/her full name, profession and affilia­tion(s) published in the public domain
* Members are responsible for reviewing protocols to safeguard the rights, dignity and welfare of study participants
* Members are responsible for reviewing progress reports
* Members are responsible for oversight visits to monitor ongoing studies approved by ARERC
* Members are obliged to keep ARERC documents secure, private, and confidential
* Members should attend ARERC meetings regularly and participate fully and actively in deliberations
* Members should participate in continuing education activities in research ethics, RE
* Members must declare any COI for any protocol, and withdraw from the review of that protocol
* Members must maintain privacy and confidentiality of documents and deliber­ations of IRB meetings
* Membership may be terminated voluntarily. The member should write a resig­nation letter to the appointing authority through the IRB Chairperson giving at least a one-month notice.

## 4.2. Terms of reference (TOR) for committee activities

### 4.2.1. Committee Meetings

***Scheduled Full (Convened)*** *ARERC****Meetings***

The calendar dates and time of scheduled full (convened) IRB meetings should be agreed upon and confirmed by the committee and made public.

The frequency of the scheduled full (convened) IRB meetings should depend on the workload in terms of volume of applications submitted as well as the availability of IRB members who have other duties at their places of employment.

A quorum is more than 50% of the total number of IRB members.

The quorum may invite non-voting (relevant experts) to effectively review the protocols on that days agenda. The presence of a lay person is required. The community representative, although not required, is essential.

The ARERCSecretary should send an agenda; minutes of the previous meeting; notice about the date, venue and time of the next scheduled meeting; and other relevant documents to all ARERC members at least ten working days before the meeting

In the absence of the chairperson, the vice chairperson chairs the meeting. However, in the absence of the chairperson and the vice chairperson, the meeting will be cancelled

Applications should be submitted to the *ARERC* Secretariat at least three (3) weeks prior to the next scheduled meeting that the applicant wants his/her applications reviewed.

The Secretariat should prepare and distribute a tentative agenda based on the applications received, matters arising from the previous meeting, serious adverse events (SAEs), expedited reviews performed, continuing review applications, and amendments.

The general conduct of the meeting should be as follows:

Meeting called to order by the secretary in consultation with the Chairperson

Adoption of the agenda, with or without changes

Call for a vote to approve the minutes of the previous meeting, all members should agree with minutes

Declaration of COI

Other business

Adjournment of the meeting by the Chairperson

**Ad Hoc /Extraordinary** ARERC**Meeting**

Ad hoc/Extraordinary ARERC meetings should be held if there is an urgent issue or issues that do not qualify for expedited review but require a full (convened) IRB meeting.

The Secretariat should circulate a notice giving the date, venue, time, and agenda of the ad hoc/extraordinary meeting at least 48 hours before the meeting.

The general conduct of the meeting should be as follows:

Call meeting to order by the Chairperson

Adoption of the agenda and communicating to the ad-hoc meeting members

Relevant documents should be made available to IRB members at least 24 hours before the meeting

A quorum must be present for the ad hoc meeting to conduct business.

Adjournment of the ad hoc meeting by the Chairperson

Minutes of the ad hoc meeting should be circulated at the next scheduled ARERC meeting.

A vote to approve or request modifications should be made.

### 4.2.2. Termination of Membership

* Membership may be terminated voluntarily. The member should write a resignation letter to the appointing authority through the ARERC Chairperson giving at least a one-month notice.
* The Chairperson may resign by sending his/her resignation letter to the appointing authority after informing the committee at its next meeting.
* Membership should be terminated by the appointing authority on the advice of the ARERC if a member is going to be away for more than one year.
* Membership could be terminated by the appointing authority upon advice of the ARERC if the member has been absent from five consecutive meetings without offering an explanation.
* Membership should be terminated by the appointing authority for misconduct that tarnishes the credibility of the ARERC as determined by the ARERC.
* Membership should be terminated if a member is convicted of a criminal offence.
* Membership should be terminated by the appointing authority in consultation with the ARERC if a member is suffering from a chronic incapacitating illness that significantly reduces the ability to process information and make rational independent decisions.
  + Membership should automatically terminate when a member dies
* •There should be formal removal process in case of rogue committee member

### 4.2.3. Dissolution of ARERC

The ARERC should automatically cease to exist when the institution at which it is based ceases to exist.

### 4.2.4. Management of conflict and arbitration mechanism

Addressing research ethics issues by peer-based mechanisms will uphold scientific autonomy, be more cost-effective, and likely resolve issues in a peaceful way thereby creating a more harmonious atmosphere. In case of conflict arise at any stage of the review process an independent one-time committee of arbitrator shall be installed. The committee members must display impartiality, independence and objectivity in an arbitral tribunal which is crucial during the process of resolving. The committee member or invited expert with a COI will be required to excuse himself/ herself from the meeting during discussion and decision of any arbitration process. In addition, during conflict management, possible conflicts between implementing any of the Three Rs and delaying scientific progress would usually be resolved in the interest of scientific development. Upon calling independent experts as a committee member for arbitration he/she shall sign privacy and confidentiality agreements and COI forms to ensure that the information in the protocol is protected and that consultants do not have any conﬂicts.

## 4.3. Mandate and types of proposal to be reviewed by ARERC

The following are the list of research protocols mandated to be reviewed by ARERC

* Zoonotic diseases (Emerging and reemerging diseases of public health significance), exotic zoonotic diseases, research involving importation of highly pathogenic organisms
* Economically important trans boundary diseases having national interest
* Research involving animal genetic resources and genetically modified animal research/organisms
* Research involving endangered animal species
* Research involving recombinant vaccines
* Internationally collaborative research involving multi-sectoral agencies

## 4.4. Functions and review mechanisms

### 4.4.1. General Guidelines for research review mechanisms

Institutional Review Board (IRB) or Institutional Animal Care and Use Committee /ARERC complies with the regulations and recommendations for the care and ethical treatment of animal participants involved in research through the Animal Welfare Act and other related Acts & regulations & directives on Animals & animal products of the country.

Additional regulations may provide protection to species and all appropriate state and federal permits must be obtained prior to conducting field or laboratory research on animals protected by the Endangered Species Act Wildlife and Fisheries, and other state and local regulations.

The Institutional Animal Care and Use Committee (ARERC)/IRB for the protection of animal participants, is charged with the responsibility of reviewing, prior to its initiation, all research involving animal participants (whether the Project is funded or not). The ARERC is concerned with evaluating the care and treatment of participants in research ensuring the ethical treatment of animal participants.

The ARERC intention is not to hinder research; its only objective is to ensure that the welfare of animal participants is protected and that the project complies with federal/country standards. The ARERC is composed of experienced & educated researchers from different areas in the biological sciences.

### 4.4.2. Review Criteria

The national ethics review body shall oversee the humane care and use of animals and their genetic resources involved in research in accordance with federal and institutional regulations, and sponsoring agency policies and procedures. Assure that all key personnel involved in animal and genetic related research complete the required education for the humane care and use of animals and laboratory safety and radioactive materials in accordance with federal, state, and local regulations and Institution and sponsoring agency policies and procedures.

Supports and endorses cooperation with Institution compliance and monitoring efforts related to animal welfare and reports instances of noncompliance to the appropriate compliance office.

All research involving vertebrate animal participants (i.e. exploratory, descriptive, and experimental) must be reviewed by the ARERC /IRB. If the proposed study has not been completely designed at the time that a research proposal is submitted to a sponsor, provisional approval may be granted. Final approval must be sought when the research plans are complete and before the involvement of animal participants in the project.

Although ARERC review of research involving non-vertebrate animals is not required, the committee strongly suggests that spirit of the Animal Welfare Act and other federal guidelines be considered as part of the ethical responsibility of the researcher. To this end, the ARERC will conduct a Courtesy Review of such proposals at the request of the researcher and provide recommendations.

While the ultimate responsibility of conducting research in an ethical manner that complies with federal, state, and local regulations rests with the researcher, the ARERC reviewers will seek to determine that:

The transportation, care, and use of animals are in accordance with the Animal Welfare Act and other applicable federal laws, guidelines, and policies.

Procedures involving animals and their genetic resources are designed and performed with due consideration of their relevance to animal health and production the advancement of knowledge, or the good of society.

The animals selected for a procedure are of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulations, and in vitro biological systems should be considered.

Proper use of animals, including the avoidance and minimization of discomfort, distress, and pain when consistent with sound scientific practices is imperative. Unless the contrary is established, investigators should consider that procedures cause pain or distress in humans may cause pain or distress in other animals.

Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on un anesthetized animals paralyzed by chemical agents.

Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

The living conditions of animals are appropriate for their species and contribute to their health and comfort.

The investigators and other personnel are appropriately qualified and experienced for conducting procedures on living animals.

Principal investigators are responsible for:

choosing the most appropriate methods for their work, in consultation with veterinarians and other experts as needed;

detailing all animal-based methods in writing to the animal care committee within the animal use protocol forms provided for this purpose by the animal care committee;

answering questions from the animal care committee on any aspect of animal-based work, including:

why animals cannot be replaced, if this is the case;

why the animal model and proposed numbers of animals have been chosen;

what refinements to animal use are proposed and what additional ones could be considered (in some specific cases, certain elements that would normally be refinements may not be appropriate, in which case the principal investigator should provide justification of the proposed choice); and

What can be learned from previous, similar work?

Reports serious violations of approved protocol to the ARERC/IRB particularly any that may affect animal safety.

Prepares and submits animal studies protocols or changes in accordance with federal regulations and institution and sponsoring agency policies and procedures.

Submits proposed changes to the protocol for approval as required and assures that changes are not implemented prior to approval.

Reviews protocol at inception and as required thereafter for completeness, accuracy, and improvement opportunities.

**Considerations during Scientific Review including the following:-**

Importance and novelty of the scientific question

Strength of the scientific design and methodology

Feasibility of the research as designed

Appropriateness of the statistical analysis plan

Estimate of the probability of meeting the enrollment goals

Need for, and structure of, a Data and Safety Monitoring Board/Data Monitoring Committee (DSMB/DMC)

Assessment of the thoroughness of the proponent’s evaluation of the relevant literature and previous studies, if available

Strength of the qualifications of the investigator to carry out the protocol and the facilities available to him or her

Appropriateness of the inclusion/exclusion criteria

Dissemination plan (to enrolled participants and through formal publication)

### 4.4.3. Detail Review mechanisms

There are three possible mechanisms by which initial research proposals involving animal subjects and genetic resource related are reviewed;

* Exemption of review,
* Full board review,
* Expedited review,

The first mechanism, exempt review, is conducted by the secretary/chair-person of IRB/IAUCC.

The latter two, full & expedited review, are conducted by the IRB.

**Exempt review**

Only projects that involve hands-on work with vertebrate specimens that are alive during or immediately prior to the project require exempt review. Projects that involves non-vertebrate species or non-living vertebrate specimens such as museum specimens, preserved specimens, or other animals that are not euthanized in order to conduct a project are not subject to review, nor are projects that consist solely of field observations of animals in their natural habitats.

Research with animal subjects may qualify for exemption if, and only if,

all research procedures fall within the exemption categories listed AND b) the project does not involve any of the animals or procedures listed under “Restrictions”

* Restrictions:
* Research cannot be exempted if any of the following are involved:
* Procedures which expose participants to greater than minimal risk;
* Research involving endangered species;
* Experimental research involving all animals;

**Full Board Review**

The entire ARERC /IRB will review all proposals that do not fall into the Expedited Review category. All research proposals that are not exempt and do not meet the criteria for expedited review is reviewed via this review mechanism at a regularly convened meeting. Please allow one month for Full Committee Review and subsequent notification.

**Criteria for Approval**

In order to approve a protocol, the IRB must have sufficient information to determine that all of the following criteria have been met:

The research design is scientifically sound and will not expose participants to unnecessary risk.

Risks to participants are reasonable in relation to anticipated benefits to the participants and to society.

Risks to participants are minimized and, when appropriate, a plan is in place to monitor data collected to ensure the safety of participants.

Selection of participants is equitable given the purposes of the research and the setting in which it will be conducted..

Additional safeguards are in place to protect participants who are likely to be vulnerable to undue influence or coercion.

Adequate procedures are in place to protect the welfare of participants and maintain the confidentiality of data.

Depending on the quality of information presented to the Board and the degree to which the preceding criteria are met, the initial review will result in one of the following outcomes.

**Outcomes of Review**

**Approve**: If all of the preceding conditions have been met, then approval is granted to proceed with the project as outlined in the IRB application. The investigator is notified of approval in writing.

**Conditionally Approve**: If the IRB determines that risks to subjects are minimal but minor changes or clarifications are required that do not alter the conduct of the project, then a conditional approval may be granted. In the case of conditional approval, the conditions that must be met to secure approval are outlined in a letter to the investigator. The investigator must respond in writing to the conditions. This response is reviewed by the IRB Chair and/or other designated members to determine if conditions have been met. The research may **not** proceed until all conditions have been met and full approval is secured. Once it is determined those conditions have been met, the investigator is sent a letter of approval and the research may then proceed as outlined.

**Disapprove**: If the IRB determines that a project does not meet the criteria for approval and there are serious concerns related to one or more criteria, the IRB may disapprove a project. The investigator is informed of this decision in writing and is given feedback regarding the reasons for disapproval.

**Expedited Review**

This Guideline allows certain types of research to be reviewed using "expedited" procedures Protocols that are reviewed via an expedited process are evaluated by the same ethical standards and must meet the same approval criteria as those that receive full IRB review. Thus, the same general Application for IRB Review must be submitted when applying for expedited review. However, the review process does not require discussion at a convened IRB meeting.

In the case of an Expedited Review, the chairperson of the ARERC/IRB chooses a limited number of members to review the proposal by email. If the limited groups of reviewers have significant concerns, a Full Committee Review may be warranted. Informal consultation with the ARERC chairperson may assist the applicant in determining the best type of review to request

Typically, the IRB is able to provide Investigators with the review outcome of an Expedited Review within 15 business days of when the Application was submitted for review.  Investigators will be sent an email notifying them of the review outcome.

In order to be eligible for expedited review, a research protocol must meet the criteria outlined below. In determining whether a project is eligible for review under the IRB expedited review procedure, the a) level of risk, b) the nature of the participant population, and c) type of research procedures must be considered.

**Level of Risk**

To be eligible for expedited review, research must involve “minimal risk” to participants. Some regulations define “minimal risk” as follows: “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.’’

In deciding whether to request expedited review, the researcher must make an initial determination that the study involves “minimal risk” to participants. Ultimately, however, the Expedited Reviewer will determine the risk level of the proposed research.  If the Expedited Reviewer determines that the Protocol involves greater than minimal risks the Protocol must be reviewed at a Full Board IRB Meeting.

**Nature of Participant Population**

Studies using the following populations may not be reviewed under the expedited procedures. Research to be conducted on endangered species includes all experimental research involving rare and endemic animals.

**Research Procedures**

For minimal risk research, Federal Regulations designate certain categories of research procedures as being eligible for expedited review. .

An IRB member conducting expedited review has the authority to request additional information, to approve a project, to conditionally approve a project and specify conditions of approval, or to table a project for re-review. They do not, however, have the authority to disapprove a project. Expedited reviewers must refer any project which they would have disapproved to the full IRB. They may also refer any project to the full IRB if, in their judgment, full review is warranted.

**Continuing Review**

In its initial review of the proposal, the ARERC will consider the extent of continuing review needed. All proposals shall be reviewed annually, but in certain research the participants are exposed to more than usual risk; such proposals may be reviewed at more frequent intervals appropriate to the research. This review interval will be determined at the time the research is approved and may be changed at the discretion of the ARERC. In each such review, the principal investigator will be required to promptly report the status of the research activity, and any proposed changes in the research activity. If the research is still in progress, the investigator will affirm that the approved research protocol involving animal participants is being followed.

## 4.5. Applications for review

All research protocol applications to the ARERC must be channeled through the ARERC Secretariat. The secretariat shall then register the accepted protocol on application registration logbook.

In order to submit a protocol to the Ethics Committee, the principal investigator will find the information in this guide useful. For ethical review of protocol, the Committee needs the following materials:

1. Paper copies of research protocol and an electronic version (in MSWord or pdf format).

The protocol should have the following sections:-

Cover page that shows:

Title of research, Full Names and Qualifications of investigators, Sponsors(where applicable), Other Collaborating Institutions and Investigators

Corresponding Investigator, who must be the Project Principal Investigator (PI) or Local PI of the research and bears legal responsibility for the research.

The research proposal should contain enough information to allow the committee judge the ethical aspects of the research.

The protocol may contain the following sections:-

Background of Study -Describing current knowledge about the research

Rationale for the study

Objectives of the study

Research Methodology may contain

Study design -stating clearly the nature of the study (descriptive, drug trial, experimental

Sample size determination

Sampling strategy/Interview including inclusion/exclusion criteria/ frequency of interviews

Statement on invasive sampling (blood, tissue etc) inclusion/exclusion criteria and frequency of sampling

Data collection procedure

Physical examination procedure if indicated

Follow up details if required

Laboratory procedure to be used

Intervention to be used

Data analysis method to be used

Copies of Questionnaires, Survey instruments, Case report forms and Samples of Drug or other Devices to be used in the study must be included in the protocol

The protocol should contain an ethical considerations section as a separate entity in which a researcher is to clearly identify the potential ethical problems that may arise in the research and address these.

2. Principal Investigator’s CV, containing enough information to judge the ability of the PI to conduct the research

3. Supervisor’s attestation statement (Where applicable–in student’s research).

4. Co-Investigators attestation statement. (Where applicable) or Copy of letter(s) of support from co-investigator(s), laboratories and sources of required resources (where the researcher indicates that (s) he will be collaborating with others.

5. Sponsor’s attestation statement i.e. letter of sponsorship. (Where applicable)

6. Materials Transfer Agreement (MTA -Where samples will be shipped out of Ethiopia

7. The informed consent form on institutional or departmental letter headed paper.

When all prescribed application materials have been assembled, here are the steps to follow by the PI:

Write an application letter to the Chairperson, Ethics Committee

Complete an application form

Compile all prescribed application materials and ensure that they are properly numbered and do not have many typographical errors

Ensure that all relevant institutional officials have signed off on the protocol including a Supervisor in case of student’s research

If applicable, attach a copy of proof that the PI have recently undertaken satisfactory research ethics training (institutional or online).

# 5. ETHICS REVIEW COMMITTEE (ERC) OFFICE

## 5.1. Organizational Structure

To effectively and efficiently deliver research ethics review services, functional and structural arrangements are established at the National, and Institutional levels as depicted in the Organogram below. The research ethics directorate at the MoSHE oversees coordinate and regulate the ERERC and IRB’s activities. Moreover MoSHE shall give accreditation to IBRs by commissioning the ARERC . The established IRB shall prepare its own TOR following the guideline prepared by ERERC .

There shall be properly channeled communication between:-

I. IRB and ERERC

II. PI and ERERC /IRB

III. ERERC and MoSHE

## 5.2. Administrator and term of reference for committee members’ Appointment

All the members will be appointed, reappointed or retired by MOSHE in consultation with the relevant stakeholders. In cases where members come from diverse institutions, the appointment should be upon the recommendation of the institution where the potential ARERC member is based. Each appointment shall normally be for a term of two years. It is recognized that in some circumstances, the availability of suitably qualified potential members will require some members to serve for longer periods. Chairperson and vice chairperson shall be appointed by the majority of ARERC members .

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# SECTION III. PLANT RESEARCH ETHICS REVIEW GUIDELINE (1ST EDITION)

## Background

## Introduction

It is generally known that agriculture as a long history. Starting approximately 12,000 years ago, the domestication of plants and animals began independently in several different places, including centers in East Africa, West Asia, East Asia, Central America, and South America. Domestication also may have occurred in other locations, although convincing archeological evidence has not been found(Ogueri, 2005). In the domestication process, humans manipulated animals, plants and the environment in various ways to increase the availability of the desirable species and desired traits of these species.

In the late twentieth century, systematic thinking about the values and norms linked with the food system farming, resource management, food processing, distribution, trade, and consumption came to be referred to as *agricultural ethics*. Agricultural ethics in corporates elements of philosophical ethical analysis with concerns about particular *subject areas* that arise in association with the food system(Ogueri, 2005). Aspracticedbyphilosophersandscholarsfromreligiousstudies,thesocialsciences,andtheagricultural disciplines themselves, agricultural ethics has grown from the work of a handful of philosophically trained individuals in U.S(*Local Food and Community Development - Google Books*, n.d.).Worldwide collection of academics, scholars, farmers, policymakers, and activists, thinking and writing about these issues.

The main purpose of agricultural research involving plant, animal and microbial genetic resources is better understanding of the genetic diversity, phenological traits qualitative and quantitative characteristics, disease and stress reaction their physiology, storage behavior etc.… of the genetic resources. More over, as evidence-based practice has become necessary attheturnofthe21st century, and quite understandably, existing procedures and practices are challenged continuouslyfortheireffectiveness,efficiency,quality,accessibility,andacceptability by the community.

However, in the quest to ensure agricultural development and knowledge, conservation and proper utilization of the genetic resources must be insured at all times. Utilization of the Genetic resources must be based on ethical, legal, and regulatory requirements applicable in Ethiopia about the use of the country’s genetic material.

The EBI\_EIAR germplasm research for development focus is on conservation and the effective use of genetic diversity and the further development and deployment of EBI\_EIAR germplasm for the benefit of improved and more sustainable food and nutrition security, poverty reduction, and environmental sustainability

For all research involving Genetic resources and biological materials/specimens of plant and microbial origin, investigators should be aware of ,and are obligated to, respect and adhere to all ethical, legal, and regulatory requirements applicable in Ethiopia.

In this rapidly advancing, complex, and sophisticated era of genetic studies, as well as collaborative research and genetic resource transfer being common place, over sight and regulation is imperative to properly safe guard the rights and welfare of the Agricultural biodiversity/Biological resources.

For research to be ethical, all of the following eight criteria’s must be met:

**Ethical justification and scientific validity:** The research must be rigorous in its methodology. For research to be ethical, the methods must be valid and practically feasible,theresearchmusthaveaclearobjective,bedesignedusingsoundscientificprinciples,havesufficientstatisticalpower,andbebasedonadequateknowledge of the scientific literature.

**Scienceandsocialvalue:**Theproposedmethodology shoulddemonstratevalidscientific basis/ground, ensure the proper utilization of the genetic resources and benefit sharing to the communitywheretheresearchisconducted.However,theproper conservation for sustainable utilization shouldoutweighanybenefittothesocietyor gaininknowledge.

**Favorablerisk-benefitratioto the geneticresourcesand theircommunities:**Risks toAgricultural biodiversity/Biological resourcesshallbeminimizedthroughusing appropriate methodology that are consistent with acceptableresearchdesignandpotentialbenefitsenhanced. Themaximumbenefit shouldbeprovidedatthelowestpossiblerisk,andriskstogenetic resources shallbereasonableinrelationtoanticipatedbenefits.

**Fairselectionandenrollmentofbiological resources:***“Scientificobjectives,not vulnerabilityorprivilege,andthepotentialfor anddistributionofrisksandbenefits, shoulddetermine communitiesselectedasstudysitesandtheinclusioncriteria forindividuals…”*Thejustificationforselectionandtheequitablenatureofselection ofresearchsubjectsshouldbedescribed.

**Privacy:**Privacyshouldberespected,confidentialitymaintained,theopportunityto withdrawatany timeorrefuseanycomponent(s)oftheresearchshouldbeavail- able,andthewell-beingofgenetic resourcesshouldbemonitored.,

**Independent/IRB review:**“*Individualsthatarenotaffiliated withtheresearch mustreviewtheresearchandapprove,amend, orterminatetheresearch.*”How- ever,individualsinvolvedinindependentreviewwithanyconflictsofinterestmay besummonedtoprovideinformationtotheIRB.

**Communityengagement:**Researchersareencouragedtoinvolve thecommunityindecisionmakingaboutthedesignandconductofthestudy.Be- sides,investigatorsshouldconsiderthelocalcustoms, traditions,cultureandreligiouspracticesofthecommunitywheretheresearchisproposedtobeconducted.

## Preamble

MoSHEattachesthehighestprioritytomaintaininghighstandardsofintegrity,responsibility,andaccountabilityinallresearch conducted inEthiopia.

Inaddition, MoSHEobligatesthat ‘ResearchwithAgricultural biodiversity/Biological resourcesshould becarried outonlybyorstrictlysupervised by,suitably qualified andexperiencedinvestigatorsandinaccordance witharesearch methodologythatclearlystates theaimoftheresearch, the reasons forproposingthat itinvolves Agricultural biodiversity/Biological resources,the nature anddegree ofanyknownriskstotheGenetic resources, thesourcesfromwhichitisproposedtoaccess the genetic resources,andthe way proposedfor getting permit to access the proposed genetic resources. Themethodology shouldbescientificallyandethically appraisedbyoneor moresuitablyconstitutedreviewbodies, independentofthe investigators.’

MoSHEensures thatthis guideline basicallyoperate withinthe legalframeworkof Ethiopiaand that the IRBsoperateindependentlyand withoutinfluenceand coercion.Furthermore,MoSHEdemands thatmembership ofIRBs shouldbelargeenough toensurearobustdiscussionofresearch methodology.Additionally,IRBmembership shouldhave ahealthymixofrepresentationbydifferentgenders, disciplines, sectors, andlaypersons.

Whilethisdocument focusesprimarilyonguidelinesforIRBs,itemphasizesthatat- attentionshallbegiventothewidersystemofAgricultural biodiversity/Biological resourcesprotections of whichIRBsareapart.TheseguidelinesempowerIRBstoperformeffectivelyand efficientlywithbestintentions.Thereviewguidelinesaredevelopedtooperateinthe existingresearch systemswiththefollowingobjectiverealities**:**

Constitutional and legalrights,relevantpoliciesrelatedtoAgricultural research and science exist.

Theseguidelinesareexecuted under theLawofEthiopia.IRBsoperateunder explicitlegalauthority.

Allresearch withAgricultural biodiversity/Biological resourcesissubjecttotheoversightofanIRB.

MoSHEhastheprimaryresponsibilityforensuringthatIRBsaresubjecttoadequateoversight.

Mechanisms areinplace toensureIRBsworkeffectivelyand efficiently.IRBs arepartofalargerresearch participant protection programs that alsoinclude trainingofIRBmembers andinvestigators.

Procedures exist to ensure clear and efficient communication, harmonization of standards, networking, and cooperation among the PMGRRERC and other IRBs, and between different levels of review and publication committees in departments/ units of institutions. In addition, procedures exist for the coordinated review of multilocation research within Ethiopia or international collaborative research.

Mechanisms exist to ensure that IRB activities are coordinated with national regulatory authorities’ oversight of drugs and medical devices

Mechanisms arecreatedforobtainingcommunity inputintotheethicsreview system.

AsystemexistsforregistrationofIRBsthatoperateinEthiopia.

MoSHEattachesemphasis thatthisguidelineispartofanefforttoestablish, facilitate andstrengthen aneffectiveagricultural research systeminEthiopia.Theaimoftheagriculturalsystemistoadvanceanduseofscientificknowledgetoimproveagricultural development.Thekeyfunctionsofthisagriculturalresearch arestewardship,of whichresearchethicsisapart,financeofthesystems, creation ofand sustaining resources,andproductionanduseofknowledge.Hence,

**Understandingandconsidering**

Theshortcomings ofthe existingguidelines inthe faceofthe wideningland- scape of researchareas,complexityof research procedures, andevolvementof geneticstudieswiththeconsequentbiobanks,

Thecriticalimportanceofestablishing astrongAgriculturalresearchsystem,

Therelevanceandresponsibilityofensuringstandardizedresearch ethicsreview alloverEthiopia,

Theneedtoensure independenceofIRBoperations anddecision-making from influencebyanyonewhosponsors, conductsorhoststheresearch itreviews,

Theneedforensuring networkingandcollaborationofIRBs,both localand international,

TheincreasingnumberofAgricultural teachinginstitutions andwiththemthenumberandqualityofresearch,

Evidence-based practiceistheorderoftheday,and

**Cognizantof**

Therapidlyadvancingandcomplexresearch relatedtogenetic,biomedicalscience,andtransferof plant, animal and microbial genetic materials,

TheincreasingnumberandscopeofcollaborativestudiesbynumerousinvestigatorsandinstitutionswithinandoutsideofEthiopia,andwiththeexistingpol- icy,academic andadministrative environment, theincreasinginterestofdonors tosponsorresearch inEthiopia,

Researchparticipants’protection,thatshouldinvolvenotonlyresearch methodology review,but alsoethicallysoundresearchparticipant-investigator interactions, continuous safetymonitoring,adherencetoapprovedresearch methodology,andqualityimprovementinresearch,

Thedutytoensure mechanismstomakeIRBoperations transparent,accountable,consistent, andofhighquality;establishing mechanismsfor IRBstoemployreliablemeans toevaluatewhetherthestaffandmembers routinelyfollow theIRBpolicies,rulesandguidelines; theneed forbothinternalandexternal evaluation; thedemand toaddress complaints andgrievancesfromallparties involved inresearch (researchers,research participants,communities, sponsors,andothers),

Thatresearch shouldbecarriedoutinfullcompliancewith,andawareness of, standards,laws,regulationsofthecountry, aswellaslocalcustoms, community,andthemixofsocial,traditional,andculturaldiversity,

MoSHEdevelopedthisNational Research EthicsReviewGuidelinestoconserve and ensure the sustainable utilization of all Genetic resources in all research proposed to be conducted in Ethiopia, based upon the agricultural science and Technology Policy and the responsibilities assigned to the MoSHE.

Nootherguidelinesandrequirements areallowedtodiminishorremoveanyof the protection of the genetic resources setforthinthisNational ResearchEthics ReviewGuidelines.

## Scope of Application

ThisGuidelineisapplicabletoalltypesofresearch thatinvolvesAgricultural biodiversity/Biological resources, includingbutnotlimitedto:

Studiesofaphenological, nutritional, molecular, biochemical, orpathologicalprocesses

Genetic diversity related research, yield and yield related trials,disease and stress related researches,andotherinvestigationalproducts

Qualityimprovementresearch

Research relatedtotraditional medicinal plants.

Researchthatmayincludeoneor acombinationofobservations;interviews,internet based,mail-based,andtelephoneresearch; focusgroupresearch; surveyandresearch withbiologicalsamples.

Furthermore, theguidelinesareapplicable inresearch proposedtobeconducted by allsectors andorganizations. Theseinclude, butarenotlimitedto,public,private, faith-based,indigenous and internationalnon-governmentalorganizations(NGOs), bilateral,multilateral,andUnitedNations’agencies.

# 2. Objective

## General objective

The objective of this guideline is to ensure ethical and sustainable utilization of Agricultural biodiversity which is the outcome of the interactions among genetic resources, the environment and the management systems and practices used by farmers and to ensure sharing the benefits arising from the utilization of genetic resources that are held by indigenous and local communities and their knowledge.

## Specific objective

To ensure the right and autonomy of the farmers and the society to decide to participate in the research activities and only in voluntary.

To ensure the conservation of the biodiversity maintained by the society and benefit sharing from it.

To provide a legal framework to benefit all sector of the society from the reperch and ensure the equity.

To create awareness among researchers, research institutes, donors, policymakers, and farming community on basic ethical principles

To monitor the benefit gained by the society (the farmers) from the research output and royalty sharing.

To regulate the movement of plant and animal microbialgenetic resources

To regulate the impact of the research activities on the conservation of the Biodiversity

To ensure rigorous ethical research proposal or protocol review

To ensure timely research methodology and project proposal review and communication of the decision

To ensure strong collaboration among different stakeholders for research proposal and research methodology development with the participation of collaborative research institutes.

To ensure the interdisciplinary collaboration during research proposals development and the project lifetime.

To strengthen the cooperation and integration of the local IRBS at local and international levels.

To put in place legal consideration on researchers, to undertake an ethical review prior to the implementation of the studies.

# Ethical principles

High ethical standards in Agricultural research can be achieved only when investigators aspire to such standards in their research activities. for the conservation and sustainable utilization of agricultural biodiversity in research, all Research Ethics Review Committees (RERCs) and IRBs, regardless of their level, shall promote three basic ethical principles:

* proper deployment of genetic materials
* Benefiting sharing
* justice.

In general, RERCs shall ensure that investigators have thought of ethical issues, specifically that no harm will be done and no damage of the genetic resources in the name of research, regardless of the research question planned for exploration. However, in certain circumstances, the weight given to each of these three basic ethical principles may differ in accordance with the type of the research and the setting where the research is conducted. Nevertheless, the IRB should ensure that the following basic ethics principles are met.

## Proper deployment of genetic materials

The research activities should always be in line with the conservation and sustainable utilization of the genetic resources. Besides, the researcher should respect the benefit of the farming community who conserved the biodiversity to be used in the research activities and should provide benefits for society after the research activities completed. Respecting the natural resource should be an integral and important part of the researchers since all the agricultural activities and society is highly dependent on this resource.

## Benefit sharing

Access to genetic resources and the fair and equitable sharing of the benefits arising from their utilization is one of the three objectives of the Convention on Biological Diversity (CBD). [Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization](https://www.cbd.int/abs/)(Gómez-Castro & Kipper, 2019). This agreement created a framework that balances access to genetic resources, including those related to [traditional knowledge](https://www.cbd.int/traditional/Protocol.shtml) of indigenous and local communities, on the basis of prior informed consent and mutually agreed terms, with the fair and equitable sharing of benefits, thereby contributing to the conservation and sustainable use of biodiversity. The Protocol entered into force in 2014, 90 days after the date of deposit of the fiftieth instrument of ratification.

The Nagoya Protocol is the first international instrument of particular relevance to indigenous and local communities negotiated since the adoption of the UN Declaration on the rights of indigenous peoples (Dowie, 2009). As such it is a significant step in mainstreaming indigenous rights as a cross-cutting issue in international negotiations.

## Justice

Justice connotes fairness and equity in the distribution of the benefits and burdens of research to the farming community.

At the core of the Nagoya Protocol are obligations related to access to genetic resources, the fair and equitable sharing of benefits arising out of genetic resources, as well as compliance with prior informed consent and mutually agreed terms.

The principle of justice requires equality in the distribution of benefits and burdens among the population groups likely to benefit from the research. Distributive justice means that no segment of the population should be unfairly burdened with the harms of research. It thus imposes particular obligations toward individuals who are vulnerable and unable to protect their own interests. Conversely, distributive justice imposes duties neither to neglect nor discriminate against individuals and groups who may benefit from advances in research.

Justice also demands balancing the benefits and burdens to the community where the research is undertaken.

In addition, the investigators shall assure that information obtained in the course of the investigation remains confidential to protect participants from possible harm. Data unlinked from individuals or groups does not jeopardize confidentiality. The privacy of individual participants also needs to be protected throughout the investigation by the investigators.

# Institutional Authority and purpose

## Institutional authority

PMGRRERC and IRBs are established under the authority of the Ministry of Science and Higher education, but function independently. The MoSHE requires all research involving Agricultural biodiversity / Biological resources to be reviewed and approved by APMGRRERC or one of the MoSHE accredited and registered IRB sprirt initiation of any research related activities, including employment and screening of the genetic resources.

## Purpose of PRERC, IRBs

The PRRERC and IRB’s objectives to protect the conservation and sustainable utilization of Agricultural biodiversity/Biological resources in agricultural research and conservation activities. The IRB reviews and over sees research on Agricultural biodiversity/Biological resources to ensure that it meets the ethical principles mentioned in this guide line, conventions on biological diversity (CBD), variety release guidelines and principles, and that it complies with legal requirements and other pertinent regulations, guidance, and local laws.

* The PRERC and IRB’s duty is to in form and assist the investigators and advisors on ethical and procedural standards related to the use of agricultural biodiversity/Biological resources in research, to facilitate compliance with this guidelines, Ethiopian law, and inter national regulations.

However ,the primary responsibility for assuring that the conservation and sustainable utilization of the Agricultural biodiversity/Biological resources properly handled are rests upon the investigators conducting the research. Others engaged in the conduct of the research including host institutions and sponsors share this responsibility. Faculty advisors serving as Principal Investigators (PIs) to students who conduct research have an obligation to carefully consider whether the students are qualified to safeguard adequately the conservation and sustainable utilization of the Agricultural biodiversity/Biological resources.

The PRERC and IRB have the authority to ensure that research studies conducted under its jurisdiction are designed and conducted in a manner that protects the conservation, sustainable and proper utilization of the Agricultural biodiversity/Biological resources Specifically: -

The PRERC and IRB reviews, and has the authority to approve, require modification, or dis approve all research activities that fall within its jurisdiction.

The PRERC and IRB have the authority to conduct continuing review as it deems necessary to protect and ensure the conservation and sustainable and proper utilization of the Agricultural biodiversity/Biological resources, including requiring progress reports from investigators.

The PRERC and IRB may suspend or terminate approval of a study not being conducted in accordance with the PRERC and IRB’s requirements or that has been associated with unexpected serious harm to Agricultural biodiversity / Biological resources or others.

The PRERC and IRB have the authority to observe or have a third party observe the informed consent process and/or audit the progress of any study in its jurisdiction as it deems necessary to protect the Agricultural biodiversity/Biological resources.

The PRERC and IRB may place restrictions on a study.

## Use of Policies, Procedures

The PMGRRERC and IRB members and its Secretariat staff must maintain and follow all written policies and procedures consistent with Ethiopian regulations, good biological research practices, good practice in handling genetic resources, and ethical breeding procedures when reviewing proposed research.

# 5. Ethics Review System

The MoSHE through the Ministry of Justice ,shall ensure that Agricultural research ethics review is supported by an adequate legal frame work that resonates with this guideline. MoSHE shall strive to put in place an appropriate and sustainable system to monitor the quality and effectiveness of research ethics review. In addition, MoSHE isresponsibletoensureexistenceofmechanismsfornetworkingandcooperationamongIRBs at different levels, as well as IRBs of international standing in collaborative research.

All agricultural research involving Agricultural biodiversity/Biological resources must under go review by the PRERC or an independent IRB. In Ethiopia, ERCs are established at three levels: National Ethics Committee (NEC),Institutional (IRB Level A) and (IRB Level B).The composition and mandates of these ERCs are stated below. It is important to note that decentralization of the activities of the PRERC and subsequent establishment of new and empowerment of already existing Institutional IRBs, shall be realized.

## Organizational Structure

To effectively and efficiently deliver research ethics review services, functional and structural arrangements are established at the National, and Institutional levels as depicted in the Organogram below.

* 1. **O**rganizational Structure

Plant and Microbial Genetic Resources Research (PMGRRERC) ethics review committee (15-20

Guideline revision, Registration and Accreditation of IRB

Ethics review

Following up and monitoring

Training and capacity

IRB-A

IRB-B

Ministry of Sciences and Higher Education (MoSHE)

Research Ethics Directorate/Secretariat

Director General of MoSHE

## Plant Research Ethics Review Committee

The purpose of the PRERC is to safeguard the dignity, rights, safety, and welfare of all actual or potential research participants and/or communities. The PRERC is mandated to review research protocols and the supporting documents on their scientific and ethical merit. Furthermore, the PRERC is mandated to assure that proposed research resonates with the Agricultural research directives as stipulated on the Agricultural research and extension.

### Composition

Shall have members with professional competence and mix of varying backgrounds, gender representation, a community representative, training and experience in research ethics.

Minimum number of members is fifteen (15). The details are described below.

### Mandates and Functions of PRERC

Develop research review guidelines and standards

Accredit and recommend licensing and registration of IRBs by MoSHE

Solicit funds to build capacity at all levels of IRBs

Organize and deliver research ethics training to IRBs at all levels using different media (classroom, on-site, internet-based); develop standardized training materials for countrywide use.

PMGRRERC Protocol Review - The PMGRRERC is responsible for giving final ethical decisions on:

All field and laboratory trials involving new genetic materials from abroad, crossing of exotic genetic Resources, introduction of Agro-chemicals and introduction of other biological agents and alien invasive species (AIS). For a llresearch that involves introduction and export of genetic resources in to and outside of the country, authorization and monitoring by EBI to get an import and export permit is a requirement before submitting a protocol for review and approval.

Multi-center collaborative research, including student theses (MSc, PhD, post-doctoral studies) that inherently exhibit more than minimal risk, and experimental trials.

Research which is funded by companies producing the experimental product.

Experimental research which is carried out by a national agency or agencies with international collaboration.

Projects that require transfer of Biological materials(DNA samples, seeds, microbes, semen or any specimens).

Umpire complaints, disputes, appeals and grievances on functions and review processes of IRBs submitted by researchers or institutions.

Monitor and evaluate IRBs at all levels.

Facilitate experience sharing among local and international IRBs.

Facilitate international registration of Level-A IRBs such that their reviews are accepted by funding agencies.

Review of trials that are funded by breeding companies,

Review very urgent research projects that are of national interest and priority, and

Policy-advocacy and creating community awareness on ethical principles in research, and legal and regulatory reforms, and changes related to research involving Agricultural biodiversity/Biological resources.

## Institutional Review Board, Level-A

These IRBs can be regional or institutional. These are IRBs that have the capacity to review, monitor, document research protocols and under takings involving Agricultural biodiversity/Biological resources in the region or the institution where they are based, or other institutions that do not have their own IRB and beyond. Similarly, Level-A IRBs shall be capable of safeguarding the rights, autonomy, safety, and welfare of the farmers’ and the Agricultural biodiversity/Biological resources.

### Composition

Shall have members with professional competence and a mix of varying back- grounds, gender representation, a community representative, training on research ethics, and experience similar to or equivalent with the PMGRRERC.

Minimum number of members is five (5).

### Mandates and Functions

Organize and deliver research ethics training to researchers in the region or the institutions.

Develop SOPs, that govern the IRB’s research review procedures.

Submit progress report of the IRB’s functions annually to the PRERC

Inform the PMGRRERC on occurrence of frequent, unexpected severe adverse effects (SAEs) related to research reviewed and approved by the IRB,

Review and approve research protocols similar to the PMGRRERC except:

Genetic research, stem cell research

Research involving biological resource transfer out side of Ethiopia provided that the IRB notifies the PRERC Multicenter international collaborative research of experimental nature.

Introduction of new cultivars, donated/repatriated germplasm, chemicals not registered for use in Ethiopia

Review of trials that are funded by breeding companies or factories

Solicit funds to build its and other IRB’S capacity

## Institutional Review Board, Level B

These can be regional or institutional IRBs. These are IRBs that have the capacity to review, monitor, and document research protocols and undertakings involving Agricultural biodiversity/Biological resources from the institution where they are based or other institutions that donot havetheirownIRBs,accordingtothemandatesandfunctionsstatedbelow.Similarly,LevelBIRBsshallbecapable of safeguarding the rights ,autonomy, safety, and welfare of the farmers’ and the Agricultural biodiversity/Biological resources. These IRBs may not have the expertise and experience of Level A IRBs ,in which case the protocols can be reviewed by Level A IRBs of other institutions.

### Composition

Shall have members with professional competence and a mix of varying back- grounds, gender representation, a community representative, training on research ethics, which may not be similar to or equivalent with the PMGRRERC.

Minimum number of members is five (5).

### Mandates and Functions

Organize and deliver research ethics training to researchers in the region or the institution.

Develop SOPs that govern the IRB’s research review procedures.

Submit progress report of the IRB’s functions annually to the R.

Inform the PMGRRERC on occurrence of frequent, unexpected SAEs related with research reviewed and approved by the IRB.

Review and approve research protocols that involve minimal risk.

Solicit funds to build its own capacity

## Secretariat of the PRERC

The secretariat of PMGRRERC reports to the director general of MoSHE. The director general of MoSHE is a voting member of the PMGRRERC.

**Responsibilities of the Secretariat:**

Receive applications from other IRBs.

Ensure the completeness of application documents for ethical review.

Distribute protocols to all ethics committee members and/or external reviewers, as applicable and when directed by PRERC chairman or delegate.

Facilitate regular and extraordinary meetings in consultation with the Chairperson of the PRERC .

Communicate decisions of the PRERC to the applying institution with a copy to the PI.

Archive all project-related protocols, correspondence, decisions and minutes of the PRERC .

Receive periodic progress reports from investigators and annual reports from other IRBs.

Facilitate the accreditation and registration of IRBs based on the recommendation of the PRERC and endorsement by MOSHE.

Propose revision criteria for registration and accreditation of IRBs.

Facilitate networking among the PMGRRERC and other IRBs.

Facilitate the monitoring and evaluation of the ethical implementation of research.

Organize, support, and facilitate the conduct of research ethics training at National and Institutional levels.

Manage and facilitate all official correspondence of the PMGRRERC and

Solicit funds for realization of the duties of the PRERC .

## Terms of Reference

Each IRB shall develop its own terms of reference. The TOR of the PRERC can be found in Appendix III**.**

## PRERC Office

Physical Location and Security - The PMGRRERC should have a dedicated office

located in the premises of MOSHE.

Only the PRERC Secretariat should be authorized to have access to the

PRERC documents unless ordered by a court of law

PRERC documents should be kept secure in locked cabinets and only accessed

by authorized personnel.

## PRERC Operations

The PRERC operations office should be spearheaded by the PRERC Secretariat as per instructions from the PRERC through the Chairperson or his/her designate.

The PMGRRERC operations should be separate and independent of the administration of MOSHE.

Applications to the PMGRRERC must be channeled through the PMGRRERC Secretariat.

All decisions and communication from the PRERC to the applicant must be conveyed through the Secretariat.

## Registration and Accreditation

All IRBs in Ethiopia have to be accredited by the PRERC, and registered and licensed by the Secretariat of the PRERC at MOSHE.

Registration and renewal of all IRBs shall be done every two years from the date of registration or renewal of the IRB.

When IRB members are replaced for any reason, these outgoing members shall be notified in writing. The reason for termination of membership shall be clearly described in the letter.

Review procedures, TORs, and the review forms should be standardized.

The minimum acceptable number of members on any IRB is five.

No IRB can have even numbered members for the sake of decisions,particularly when there is a need to vote.

IRBs shall have members with a varied professional mix and there should be at least, one member from behavioral sciences, law, or humanities, be gender sensitive and ensure community representation by a lay person.

No IRB can be composed entirely of a single profession, similar gender, or

without a community representative.

Following registration, a letter of accreditation shall be given to IRBs by the Secretariat.

## Establishment, function and review procedure

### Definition

Institutional Review Boards (IRBs) are independent committees established in an institution to conduct initial and continuing review of research projects with the primary goal of protecting the Conservation sustainable utilization and fair and equitable sharing of benefit arising from the use of agricultural biodiversity. All institutions in Ethiopia conducting research in agricultural biodiversity should establish IRBs in line with the research ethics guideline. Those institutions not able to establish their own IRBS can use IRBs of another institution registered by National IRB.

## Establishment

### Appointing Authority

The Head of the Institution is the authority responsible for the appointment of IRB members. In cases where members come from diverse institutions, the appointment should be upon the recommendation of the institution where the potential IRB member is based.

Members are selected in their personal capacities based on their scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and efforts for the Board’s function.

Appointments should consider the age and balanced gender distribution, and relevant but diverse professional representation.

The appointing authority should write an appointment letter to the prospective member inviting him/her to be a member of the IRB.

Members will sign a confidentiality agreement and conflict of interest (COI) form upon the appointment.

### Applying to Establish an IRB

An institution that want to establish an IRB shall apply in writing for registration and further approval at the National Secretariat at MoSHE, and include the following requirements: -

A statement that the IRB will follow the guidelines as stipulated in this document, law, relevant regulations.

A list of IRB members identified by name, qualifications, profession, current National agricultural Research Ethics Review Guideline, CV, representative capacity; any changes, in due process or in IRB membership must be reported to the secretariat.

Written SOPs for the activities of the IRB: composition of IRB members; conducting initial and continuing review of research,and reporting its suggestions/ opinion and decisions to the investigator and the institution; expedited review process; follow-up and monitoring of approved studies.

The PMGRRERC Secretariat presents the application to the PMGRRERC who shall examine the institution’s application, and if satisfied, will recommend to MoSHE for endorsement of the registration and authorize in writing, the establishment of the IRB. The process of application and response from MoSHE should not exceed three months.

### Composition

The IRB should consist of a reasonable number of members, who collectively have the qualifications and experience to review and evaluate the science and ethics of the proposed research.

Each IRB shall be composed of at least five (5) members, with varying backgrounds to ensure a complete and robust review of research activities commonly conducted by the institution. It must be multidisciplinary and multi-sectoral in composition, including persons with relevant but diverse scientific expertise, balanced age and gender distribution, and who have the qualifications and experience to review and evaluate the scientific and research ethics aspects of research methodology.

All IRBs shall have at least one member whose main area of expertise is in the scientific field and at least one member whose primary area of expertise is in a non-scientific field.

Each IRB shall include at least one member who is not otherwise affiliated with the institution or have a close family member working in the institution.

The IRB should have at least one community representative, who does not necessarily have to have any scientific expertise, but may be a layperson that represents the interests and concerns of members of the community and is familiar with the community’s values, customs, traditions, and culture.

All IRB members should at the minimum take one basic training on research ethics within one year of appointment.

## External Reviewers

If a protocol requires expertise that is beyond the competence of the IRB members or the IRB needs additional opinion in the review process, the IRB may engage independent experts to review and give their opinion.

The Secretariat should keep an updated list of experts along with their CVs, which should be reviewed annually by the IRB.

Independent experts must sign privacy and confidentiality agreements and conflict of interest (COI) forms to ensure that the information in the protocol is protected and that consultants do not have any conflicts.

The IRB may ask questions that could guide the review of the experts.

The expert may be invited to attend or consult by telephone an IRB meeting but he/she cannot vote in the meeting.

## Independence of IRB

The IRB must be independent from the appointing authority, hosting institution, investigators, sponsors and any other stakeholders in its review and decision-making processes.

If there is any conflict of interest (COI) regarding a particular research project, IRB members must declare their COI and excuse themselves from the review process. This is critical to ensure an objective assessment of the research project.

COI can be declared at the time research protocols are submitted, upon receiving the IRB agenda prior to the meeting and at the beginning of each meeting.

IRB members who have a COI related to any research activities must not participate in any initial or continuing review of that specific research or related matters except to provide relevant, factual information that may be requested by the IRB. The conflicted IRB member cannot deliberate or vote on those research activities or related matters.

The IRB member or invited expert with a COI will be required to excuse himself/herself from the meeting during discussion and decision.

An IRB member or invited expert assigned to carry out an expedited review on a research project (or related matter) for which conflict has been identified must notify the IRB Chairperson or Secretary so that the research project may be reassigned to another person.

## Terms of Office

Membership should be for a period of two (2) years.

Membership may be renewed for two terms, however at least one-third National agricultural Research Ethics Review committee of the former members should be retained at every point in time. Thus, the maximum tenure of IRB members is four (4) years.

For continuity and the smooth operation of the IRB office, the IRB Secretariat may serve up to a maximum of five (5) terms, which translates to a maximum of fifteen (15) years.

For a permanently employed secretariat, tenure is not limited provided he/she is still under the employment of the IRB. If, in the event of additional qualified personnel being hired/trained, this time limit may need to be reviewed.

## Duties and Responsibilities of IRB Members

### Chairperson

In order to enhance independence of the PRERC, the Chairperson should not be affiliated with MoSHE. In other IRBs, the Chairperson can be a member of the institution.

The Chairperson should be selected by the IRB members through a process of nominations followed by secret ballot voting; the committee is obliged to inform the appointing authority.

The Chairperson should have the authority to sign official IRB documents such as approval certificates.

Should the Chairperson decide to step down as Chairperson of the IRB, he/she should inform the board in writing at least one month in advance; the committee is obliged to inform the appointing authority.

### Vice Chairperson

The Vice Chairperson should be selected using the same process as for the Chairperson.

The Vice Chairperson Should Chair meetings and sign official IRB documents when the Chairperson is not available.

The Vice Chairperson may sign official IRB documents such as approval certificates if the Chairperson is not available.

In the absence of both the Chairperson and Vice Chairperson, the IRB members should select an Acting Chairperson to chair the current meeting provided a quorum is satisfied.

The selected Acting Chairperson should sign minutes of previous meetings confirmed during his/her Chairpersonship.

The Acting Chairperson should not have authority to sign official IRB documents such as approval certificates but may sign minutes confirmed during his/her Chairpersonship.

The process of resignation should be the same as that for the Chairperson.

### Members

Membership becomes effective upon accepting an invitation from the appointing authority. Acceptance must be indicated by the member’s dated signature.

A member should be willing to have his/her full name, profession and affiliation(s) published in the public domain.

Members are responsible for reviewing protocols to safeguard the rights, dignity and welfare of the farmers and the society.

Members are responsible for reviewing progress reports.

Members are responsible for oversight visits in order to monitor ongoing studies approved by the IRB.

Members are obliged to keep IRB documents secure, private, and confidential.

Members should attend IRB meetings regularly and participate fully and actively in deliberations.

Members should participate in continuing education activities in research ethics (RE)

Members must declare any COI for any research project, and withdraw from the review of that research project.

Members must maintain privacy and confidentiality of documents and deliberations of IRB meetings.

## Orientation / Education of Members

New members should undergo orientation training upon joining the IRB in order to familiarize them with basic agricultural research ethics. Such training should be organized by the IRB Secretariat, the host institutions and/or any other players involved in such training.

Continuous training of IRB members on agricultural research ethics and other relevant areas such as Good research Practice (GCP) and experimental designs should be conducted as necessary.

Current CVs and records of training of all members should be kept on file by the IRB Secretariat in the IRB office.

## Termination of Membership

Membership may be terminated voluntarily. The member should write a resignation letter to the appointing authority through the IRB Chairperson giving at least a one-month notice.

The Chairperson may resign by sending his/her resignation letter to the appointing authority after informing the committee at its next meeting.

Membership should be terminated by the appointing authority on the advice of the IRB if a member is going to be away for more than one year.

Membership could be terminated by the appointing authority upon advice of the IRB if the member has been absent from five consecutive meetings without offering an explanation.

Membership should be terminated by the appointing authority for misconduct that tarnishes the credibility of the IRB as determined by the IRB.

Membership should be terminated if a member is convicted of a criminal offence.

Membership should be terminated by the appointing authority in consultation with the IRB if a member is suffering from a chronic incapacitating illness that significantly reduces the ability to process information and make rational independent decisions.

Membership should automatically terminate when a member die.

## Dissolution of IRB

The IRB should automatically cease to exist when the institution at which it is based ceases to exist.

## Committee Meetings

**Scheduled Full (Convened) IRB Meetings**

The calendar dates and time of scheduled full (convened) IRB meetings should be agreed upon and confirmed by the committee and made public.

The frequency of the scheduled full (convened) IRB meetings should depend on the workload in terms of volume of applications submitted as well as the availability of IRB members who have other duties at their places of employment.

A quorum is more than 50% of the total number of IRB members.

The quorum should include members with the relevant expertise to review the protocols on that day’s agenda. The presence of a lay person is required. The community representative, although not required, is essential.

The quorum should be present before a full (convened) IRB meeting is held.

IRB Secretary should send an agenda; minutes of the previous meeting; notice about the date, venue and time of the next scheduled meeting; and other relevant documents to all IRB members at least ten working days before the meeting.

Applications should be submitted to the IRB Secretariat at least three (3) weeks prior to the next scheduled meeting that the applicant wants his/her applications reviewed.

The Secretariat should prepare and distribute a tentative agenda based on the applications received, matters arising from the previous meeting, SAEs, expedited reviews performed, continuing review applications, and amendments.

The general conduct of the meeting should be as follows:

Meeting called by the secretariat consultation with the Chairperson

Adoption of the agenda, with or without changes

Call for a vote to approve the minutes of the previous meeting

Declaration of COI

New business (new protocols)

Other business

Adjournment of the meeting by the Chairperson

**Ad Hoc /Extraordinary IRB Meeting**

Ad hoc/Extraordinary IRB meetings should be held if there is an urgent issue or issues that do not qualify for expedited review but require a full (convened) IRB meeting.

The Secretariat should circulate a notice giving the date, venue, time, and agenda of the ad hoc/extraordinary meeting at least 48 hours before the meeting.

The general conduct of the meeting should be as follows:

Meeting called by the secretariat in consultation with the Chairperson

Adoption of the agenda

The issues for which the ad hoc meeting was convened

Relevant documents should be made available to IRB members at least 24 hours before the meeting.

A quorum must be present for the ad hoc meeting to conduct business.

Adjournment of the ad hoc meeting by the Chairperson

Minutes of the ad hoc meeting should be circulated at the next scheduled IRB meeting.

A vote to approve or request modifications should be made.

## Mandates and Functions of IRBs

The purpose of IRBs is to contribute to the Conservation sustainable utilization and fair and equitable sharing of benefit arising from the use of agricultural biodiversity by all the farmers and the society participating in the research project, by making an independent scientific and ethical review of research before the commencement of research activities. Therefore, the major responsibility of IRBs is to safeguard the rights, safety, and well-being of farmers and the society. The goals of research, while important, should never be permitted to override the misuse and damage of the genetic resources, proper conservation and utilization of agricultural biodiversity. IRBs should provide independent, competent, and timely review of the ethics of proposed studies. In their composition, procedures, and decision-making, IRBs need to have independence from political, institutional, professional, and market influences. They need similarly to demonstrate competence and efficiency in their work. They also need to ensure that there is regular evaluation of the ethics of ongoing studies that received a positive decision. Therefore, the functions of the IRB are:

### Initial review

The IRB must determine that the following requirements are satisfied before it approves a research project:

The benefit of the research project to the farmers and the society. The risk of the research on the society and agricultural biodiversity.

The sampling strategy is practicable

Determine that informed consent will be obtained from the farmers, the society and respective government and biodiversity institute

Determine that informed consent will be appropriately documented

### Informed Consent

The IRB must determine that the consent is documented using a written or verbal informed consent form,

The consent form should be approved by the IRB.

The consent form must be signed by the farmers, the community leaders and respective government organization.

The farmers and community should get the detail information about the research to be conducted in their farm field. After the farmers are informed if interested, he can give his word to the researcher and sign on consent form. Generally, the consent form should explicitly indicate the following:

A statement that the study involves research, the purpose of the research, the expected duration of the research, the land required and the obligation required from the farmer side.

Reasonably expected benefits to the farmers as well as the community.

Compensation for the yield loss encountered during the research activities. The compensation will be estimated based on the productivity of the crop and the area under the research project activity.

For animal research the investigator should provide a detail information about the damage can be caused during the experiment period and how the compensation is provided if a damage happens on the experimental animals.

For social science experiments (Economics and extension) research the participant farmers should be informed a head of time what is the objective of the research and the developed questioner should consider the religion, norm and culture of the society.

If the informed consent for the research activities did not involve the farmers and a specific community directly, the document can be given from the institution the researcher employed and the document can be signed by the head of the institution.

### Assent

For the on-farm research activities to be conducted in the farmers field, the assent will be sought from the head of the family in consultation with all the member of the family specially the wife. Any agreement obtained from the family member without consultation of their members will not be valid.

For research activities to be conducted in the research centers and laboratories the Assent can be obtained from the head of the research organization.

### Waiver of Informed Consent Documentation

Waiver of informed consent or documentation of informed consent should be approved by the IRB. The investigator must secure an explicit waiver of consent from the IRB. The IRB may waive some or all of the elements of an informed consent and/ or a signed or thumb printed consent form for some or all of the research participants of a particular study, if the IRB determines that:

The research project carries no more than minimal risk,

If the research or demonstration project is to be conducted or approved by federal or regional government and

is designed to study, evaluate, or otherwise explore public benefit or service programs; possible changes in or alternatives to those programs; possible changes in methods or levels of payment for benefits or services under those programs

### Continuing Review

The IRB conducts continuing review of all approved studies at intervals appropriate to the degree of risk that the Agricultural biodiversity/Biological resources are exposed, but not less than once a year.

The investigator should submit the IRB progress report, unless it designates otherwise.

All changes in approved research projects should be reported and approved by the IRB before implementation, except where necessary to eliminate immediate apparent risks.

### Suspension and Termination of Approval

The IRB has the authority to terminate or suspend its approval for research projects if it considers is appropriate such as:

The research is not being conducted according to the approved consent, or according to applicable guidelines,

The research has been associated with serious harm to society, and

The research creates a potential threat to the safety and welfare of farmers and the community.

The termination or suspension of approval should include a statement of the reasons verifying the IRBs decision and be reported to the investigator; the sponsor of the research and appropriate institutional officials.

# 6. Review Mechanisms

Each IRB must have written procedures, including procedures to be followed in their review mechanism. The following are the minimum requirements for an IRB review mechanism.

## 6.1. General Requirement

The IRB shall review proposed research at convened meetings at which more than 50% of the members of the IRB are present, including at least one member who represents the interests of the community.

In order for the research project to be approved, it shall receive the approval of a simple majority of those members present at the meeting. The only exception to this procedure shall be in the case of expedited review as outlined in Section

Each IRB shall decide the frequency of its meetings, which should be announced.

An IRB shall require that information given to research participants as part of informed consent complies with the general requirements for informed consent as prescribed by this guideline.

An IRB shall notify investigators in writing the outcome of the review of the research project. Such notice shall be provided to the investigator within 15 days from the date of IRB review of the research methodology. In case the IRB does not approve a research activity, it shall include in its written notification a detailed statement of the reasons for its decision.

## 6.2. Exempted Review Procedures

Research activities in which the only involvement of the Agricultural biodiversity/ Biological resources will be in one or more of the specific categories stated below can be considered as exempt:

Education: Research conducted in established or commonly accepted educational settings, involving normal educational practices.

Education: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observation of farmers' perception, provided the research participants cannot be identified.

Research, involving the collection or study of existing data, documents, records, available DNA samples, accessions, if these sources are publicly available or recorded without identifiers. Or, if the information is recorded by the investigator in such a manner that the germplasm/semen/microbes cannot be identified, directly or through identifiers linked to the subjects.

Evaluation or examination of government projects or programs designed to explore public benefit or service programs; procedures for obtaining benefits or services under those projects or programs; possible changes in or alternatives to those programs or procedures.

Quality assurance activities.

All research including that in the exempt categories must meet, at a minimum, the principles of germplasm handling, beneficence and justice. The exemption determination other than mentioned above will be based on regulatory and institutional criteria and documented.

### 6.2.1. Exempt Study Submission Requirements

Research activities that meet the requirements for one or more exempt research categories must be endorsed by the IRB.

The investigator must complete the appropriate Exempt Application and submit the application along with (if appropriate)

Questionnaires, surveys, assessments, interview questions, and tools.

Consent statements, informed consent forms/scripts, and assent forms/scripts.

Advertisements and letters of permission.

### 6.2.2. Exemption Categories and Determinations

Research activities in which the only involvement Agricultural biodiversity/Biological resources will be in one or more of the exempt categories, can be approved as exempt. The chair or the chair’s designee, the IRB secretary/administrator, will complete the appropriate exempt category form to review the protocol and make a determination.

### 6.2.3. Assessment of the research

The review of the research will also include:

Whether the research has a sound research design

Assuring there is minimal risk to the germplasm

Ensuring that the investigator has the resources, time, and expertise to conduct the study.

The reviewer may require additional protections to meet the principles, including a level of informed consent appropriate to the research, or review by the full (convened) IRB.

Policies do not allow exemption of research involving video or digital recordings, and surveys or interviews that are extremely sensitive or personal. Allowance of audio recording is dependent on the research, is determined on a case-by-case basis, and must be documented.

Approval Period - At the one-year anniversary of the approval, an email is sent to the investigator requesting an update on the status of the study. During the approval period, the investigator needs to keep the IRB informed of any changes in the study, so that the IRB can ensure that the study continues to meet the exempt criteria. The investigator may close the study when data collection has ended

Documentation of Exempt Review - If the study qualifies for exempt review, the reviewer will complete the appropriate Exempt Category Form which will be used as documentation.

Investigator and IRB members notification

The investigator will be notified by appropriate medium of the exempt determination.

Each month claims of exemptions will be listed on the IRB meeting agenda.

## 6.3. Expedited Review Procedures

Expedited review is review of a protocol that need not be seen by the full (convened) IRB, but by one or two IRB members assigned by the chair.

### 6.3.1. Eligibility Criteria

For the review to be expedited the proposed research must:

Appropriately protect privacy/confidentiality.

Fall into one of the following categories:

Research employing survey, interview, oral history, focus group discussion

Research involving materials (data, document, records, or specimens) that were originally collected for non-research purposes.

Collection of data from voice, video, digital or image recordings previously made for research purposes.

Follow-up on changes, amendments and annual renewals:

Follow-up on changes or information requested by the Review Committee as a condition of approval.

Minor amendments to previously approved research.

Annual renewals, if the original approval was through expedited review.

The only remaining activities involve data analysis.

The review committee has determined and documented at a convened meeting that the research involves no greater than minimal risk (and there are no proposed changes that involve additional risk).

### 6.3.2. Applying for an Expedited Review

Requests for an expedited review can be submitted at any time to the Secretariat.

An investigator who wishes to apply for an expedited review should submit an application indicating the reason(s) for the eligibility of the study for expedited review.

Upon receiving an application for expedited review, the IRB secretary /Administrator in consultation with the Chairperson / Vice Chair makes the initial assessment to determine if it qualifies for expedited review.

If the study qualifies for expedited review, IRB chairperson or by one or more experienced reviewers designated by the chairperson from among the members of the IRB should be assigned to review the protocol. If the review involves a study amendment, the selected member should be a member who reviewed the previous version of the protocol.

When the protocol is approved, the investigator (s) will be notified immediately through the Secretariat.

A summary of the protocols reviewed through the expedited process should be submitted to the full (convened) IRB at its next meeting.

A decision arising from an expedited review will be provisional pending approval from the Chair/Vice Chair or the IRB. Such decisions should be communicated to the investigator in writing.

Should a protocol be disapproved by the expedited review, it should be submitted for a full (convened) IRB review.

The full (convened) IRB has the authority to confirm, modify or reverse a decision of the expedited reviewer. If the decision of the full (convened) IRB is contrary to the decision of the expedited review, detailed reasons and explanations should be recorded in the minutes.

The applicant should be informed of any modifications that the full (convened) IRB recommends and the ethical justification for such a decision.

## 6.4. Review Procedure

An expedited review covers the same issues as a full (convened) review. The reviewer has the same options as the full (convened) review committee, i.e., to approve, request modifications, or disapprove a protocol. An expediting reviewer, however, may not disapprove a protocol.

Expedited and exempt research: The chairperson should notify the IRB members about decisions made pertaining to such research using a suitable medium (full board meeting, internet, post, telephone). At that time, any member or the committee may request a re-review of the approved protocol at the full (convened) committee meeting. If this were to occur, the investigator would be notified and asked to suspend the study pending full review. Expedited reviewers refer the issue to the full committee if there is any question about the level of risk or the applicability of the activity categories before approving the protocol.

## 6.5. Decision Making Procedures

The IRB can only make decisions if a quorum is met.

A member with conflict of interest must excuse himself/herself from the review process and voting.

Non-members such as project PIs and independent experts may be consulted as part of the review process, but do not vote.

Only IRB members who participated in the review process and deliberations should take part in the decision-making process.

IRB decisions shall be either unanimous or by consensus where there is a majority decision. If the decision is by voting the number for and against should be recorded in the minutes.

### 6.5.1. IRB Decisions

The IRB may reach the following decisions after reviewing the research protocol:

Approved: if a protocol fulfills all requirements as stipulated in this guideline or

Approved on conditions: if a protocol needs modifications, further information and recommendations.

Disapproved: if a protocol is found to be unscientific and/or unethical.

### 6.5.2. Communicating Decisions to Applicants

Decisions regarding protocols should be officially communicated, in writing, to the applicant within 10 working days of the meeting where the decision was made.

Communication of the IRB decision shall include but not be limited to the following:

The name, title, and address of the applicant.

The exact title of the protocol.

The name of the study site(s) or study area.

The names and identification numbers (versions numbers/dates) of the reviewed documents.

A clear statement of the decision reached by the IRB.

The name of the IRB making the decision (letterhead of the IRB suffices),

The date of the decision and the signature of the Secretary/Administrator or Chairperson/Vice Chairperson.

In case of a conditional decision (approved on condition), any requirements by the IRB, including suggestions for revisions, should be clearly explained in writing to the applicant.

In case of a positive decision (approval), a statement of responsibilities of the applicant and any requirements as stipulated in the decision by the ERC.

The validity period of the approval what factors should be considered

The final approval certificate/letter shall be countersigned by the Chairperson/Vice Chairperson.

## 6.6. IRB Records

**Documentation**

The IRB should maintain adequate documentation of all its activities, and maintain the following:

File of detailed written procedures for the IRB.

File of each protocol, containing all versions of protocol submitted and accompanying documents such as informed consent, approved versions, approval letters, progress reports submitted by investigators, reports of injuries to research participants, and other relevant documents.

Agenda of IRB meetings, minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution.

Records of continuing review activities.

Updated member files with CVs, training documents, etc.

Final reports from investigators.

**Archiving**

All closed files shall be retained for, at least, five (5) years after completion of the research project. All documents should be kept under a proper system that ensures confidentiality. All records shall be accessible for inspection by authorized personnel.

## 6.7. IRB Review fee

The Federal Ministry of Science and Higher Education will determine the condition and the amount of review fee for protocols.

## 6.8. Requirements for Submission to an IRB

There are requirements that must be fulfilled in order for the research protocol to be accepted by the IRB Secretariat for IRB review and approval. These requirements are administrative and research protocol related issues. Special categories of research entail fulfillment of particular requirements inherent in the type of research

### 6.8.1. Administrative Requirements

The applicant must be the Principal Investigator (PI) or co-PI of the proposed research project.

A Protocol application form should be completed, signed, and dated by the PI/co-PI or his/her designee.

A signed cover letter from the PI or co-PI and the institutional details where the investigator is based (which should include a physical address, fax number, telephone number, mobile number and email address) also must be submitted.

The applicant should submit hard copies of the full research project and an electronic version.

Up-to-date signed and dated CVs of the PI and/or co-PI should be submitted.

All applications should be submitted to the IRBs depending on the location of the research site.

The IRBs shall give final official approval for studies under their mandate.

However, if an applicant has a complaint(s) against the decision of the IRBs, the study should be reviewed by the PRERC.

The PRERC or other appropriate IRB shall also review all studies under the PRERC ’s mandate and send the protocols with recommendations and remarks to the PRERC for final approval.

The Secretariat receives applications submitted using the application form from IRBs for ethics review and final decision as stated under PRERC mandates.

Upon receipt of complete applications, preliminary screening is done by the Secretariat.

### 6.8.2. Methodology Requirements

All research methodologies/protocol and related documents submitted to the IRB for review and approval must at the least include the following information:

Research project: title of the study, purpose of the study, sponsor of the study, background of the project, a rationale with full justification of the study and, plans for data management including plan for statistical analysis and publication, and budget,

Data collection tools such as questionnaires, interviews /discussion guides, checklists and case report forms must also be submitted.

Documents to be submitted for review include: Study protocol and/or methodology, protocol amendments, study/participant information sheet, current investigators’ CV, investigator’s brochure, and other materials to be used. The study informed consent process/form and information sheet, in both the official language and, when necessary, its translation into the local language is required. A back translation into the official language may be requested by the IRB. In addition, contact addresses of the PI, people to contact and the IRB that approved the research project must be included in the study information sheet.

In studies that need transport of biological substances, a request for a material transfer agreement, the type of biological material, how it is going to be processed and stored, how the material is intended to be analyzed, intent for possible future analysis, if there is one, as well as how and when it will be disposed of, must be included in the study protocol.

# 7. Types of Agricultural biodiversity related researches/trials

Conservation research

1. Plant protection research
2. Agronomic and crop management research
3. Soil and natural resource research
4. Agricultural extension
5. Socio economics
6. Plant Biotechnology research
7. Microbial biotechnology research

## 7.1. Submission requirements

1. An investigator’s brochure which provides an adequate summary of all safety, pharmacological, pharmaceutical, and toxicological data available on the study product, together with a summary of the clinical experience of the study product (e.g. recent investigator’s brochure, published data, summary of the product’s characteristics, etc.), must also be submitted.

2. If the trial involves genetic resources from abroad, import permit phytosanitary certificate to import the genetic material must be obtained from EBI and ministry of agriculture.

3. The PIs should attach a phytosanitary certificate and import permit to that particular genetic material. The investigator must assure that the IRB will have access to the genetic material file to verify experimental procedures and data are kept in accordance with the approved protocol. This should be stated in the genetic material information sheet.

4. SOPs for the experiment; Advanced event (AE) reporting format

5. The investigator should affirm that he/she has sufficient time to conduct and monitor the experiment, as well as to submit progress reports on time,

## 7.2. Investigator’s File

The investigator must prepare a file containing documents related to the experiment. During the study, the investigator is responsible for updating the file and regularly adding experiment -related documents. Identification codes of subjects shall be kept for 10 years. The Investigator’s File should contain, at the minimum:

Local regulatory requirements

IRB and other authorities’ written approval for all documents

IRB and other authorities’ written approval for protocol amendments

Correspondence with the IRB

Approved protocol and amendments

All signed and dated informed consent forms

Investigator’s and Co-investigators’ CVs

Investigator’s SOPs

Notification and documentation of serious adverse events

Specimen management procedures, experiment supplies/equipment

Investigator interim and final report/summary of the experiment

## 7.3. Passport Data

The genetic resources passport data should, at the minimum, contain the following original information:

accession number: Genus name, Species name, specific locality, coordinate (lat., long. and alt.) region, district and/or kebele date of collection and characterization data.

Protocol identification number/study reference

Dates of first screening and/or enrolment in the experiment, treatment name, standard checks and entries on test.

detailed plan of agronomic practices and treatment applications.

Dates of assessment/scoring visit and name of individual responsible for making the assessment

Serious adverse climatic event and related treatment.

Dates of laboratory specimen/sample collection.

## 7.4. Monitoring

Compliance to approved protocol must be followed during the course of the research.

Deviation from the protocol is acceptable only to manage/treat a serious adverse event that endangers the genetic material or is presumed to result into serious or permanent damage to the biodiversity. In such acceptable cases of protocol deviation, the IRB, agricultural monitor and the sponsor must be notified immediately. The protocol deviation must be appended to the approved protocol. And, the investigator should subsequently make a request for protocol amendment while applying for renewal of the research.

The investigator should regularly submit a progress report; the progress report should include reports of the DSMB.

## 7.5. Plant Research

Genetic screening should be distinguished from genetic testing at the outset. The terms are often used interchangeably, although they represent two different forms of genetic practice. Genetic screening is carried out on groups of plants, animals or microbes, which could consist of a section of the population defined by phenotypic or morphological characters, or a subgroup within the population, or within broad groups in which genetic factors may be responsible for certain variability. Genetic Research: is defined as research conducted by investigators solely for the purpose of generating scientific knowledge about genes and/or the genetic basis of variability within, between and among the populations. Genetic data can be used for population genetics studies, diversity analysis, identify genes responsible for a particular qualitative trait, yield and yield related traits, traits for resistance to stress etc... Genetic Testing: A procedure to detect the presence or absence of, or change in, a particular gene or chromosome, including an indirect test for a gene product or other specific metabolite that is primarily indicative of a specific genetic change. Genetic Screening: Large-scale systematic genetic testing offered in a program to a population or subsection thereof intended to detect genetic characteristics in plant, animals and microbes.The protocol submitted should contain enough information on background, nature and scientific justification for the proposed study.

In genetic studies involving acquisition of biological samples, the procedure to be used to obtain samples, the type and amount/size should be clearly stated. Issue of identifiers and how the Standard Material Transfer Agreement (SMTA) will be maintained should be addressed.

The collection, processing, handling, storage, transfer of use of the biological materials and data should be conducted in a manner that insures the proper and sustainable utilization of the genetic resources. During the informed consent process, there should be a clear statement that the study is for genetic research purposes. It is ethically imperative that clear, balanced, adequate and appropriate information about the genetic material shall be clearly stated

The informed consent process should cover the plant animal or microbial genetic materials and data to be collected, data anticipated to be derived from the analysis of samples, and the safety and other records to be accessed, their intended uses, storage, and duration of storage.

Use of genetic materials beyond what is stated in the protocol must have the consent of EBI in case of secondary use, i.e., research other than what it was collected, may be done only on anonymized samples and after getting prior approval by the IRB.

Where subsequent use of biological materials or data is envisaged that would not be consistent with the original informed consent, a new consent should be obtained from EBI or request for waiver of consent from IRB.

The protocol should articulate clearly duration and place of storage of genetic material and data

## 7.6. Collaborative research

Collaborative research is research that is conducted by investigators from more than one institution. If one of the collaborating institutions or investigators is based outside of Ethiopia, then, the research is termed “international collaborative research”. Besides the collaborative research should enforce the different discipline integration within institute and across institutes.

### 7.6.1. Requirements

International collaborative research should be in line with the agricultural research priorities of Ethiopia and must be consistent with the Agricultural policy and must be responsive to the growth and transformation of the country.

The research must be consistent with the Health Science and Technology Policy and must be responsive to the health needs of Ethiopians.

The research should contribute towards strengthening national research capacity to carry out similar research independently, including providing research ethics training to members of the investigation team. The sponsor/donor should agree in advance that products will be made reasonably available after completion of the study, and the farming community must have access to the result of the research

All collaborative research must have a Principal Investigator or a Co-PI actively working in Ethiopia. Also, the PI or Co-PI must be employed or affiliated to a recognized institution or organization in Ethiopia. The research procedure should consider, to the extent possible, socio-cultural conditions in the community where the research is presumed to be conducted. In all collaborative research, all involved institutions are required to review and write a recommendation of approval before submission to IRBs mandated to review and approve such collaborative research. In the event the involved institutions do not have a functioning IRB, the research protocol and other documents can be submitted directly to any of the IRBs mandated to review and approve collaborative research. However, to avoid duplication of review efforts by IRBs, the PMGRRERC may choose to conduct joint reviews in part or in whole, accept the review of another qualified IRB, or make other arrangements to establish oversight responsibilities. Adoption of a paternalistic approach by research sponsors/donors towards institutions in Ethiopia or the research priorities of the government, is unacceptable.

### 7.6.2. Monitoring

When conducting collaborative research studies, each institution is responsible to ensuring the proper and sustainable utilization of the genetic resources and fair and equitable benefit sharing to the farming society and for complying with all applicable regulations. The IRB that reviewed and approved the collaborative research is primarily responsible for monitoring the ethical conduct of the research procedures. However, the National IRB can monitor the proper conduct of the research whenever it deems further oversight is necessary. Any modification, amendment, or change in the approved collaborative research protocol should be made at each collaborating institution. Material transfer agreements must be obtained whenever applicable.

## 7.7. Plant animal and microbial biological materials

### 7.7.1. Definition

Biological materials/germplasm include any substance obtained from a from plants, animals, and microbes including, but not limited to, vegetative part, seeds, buds, DNA/protein extracts animal blood, urine, skin, and other associated bio-products obtained from the genetic resources.

### 7.7.2. Acquisition, Storage, Secondary Use

The acquisition, storage, and future use of samples from research the genetic resources in Ethiopia shall be guided by the following procedures:

There should be a separate informed consent process for obtaining the genetic resources samples for storage and for future use.

EBI should know the purpose of sample storage, quantities of samples to be stored, place where samples will be stored, duration of storage, policies that will govern use of the samples in future research, potential risks and benefits of storing samples for future research and any other information deemed necessary by the Investigators, IRBs. EBI should takes the custodianship of the samples. Any future research study on such samples is subject to review by an IRB.

### 7.7.3. Procedure for Exchange / Transfer

When it is necessary to transfer samples for storage abroad, EBI shall negotiate an appropriate contract with the recipient institution. This contract shall be in the form of a Standard Materials Transfer Agreement (SMTA). The specific details of the SMTA should include, among other things, purpose for the transfer/ export, clear arrangements for collaboration and benefit sharing, a framework for accessing and sharing data, restrictions to third party transfer, and annual reports to the host institution/EBI on the status of the samples.

It is required that an Ethiopian scientist must be included as co-investigator in all future studies using the genetic materials collected from Ethiopia.

The IRB in Ethiopia shall review all research studies on stored genetic resources samples.

### 7.7.4. Regulatory Oversight of Research

Regulatory oversight of research involving Agricultural biodiversity/Biological resources is exercised at two levels. At the country level, the PMGRRERC, which is established by MOSHE, is the primary responsible organ for oversight. At the institutional level, the organization’s IRB, accredited by MOSHE, oversees all research being conducted under its jurisdiction. For research involving germplasm (plant, animal, microbial), an additional approval to import/export and use the germplasm should be solicited from the access and benefit sharing (ABS). The legal obligations in research shall be overseen by MOSHE and ABS IRBs, and Data and Safety Monitoring Board (DSMBs) are primarily responsible for safeguarding the proper utilization of the genetic resource. The Institutional Biosafety Committee (IBC) and Community Advisory Board (CAB) shall ensure public/community wellbeing.

### 7.7.5. Ministry of Science and Higher Education (MOSHE)

MOSHE is established by the ‘Definition of Powers and Duties of the Executive Organs of the FDRE (Amendment) Proclamation No. 603/2008’ on October 24, 2008. Under the Proclamation, MOSHE took over the rights and obligations of the ESTA and, under Article 20, is bestowed with the powers and duties to:

Forward recommendations based on studies for adopting and revising policies, strategies, laws and directives on the development of science, technology and innovation activities.

Prepare science, technology and innovation master plans; provide guidelines for…, programs and projects; monitor and evaluate their implementation.

Set priorities for the country’s research activities.

Direct, coordinate and support science, technology and innovative activities, and countrywide research programs

Support and strengthen institutions that undertake research and development activities.

### 7.7.6. Institutional Review Boards (IRB)

IRBs are established by institutions whose mandate includes carrying out research. The primary function of IRBs is initial and continuing review, monitoring research to ensure adherence to the approved protocol in order to safeguard the rights and welfare of research participants, train faculty on research ethics, accredit, register, and monitor other IRBs, and develop guidelines applicable to all research in Ethiopia.

## 7.8. Data and Safety Monitoring Board

### 7.8.1. Definition

A Data and Safety Monitoring Board (DSMB) is an independent committee composed of a multidisciplinary group of experts established by the research sponsors to assess and report the ongoing scientific and ethical integrity of a study by reviewing and evaluating (unblinded as necessary) data at regular intervals.

The DSMB should ensure that the study is conducted and the data are handled in accordance with the provisions of the research protocol and monitors adverse events and safety data.

A DSMB should be established before the commencement of any research involving germplasm/genetic resource and its composition submitted to the IRB.

All the pre-breeding and breeding activities up to verification trials proposed to be conducted in Ethiopia should have a safety monitoring plan, and a DSMB as recommended by an IRB.

DSMBs should be established in studies where interim data analysis is required to ensure the proper and safe handling of the germplasm involved in the research. Other interventional studies, such as verification trials, may be required to set up DSMBs on a case by case basis.

Sponsors should consider the need for establishing a DSMB prior to undertaking a particular study. An ethics committee may also suggest to the sponsor that a DSMB be established for a particular study.

Recommendations of a DSMB are communicated directly to the sponsor, but the sponsor should notify other relevant parties and ensure that the recommendations are communicated to, and acted upon by, the various parties involved in the research.

### 7.8.2. Composition

A Data Safety and Monitoring Board is composed of people external to the research team. The members of the Board:

Should be independent of the sponsor and the breeding companies or industries.

Have no conflict of interest in the research they are monitoring.

Receive no scientific recognition in the form of publications or promotions from the results.

Have relevant expertise (geneticists, breeders, molecular biologists, microbiologists, biotechnologists, pathologists, botanists/taxonomists, microbiologist, statistics, ethics and additional types of expertise depending on the type of the research, e.g., anthropologists or community members for research which involve assessing cultural sensitivities).

Have fair representation from participating countries in multi-center studies.

Consist of at least three members and the size and necessary expertise of the DSMB will depend upon the research design.

### 7.8.3. Constituting a DSMB

When required by the nature of a study, a sponsor should ensure the establishment of DSMB to ensure the broadest possible coverage of potential research participants, and the validity and scientific integrity of the data. In order to generate competent reviews and sound recommendations, the DSMB should be multidisciplinary and include as appropriate, expertise in agriculture (agricultural researchers with relevant background) geneticists, breeders, botanists/taxonomists, molecular biologists, agricultural economists, Biotechnologists, microbiologists’ statistics, agricultural research trial process, and ethics. The suitability of members of a board should be determined according to the nature of the study to be monitored.

The sponsor is responsible for establishing the DSMB’s charter that defines the relationship between the sponsor and the DSMB, which should be included (or referred to) in the research protocol.

Members should not be affiliated with the sponsor, investigators, IRB reviewing the project, regulatory authorities, sites, or study staff. Members should also not have vested interest (e.g. a financial or other interest in an intervention or product similar to the intervention being studied).

A procedure should be established concerning the requirements for candidacy, including an outline of the duties and responsibilities of DSMB members.

Procedures for reporting and addressing potential or real conflicts of interest for members and independent consultants should be clearly defined in the charter.

### 7.8.4. Responsibilities

Review research protocol, informed consent documents and plans for data safety and monitoring.

Evaluate the progress of the trial, including periodic assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of the trial site, and other factors that can affect the study outcome.

Consider factors external to the study when relevant information becomes available, such as scientific or therapeutic developments that may have an impact on the safety of the genetic resources or the ethics of the trial.

Review research institutes and centers performance, make recommendations and assist in the resolution of problems reported by the PI.

Protect the safety of the genetic resources.

Conduct interim analysis of usefulness in accordance with stopping rules which are clearly defined in advance of data analysis.

Ensure the confidentiality of the trial data and the results of monitoring.

Assist the sponsor through remarking on any problems related with study conduct, enrollment, sample size, and/or data collection.

Report on the safety and progress of the trial and make recommendations to the IRB and the sponsor regarding continuation, termination, or other modifications of the trial based on the observed benefits or adverse effects.

Report the decisions to investigators who must submit those reports to the IRBs, which shall further report to the National IRB.

## 7.9. Institutional Bio-safety Committees (IBC)

### 7.9.1. Establishment

The IBC evaluates research projects that use recombinant DNA, agents that are infectious to humans, animals and plants, other potentially infectious materials, select agents and biological toxins. Institutional Bio-safety Committees (IBC) are established by institutions that undertake research on potentially hazardous substances of a physical, chemical, biological, or any other nature. Any institution involved in or planning to conduct research with potentially hazardous substances is required to set up or designate a competent IBC. Each IBC once formed shall consist of a bio-safety officer and at least three other officers with appropriate expertise in DNA, biological safety and physical containment. The IBC shall be certified by the MOSHE. It is the responsibility of the Principal Investigator to notify and provide the IBC with the research proposal involving potentially hazardous substances of a physical, chemical, biological, or any other nature. The Principal Investigator is ultimately responsible for the registration, training, and safe handling of research materials handled by their personnel. Members of the IBC shall protect confidentiality of all information given to them in the course of their work, and shall sign confidentiality agreements with their institutions.

### 7.9.2. Functions of an IBC

The IBC’s function is to minimize potential human and environmental harm that may be associated with research on or with potentially hazardous substances such as pathogens, biological toxins, radioactive material and applications of bio-technology, especially recombinant DNA techniques and processes. The purpose of an IBC is to ensure adequate containment of potentially hazardous biological agents, add a level of expert review and monitoring of potentially hazardous experiments, and provide a means of communication among researchers and healthcare providers about potentially hazardous protocols.

IBCs shall:

Notify PMGRRERC and other IRBs of any research with potentially hazardous substances in their institutions.

Conduct bio-safety review and approval of research proposals involving recombinant DNA and potentially hazardous substances.

Continued review of approved research projects.

Ensure the provision of suitable and safe storage and disposal facilities for all materials involved in work with potentially hazardous substances.

Ensure that all appropriate technical personnel of the institution have adequate training in bio-safety.

Establish a health-monitoring plan for all high-risk personnel involved in application, use and production of potentially hazardous substances.

## 7.10. Community Advisory Board

### 7.10.1. Establishment

Community Advisory Boards (CABs) are established by the investigator team. They are indispensable in orienting the investigator team about the local customs, traditions, terminologies, culture, and attitude towards research and development. Besides, CABs are important bridges to liaise the researchers with the community. CABs are critical forums to facilitate dialogue between community members, research participants and investigators. CAB members shall be selected from the community where research is to be undertaken through a stakeholder consultative process. The CAB’s role and expectations should be explicitly described in their terms of reference. Members of the CAB may include but are not limited to the following:

Individuals familiar with local laws, customs, cultural values and gender issues

Elders, opinion leaders, local chiefs

Peer leaders, women leaders

Religious leaders

Representatives of the study population

Media personnel

Professionals who understand research or science issues

### 7.10.2. Functions

The main function of a CAB is to assist investigators with understanding and incorporating community concerns into their research procedures. The functions are expressed through different ways like advising on issues central to the informed consent process, achieving successful volunteer recruitment and retention, and other related issues. The responsibilities of the CABs may vary according to the study location, size, complexity, familiarity of the investigators with the local setting, to mention but few. CABs functions are to:

Provide information on traditional beliefs and needs of the study population and their concerns regarding the research project

Provide input into the design of the research protocol as appropriate especially in the recruitment and the informed consent process

Advise investigators on acceptable and effective methods for disseminating information about the research project and its outcomes

Provide advice and support regarding retention of research participants including gender equity

## 7.11. Monitoring and Reporting

Monitoring essentially encompass four activities: continuing review, review of the consent process, review for adherence to an approved protocol and review to identify unapproved activities. Continuing review is the most common, conventional, and fundamental aspect of monitoring of an IRB. The primary function of monitoring is ensuring participant safety through assuring compliance with regulations and adherence to approved research protocols. In clinical trials, data monitoring is conducted to ensure data quality and safety. The DSMB is designated by the sponsor upon the recommendation of the IRB primarily to periodically monitor data quality and participant safety. Moreover, interim analysis of risks and benefits should be a component of monitoring to ensure safety, whenever applicable. In multi-center research, monitoring at each of the research centers should primarily be carried out by the local IRBs. However, the PMGRRERC is also responsible for oversight at selected, representative research centers, as deemed necessary. In international collaborative research, periodic progress report must be submitted, and all adverse events must be notified to the NEC. The investigator bears the major responsibility of regular monitoring and reporting of adverse events to the IRB. The sponsor is also obligated to report, or otherwise, ascertain the adverse events are reported to the IRB. Based on monitoring and reporting that includes Adverse Events (AEs) as applicable, the IRB may allow continuation, suspension, or termination of the research or recommend an amendment (a change) in the research procedure. Besides, if the research involves a drug or investigational product, the investigator must notify FMHACA.

### 7.11.1. Defining and Grading an Adverse Event

Adverse events are considered to be serious when they are fatal, life threatening, cause serious or permanent disability, cause or protract hospitalization, cause congenital anomaly, or lead to death. An AE is considered to be related with the research procedure, drug and/or an investigational product based on temporal association with and response pattern to the procedure, drug or product, and the relationship, or otherwise, to the research participant’s clinical state, other interventions unrelated to the research or concomitant therapy. An AE shall be considered unexpected if the event has not been observed or documented in a similar research involving humans; the characteristics or severity of the event is inconsistent with information in the investigator’s brochure; or the event is observed with higher frequency or severity than previously documented. An adverse event is graded as: Mild: if the event does not interfere with day-to-day activities and does not require treatment. Moderate: if the event marginally affects the day-to-day activities but can be tolerated by the participant or require out-patient treatment. Severe: if the event significantly interferes with daily activities and demands hospitalization or procedures for relief.

### 7.11.2. Follow-Up on an Adverse Event

Once an AE has occurred, the investigator shall:

Monitor the AE closely

Provide a standard care to manage the AE and follow the AE until complete resolution of the AE.

Thoroughly investigate the likelihood and extent of relationship of the AE with the research procedure, drug and/or investigational product.

The details of the AE, from occurrence to complete resolution, must be recorded and attached to the participant’s file.

## 7.12. Reporting

A serious adverse event and the measures taken to manage the AE must be reported by the investigator, in writing, to the IRB Secretariat and to the clinical monitor, if one is assigned by the sponsor, within 48 hours of occurrence of the event, even if the AE is considered not to be related to the research procedures. Mild adverse events should be reported within five working days of occurrence.

The IRB examines the AE report and the appropriateness, or otherwise, of the measures taken, and whether the measures are in accordance with the approved protocol. Measures beyond the approved protocol shall be documented in the participant’s file and reported to the IRB. The IRB ultimately decides the need for additional action.

The medium for reporting should be according to the communication means/ channel described in the approved protocol.

Anonymity of the research participant shall be respected when all information is sent/reported.

## 7.13. Compliance Monitoring

Progress reports - PIs should submit progress reports at regular intervals stipulated by the IRB as a condition for renewal of ongoing research. Periodic progress reports enable the IRB to determine whether the research is progressing according to the approved protocol. In clinical trials, the progress report should include reports of the DSMB. The IRB shall establish a follow-up mechanism to monitor the progress of all ethically approved research. The follow-up review shall be done in the following manner:

Ethics approval is valid for one year. For research that takes more than a year to complete, a renewal (continuation) application should be submitted to the Secretariat with a full progress report and justification for IRB approval.

Any amendment in the protocol at any time should be reported to the Secretariat and approval secured from the IRB.

Serious and unexpected AEs shall be reported to the Secretariat as stated above in 11.1.3

In case of a premature suspension or termination of a research, the investigator should notify the Secretariat including the reasons for the premature suspension or termination of the research and summary of the research findings.

## 7.14. Types of Monitoring and Oversight Visits

### 7.14.1. Types of Monitoring

Passive monitoring - The IRB receives information about the research that it approved and uses that information to assess the study’s progress. Active monitoring – IRB members should physically visit the research site(s) in order to assess the conduct of the studies.

Approved research should be actively monitored to ensure adherence to ethics principles, as considered necessary by the IRB.

IRB members should use the IRB’s oversight checklist in order to ensure appropriate issues are assessed during the visit.

Should research exist that has not received ethical clearance, the presence of such research should be proved through a site-visit, witnesses, and appropriate and prompt actions should be taken.

The number of IRB members needed to conduct an oversight visit depends on the workload of the monitoring team. To maximize objectivity, at least two (2) members of the ERC or delegated persons with diverse expertise and drawn from different institutions should make up the monitoring team. A monitoring team may include the community representative in the IRB.

### 7.14.2. Types of Oversight Visits

The type and frequency of oversight visits should depend on the level of risk and complexity of the research. The IRB can make the monitoring visit announced or unannounced. IRB –initiated announced oversight visit: the IRB informs the PI the date of the visit in advance. IRB-initiated unannounced oversight visit: the IRB does not inform the PI in advance of the visit. Additional monitoring visits may be made for the following reasons:

Response to reports made directly to the IRB or circulating in the community.

Increased frequency of SAE reports.

Failure to submit progress reports or a final report in time.

Reports of suspected research misconduct.

Investigators who extend their research beyond the approved time frame without formal approval from the IRB.

Investigators that are suspected of having changed their objectives and study design without the IRB’s approval.

Any other reason that the IRB feels warrants further follow-up

## 7.15. Research Misconduct

All researchers are obliged to respect the requirements set in this guideline and the law and regulations related to research. Misconduct in health research is one of the aspects that make research unethical. Research Misconduct includes but is not limited to:

Conducting health research involving human participants or that which potentially affects humans without first obtaining ethical approval.

Collecting samples or information on the genetic resources without the participation of EBI

Sharing with other investigators samples collected from the regions or EBI without ethical approval and without a signed SMTA.

Sharing samples collected prospectively from the regions with other investigators or institutions without the informed consent of EBI.

The IRB may waive the requirement for informed consent in the case of archived and anonymized samples if the justifications are considered to be ethically and scientifically sound by the IRB.

Failure to submit mandatory reports such as SAE reports, progress reports and final reports to the IRB.

Failure to report deviations from the approved protocol procedure(s) in time.

Deviation from approved protocol procedure(s) should not be made without the agreement of the IRB that approved the protocol except when it is necessary to avoid immediate danger to a research participant.

Unjustifiable deviations.

Fabricating or falsifying data, or knowingly plagiarizing others’ work.

Misuse of research funds.

Forgery of IRB documents (e.g., alteration of approval letter/certificate; Material Transfer Agreement, etc.).

### 7.15.1. Possible Actions Against Research Misconduct

The IRB may receive reports of cases of misconduct via investigators, community members, voluntary whistle-blowers, research participants, or through its oversight activities. Upon receiving such reports, the IRB should confirm the validity of the alleged misconduct before deciding on an appropriate course of action. The actions that the IRB may take after confirming the misconduct include:

1. A letter of warning written to the PI by the IRB Chair with instructions for the misconduct to be stoppedand/or rectified. The head of the in­stitution, partners, and sponsors should be copied.
2. Corrective or educational measures.
3. Frequent monitoring of research activities.
4. Recommended and more frequent reporting by the investigator of his/ her research activities.
5. Suspension of eligibility to receive research grants. The IRB may black­list the investigator for a period of time to be determined by the IRB. During that period the IRB should not approve any research protocol submitted by the blacklisted investigators. The list should be copied to the relevant authorities.
6. In the event that serious harm/injury was caused to participants as a result of the misconduct, compensation for the harm/injury should be made by the investigators, or the host institution, or both. All re­search-related harm or injury as a result of ethically unapproved re­search shall be compensated by the investigator, the host institution, or both. The compensation package should be determined by qualified and relevant authorities.7
7. Temporary or permanent suspension of the PI and other investigators from research and/or professional practice.
8. Suspension of all research being conducted by the investigator.
9. Termination of the research.
10. The host institution may also be temporarily suspended from research activities.
11. Editors of journals should refuse publication of manuscripts from un­ethically conducted research and retract articles that are already pub­lished but eventually found to be conducted unethically.
12. The host institution should refuse Publications from un­ethically conducted research.
13. In the case of criminal misconduct inform legal authorities.

### 7.16. Responsibilities of Investigators, Host Institutions, Sponsors

Responsible conduct of research requires that all stakeholders discharge the duties ex­pected from them according to this guideline and the law and regulations of Ethiopia.

### 7.16.1. Investigators

The investigator is responsible for overall conduct of the research according to the approved research methodology. More specifically, the investigator:

Shall maintain adherence to basic ethics principles,

Shall keep records of informed consent document confidentially (in a locked cabinet).

Monitor research staff to ensure the research is done according to the approved research methodology.

Shall Periodically submit a progress report to the IRB.

Shall inform the IRB and obtain approval for any changes or amend­ments in the approved protocol/procedures. Any amendment shall be appended to the approved research protocol.

Shall be responsible for periodic assessment of the quality of data man­agement as well as reporting on interim analysis whenever appropriate.

Shall ensure beneficial investigational products are available to the community after the research is completed or any product obtained out of the biodiversity should return the benefit to the society from obtained through royalty fee.

Shall provide adequate information in all publications to the reader, and to colleagues to permit the methods and findings to be properly assessed. Limits of reliability and applicability should be made clear.

Shall submit final report and findings to the IRB.

### 7.16.2. Host Institution

The institution’s culture in which research is conducted strongly influence whether ethical conduct of research is supported or valued. The host institution must work closely with the investigator. The host institution shall monitor the investigator(s)’ research activities at the institution. More specifically, the host institution shall:

Ensure that the study design is scientific and ethical

Ensure ethical implementation of the research.

Comply with legal requirements and ethics regulations as stipulated in this guideline.

Ensure that the investigators conducting the study are scientifically qual­ified and competent to carry out the research at the institution.

Facilitate and provide support for smooth and ethical implementation of the research.

Make sure that the results of the study are properly and publicly disseminated.

Ensure that guidelines, ethical principles, and related materials reach the end users and the investigators.

Provide periodical reports of ethical implementation of the study to the IRB’s Secretariat.

Take disciplinary action on the investigators for breach of any of this guidelines, regulatory and legal requirements.

### 7.16.3. Sponsors

Sponsors/Donors are responsible for providing an environment that promotes integri­ty, objectivity and the highest ethical standards of research, including standards for design, implementation and reporting. Particularly, sponsors must commit to pro­tect participants in all research. Besides, sponsors are expected to ensure research subjects and communities are not made worse off during or after completion of the research. Sponsors can accomplish these goals in the following ways:

Ensure appropriate review and approval by appropriate IRBs. If the spon­sor is based outside of Ethiopia, the sponsor must in addition produce ap­proval from an appropriate IRB where the sponsor is based. If the sponsor is an international organization, the review of protocol must maintain rigor in accordance with its own independent IRB.

Monitor the research according to a plan approved by the IRB.

Select qualified investigators and institutions as collaborators, spon­sors.

Provide ethical guidelines to all investigators.

Complying with the local ethical, regulatory and legal requirements

Promoting research integrity.

Ensuring the local relevance of the research by involving local partners in the developmental stages.

Financing the study.

Ensuring adequate safety and efficacy of investigational products, if applicable.

Ensuring safety and efficacy of investigational products, if applicable; the sponsor shall ensure investigational products are manufactured following good manufacturing practice,

Supplying and handling investigational products.

Updating investigators’ brochure as significant new information is made available.

Informing the IRB if it suspends or terminates a research with detailed explanation for the termination or suspension.

Ensuring the community where the research is conducted is informed about the research findings.

### 7.16.4. Donors

Donors are responsible for providing an environment that promotes integrity, objectiv­ity and the highest ethical standards of research. Donors can accomplish these goals in the following ways:

Ensure appropriate review and approval by appropriate IRBs.

Monitor the research according to a plan approved by the IRB.

Complying with the local ethical, regulatory and legal requirements.

Promoting research integrity.

Ensuring the local relevance of the research by involving local partners in the developmental stages.

Financing the study.

Informing the IRB if it suspends or terminates the financial support.

Ensuring the community where the research is conducted is informed about the research findings.

## 7.17. Networking

Networking and creating a dynamic relationship among IRBs are essential for:

Establishing a strong data base system to standardize and streamline set of data elements.

Facilitating coordination among IRBs.

Establishing a strong and standard ethical review system within Ethiopia and harmonize safety reporting.

Building capacity and strengthening partnership among IRBs.

Sharing of experiences among local and international IRBs.

Establishing a central web-based repository.

### 7.17.1. Networking Mechanisms/Modalities.

Information flow should be multidirectional.

All IRBs shall submit reports to PMGRRERC annually.

IRBs in federal institutions shall send their biannual reports directly to the PMGRRERC.

Reports of the respective IRBs shall include at a minimum: activities performed, support needed, problems encountered, etc.

For urgent matters, IRBs should seek information or technical help from

PRERC at any time through its Secretariat.

The PRERC will distribute appropriate guidelines and other related in- formation to other IRBs and request feedback.

The PRERC establishes working relations with local and international IRBs through its Secretariat.

Reporting at each level should be by mail, fax or email.

# SECTION IV. ENVIRONMENTAL RESEARCH ETHICS REVIEW GUIDELINE (1ST EDITION)

# 

# Background

## Introduction

This National guideline for environmental research ethics was prepared by Ministry of science and higher education (MOSHE) in 2020. The guidelines supplement existing international and national guidelines on research ethics. The environmental research ethics guideline applies to multidisciplinary disciplines, for example environmental Biology, environmental chemistry, environmental physics, climate and researches related to environment and health. Although codes, policies, and principals are very important and useful, like any set of rules, they do not cover every situation, they often conflict, and they require considerable interpretation. It is therefore important for researchers to learn how to interpret, assess, and apply various research rules and how to make decisions and to act ethically in various situations. The vast majority of decisions involve the straightforward application of ethical rules.

Environmental research bioethics centre upon notions of what is right or wrong, good or evil, fair or unfair etc. Even though, most research institutions and universities do not have written guideline for conducting research, the research review committee encourages responsible research practice. However, there should be a national environmental research ethics guideline to avoid illegal, unethical, and irresponsible research practices.

Research institutions are responsible for ensuring the guidelines are implemented and observed in their research communities and that they are routinely communicated to staff and students. The institutions should also establish procedures for preventing and dealing with scientific misconduct, in line with this guideline. They should moreover have mechanisms for addressing and resolving potential conflicts and cases of doubt relating to research ethics.

## Scope of Application

Environmental sciences are a multidisciplinary science that encompasses: Physics, chemistry, biology, earth sciences, geology, Biotechnology, climate sciences, health science…etc. The scientific research principles include observation, measurement, objective analysis, testing of hypothesis, through experimentation, replication of findings, peer review through public lectures and published work.

Researchers and scientists should have strong ethical obligation to the society and environment, and should act in the individual and public’s interest by conducting responsible research and promoting discussions on society for environment related researches.

Safety and prequestionnaire principles are major ethical concern in environmental sciences hence underline the technical standards and code of ethics is crucial. As many areas of environment science have substantial effects on the environment and society, ethical guideline for decision making covers a broad range of responsibilities, and puts strong emphasis on the following categories of science research including but not limited to:

Plagiarism and improper authorship, falsification of data, non- disclosure of information which can have harmful effects (e.g experimental trial), mis-representation of scientific experiment, violation of generally accepted research practices.

Research in biodiversity, protected and environmentally sensitive areas , exotic species,

Research in climate change problems, potential adaptation and remedies, climate change impact assessment on human perception and biophysical environment

Research studies involving toxic pollutants (heavy metal, POP) related to food, water and human samples

Environmental health risk assessment research and environment and health interaction research

Genetic research, GMOs, and other investigational products, biomedical, biochemical, or pathological processes

Research in nano-technology and environmental biotechnology applications

Human health related behavioral research, research on waterborne disease and research related to air pollution impact assessment

Research that may include one or a combination of observations; interviews, in­ternet-based, mail-based, and telephone research; focus group research; survey and research with biological samples.

Furthermore, the guidelines are applicable in research proposed to be conducted by Science departments, environmental related programs and research organizations. These include, but are not limited to, public, private, faith-based, indigenous and international non-governmental organizations (NGOs), bilateral, multilateral, and United Nations’ agencies.

# Objectives

## 2.1. General objective

The main objective of this environmental research ethical guideline is to safeguard the environment and component of the environment from harm associated with the research activity and ensure fairness in sharing the benefits among the community.

## Specific Objective

To enable the researchers responsible for conducting high-quality research characterized by scientific integrity, truthfulness, and accountability, and research institutions must create conditions that promote such practice

To create awareness among investigators, sponsors, reviewers, decision and policy makers, and individuals/communities on basic research ethics principles in environmental sciences.

Develop and integrated framework and guidance document for the application of environmental risk assessment (ERA) methodologies.

Identify and prioritize key issues related to environmental pollution ecological risk assessment in emerging scientific researches.

To safeguard research environment and its component from unnecessary/unjustifiable risk (such toxic substance, introducing uncontrolled GMOs…)

To ensure fair selection of research entity/participants and fair distribution of benefits and risks

To ensure that research holds/embraces/possesses/considers social and cultural responsiveness/sensitivities for participating individuals and com­munities

To ensure the scientific integrity, ethical standards, moral values and appropriate proce­dures for the conduct of research involving human participants, animals and plants

To monitor and evaluate ongoing and post-research ethical implications to environmental sciences

To regulate biological materials and/or plant material(sample) transfer

To ensure rigorous and robust ethical review of research protocols

To ensure timely review and communication of decision of submitted proto­col to investigators

To facilitate cooperation and networking among IRBs at local and interna­tional levels

To put in place legal considerations against research investigators/ studies undertaken prior to ethical review or unethical implementation of research studies

# **Principles of environmental ethics**

A declaration of ethical principles may include the following principles:

## 3.1. **Respect for all life, human and non-human**

**Respect for all life:** The researchers should respect all form of life regardless of its utility to human beings while conducting the research. Respect for life is different from some interpretations of intrinsic value and from right to life. This principle does indeed not mean that all living beings have the unconditional right to live, or that they are of equal value. On the other hand, experts agree that the recognition of this principle implies in practice making necessary choices between different forms of living beings (e.g. it is ethically right to kill the smallpox virus for the benefit of humankind. More generally, respect for life cannot be opposed to practices that are preconditions for the survival of human beings such as sustainable agriculture or medicine).

**Respect for Biodiversity**: Respect for biodiversity may not lead to the same practical implications as respect for life since respect for biodiversity does not necessarily involve respect for individual beings, and conversely, emphasizing the primacy of individual beings may threaten biodiversity.

**Respect the community:** the investigators have responsibility to respect the beliefs and interest of the community in the study site. They should also respect their values and customary obligations; respects their desire for self-determination and safeguard their right to own and control their knowledge and intellectual property. The investigator should also benefits and empowers traditional/religious owners. In additional, the they should acknowledges their association with and rights to and in their traditional environments including the natural and cultural resources;

**Protecting the sustainability of the biosphere**: The planet as a biosphere is vulnerable and protecting the planet is more significant than the conservation of any single individual, species or ecosystem.

## **Principle of Beneficence**

The primary research improve the welfare of the population and environmental situation by assessing and identifying the magnitude of environmental risk factors in the ecosystem that degrade the environment and also through identification and evaluation of factor or interventions which enhance the environmental situation. The principle of beneficence refers to the research project output to attempt to maximize benefits for the individual participant, community and/or the environment while reducing risk or harm. In addition, beneficence includes whether the usual care is changed or manipulated to inflict no harm, minimize harm, remove harm, and maximize the benefit to research participants and to the. Balancing the risk and benefit of the research is indispensible in the design and conduct of the research.

## Principle of environmental Justice

Environmental justice means the multi-dimensional demand and achievement for a healthy environment for all; equal access (across social groups) to environmental goods; equal protection from environmental harms; equal access to environmental information; and equal participation in environmental decision-making

Environmental justice demands equitable selection of the research participants, i.e., avoiding populations that may be unfairly forced into participating, including but not limited to, pregnant women, people with mental and physical disabilities, immigrants, refugees, ethnic minorities, marginalized groups and institutionalized persons, including children. There must be a justification for inclusion of these vulnerable groups in the research. There should be no disproportionate use of vulnerable populations. The same recruitment approach should be used in all populations. Injustice may arise when selecting participants from a specific socio-economic class, age, sex, racial, cultural, religious, creed, and institutional make up.

The principle of environmental justice requires equality in the distribution of benefits and burdens among the population groups likely to benefit from the research. These are the distribution of environmental goods (e.g., energy, water and green space) as well as environmental burdens (e.g., air pollution, toxic chemicals and flood). Distributive justice means that no segment of the population should be unfairly burdened with the harms of research. It thus imposes particular obligations toward individuals who are vulnerable and unable to protect their own interests. Conversely, distributive justice imposes duties neither to neglect nor discriminate against individuals and groups who may benefit from advances in research.

Justice also demands balancing the benefits and burdens to the community where the research is undertaken.

## **Precautionary principle**

This principle stating that research activities which may lead to morally unacceptable harm to the environment and which is scientifically plausible but uncertain, actions shall be taken to avoid or prevent environmental degradation. Morally unacceptable harm refers to harm to humans, other living beings or the environment that is threatening to human life or health or Serious and effectively irreversible or Inequitable to present or future generations or imposed without adequate consideration of the fundamental rights of those affected. ‘Precautionary Principle’ should constrain all environmental research, and that within those limitations the researcher should design experiments according to four maxims:

**Movement:** This refers to a preference for locating experiments site away from environmentally sensitive areas or to the use of non-invasive techniques such as computer modeling.

**Minimization:** which refers to a preference for experiments with fewer observations where statistical significance can still be preserved;

**Modification:** which refers to a preference for experiments that have been adapted to minimize impact on ecosystems; and

**Maximizing:** which refers to preference for experiments where the scientific output is as significant as possible.

# **4. Institutional Authority and Purpose**

## 4.1. **Institutional authority**

ERERC and IRBs should be established under the authority of the Ministry of Science and Higher Education (MoSHE), but function independently. The MoSHE requires all research involving environmental components and materials to be reviewed and approved by ERERC or one of the MoSHE accredited and registered IRBs before the initiation of any research-related activities.

## **4.2. Purpose of ERERC , IRBs**

The ERERC and IRB’s objective is to safeguard or minimize the impact of environmental science research on the environment with special consideration to the environmentally sensitive and protected areas. The IRB reviews and oversees the environmental research to ensure that it meets the ethical principles, EPA regulations and it should also complies with legal requirements, pertinent regulations, guidelines, religious and traditional beliefs laws.

4.2.1. The ERERC and IRB’s duty is to inform and assist the investigators and advisors on ethical and procedural standards related to the practices and use of chemicals on the environment in the implementation of research, to facilitate compliance with the laws of the country, this guidelines and international regulations. However, the primary responsibility is for assuring that all possible risks to the environment are protected or minimized rests upon the investigators conducting the research. Others involved (sponsors and host institution) in the implementation of the research study share this responsibility. Faculty advisors serving as Principal Investigators (PIs) to students who conduct research on the environment have a responsibility to carefully consider whether the students are qualified to protect or minimize sufficiently the impacts of the research on the area or environment.

The ERERC and IRB have the power to confirm that research studies conducted under its jurisdiction are designed and implemented in manners that do not harm the environment. Specifically:

• The ERERC and IRB reviews and has the power to approve or disapprove, require modification in all research activities that fall within its jurisdiction.

• The ERERC and IRB have the authority to conduct continuing review as it deems necessary to protect the impact of environmental researches on the area, including requiring progress reports from investigators.

• The ERERC and IRB may suspend or terminate approval of a study proposal which is not designed to be conducted in accordance with the ERERC and IRB’s requirements or that has been associated with unexpected serious harm to the environment and participants as well.

• The ERERC and IRB have the power to observe or have a third party to observe the process and/or audit the progress of any study in its jurisdiction as it deems necessary to protect the impact of environmental researches on the area

• The NRERC and IRB may place restrictions on a study.

## **4.3. Use of Policies, Procedures**

The ERERC and IRB members and its Secretariat staff must maintain and follow all written policies and procedures consistent with Ethiopian regulations, good agricultural practices, good manufacturing practices, and research ethics when reviewing proposed research.

# 5. Environmental Research Ethics Review System

National Environment Research Ethical Review Boards (ERERBs) under MoSHE should be established at the national level to provide a frame work for ethical review document for research institutions, universities and research centers, with the primary goal of protecting the right and welfare of research participants, environment and endangered/indigenous species. All research institutions, universities and research centers, involving researches that affect environment, human, animal and plants should setup IRB in accordance with these guidelines. Where research institutions, universities and research centers, cannot set up an IRB, that institution may rely on the ERERB or another institution to review their research projects, provided the IRB is registered by the National IRB.

The Ministry of Science and Higher Education should ensure the ethical review of environmental research with the support of an adequate legal framework that resonates with this guideline. MoSHE shall try to establish suitable and sustainable system to monitor the quality and effectiveness of environmental research ethics review. The MoSHE should also develop and ensure the presence of mechanisms for networking and cooperation among IRBs both at the same and different levels nationally and for collaborative research there should be at the IRBs international.

The ERERC or the IRB in the institute level should conduct review of research protocol which is designed to conduct research in environment and its components. It is important to note that decentralization of the activities of the ERERC and subsequent establishment of new and empowerment of already existing Institutional IRBs, should be realized.

## 5.1. ERERC Organizational Structure

To effectively and efficiently deliver research ethics review services, functional and structural arrangements are established at the National, and Institutional levels.

## 5.2. Environmental Research Ethics Review Committee

The purpose of the ERERC is to safeguard the dignity, rights, safety, and welfare of all actual or potential research participants and/or communities, biodiversity and the environment. The ERERC is authorized to review study proposals and the other supporting documents on their scientific and ethical merit. Furthermore, the ERERC is mandated to assure that proposed research resonates with the EPA and research directives.

### 5.2.1. Composition

The ERERC should have ten minimum members who are selected based on professional competence and with mix of different backgrounds, gender representation, a community representative, research ethics training and experience.

### 5.2.2 Mandates and Roles of ERERC

The ERERC shall have the power and responsibilities to performer the following tasks

Develop research review guidelines and standards

Accredit and recommend licensing and registration of IRBs by MoSHE

Solicit funds to build capacity at all levels of IRBs

Organize and deliver research ethics training to IRBs at all levels using different media (classroom, on-site, internet-based); develop standardized training materials for countrywide use

ERERC Protocol Review – The ERERC is responsible for giving final ethical decisions

Umpire complaints, disputes, appeals and grievances on functions and review processes of IRBs submitted by researchers or institutions.

Monitor and evaluate IRBs at all levels.

Facilitate experience sharing among local and international IRBs.

Review very urgent *research projects that are of national interest and priority,*

*Policy-advocacy and creating community awareness on ethical principles in research, and* legal and regulatory reforms, and changes related to research involving human participants.

## 5.3. ERERC Office

Physical Location and Security:- There should be ERERC should have a dedicated office located in the premises of MoSHE.

Only the ERERC Secretariat should be authorized to have access to the ERERC documents unless ordered by a court of law.

ERERC documents should be kept secure in locked cabinets and only accessed by authorized personnel.

## 5.4. ERERC Operations

The ERERC operations office should be spearheaded by the ERERC Secretariat as per instructions from the ERERC through the Chairperson or his/her designate.

The ERERC operations office should be separate and independent of the administration of MoSHE.

Applications to the ERERC must be channeled through the ERERC Secretariat.

All decisions and communication from the NRERC to the applicant must be conveyed through the Secretariat.

## 5.5. Terms of Reference

The Each IRB shall develop its own terms of reference.

## 5.6. Establishment IRB

Institutional Environment Review Boards (IRB) are independent committees established in an in­stitution or research center to conduct initial and continuing review process of research projects with the primary goal of protecting the environment, human health, plants and the rights and welfare of research participants.

## 5.7. Appointing Authority

The head/dean of the institution or Center has the power and responsible to appointment members of the IRB. The IRB members shall be selected based on their personal capacities; scientific knowledge (publication) and expertise, as well as their commitment and willingness to volunteer the necessary time and efforts for the board/committee task. The appointing authority should write an appointment letter to IIRB members. The appointment should consider age, gender and relevance diverse professional representation. The IRB members should sign confidentiality agreement and conflict of interest

# 6. Applying to Establish an Institutional Review Board (IRB)

Institution/research centers that need to establish an IRB shall apply in writing for approval and registration at the national Secretariat at MOSHE, and include the following requirements.

Statement that the IRB will follow the guidelines as stipulated in this document, law, relevant regulations.

A list of IRB members identified by name, qualifications, profession, current CV, representative capacity; any changes, in due process or in IRB membership must be reported to the secretariat.

## 6.1. Composition of the IRB

The IRB should contain of a reasonable number of members who have the qualifications and experience to review and evaluate the science, environmental as­pects and ethics of the proposed research.

The member of the IRB should be composed of a minimum of ten (10) members with different back­grounds to make the review process complete and robust. The composition of the IRB must be multidisciplinary and multi-sectoral including persons with relevant but diverse scientific expertise, balanced age and gender distribution. They should have the qualifications and ex­perience to review and evaluate the scientific and environmental ethics aspects of research protocols.

The IRBs should have at least one member whose main area of expertise is in the scientific field and at least one member whose primary area of expertise is in a non-scientific field (community member).

The IRB should have at least one community representative, who does not nec­essarily have to have any scientific expertise, but may be a layperson that rep­resents the interests and concerns of members of the community and is familiar with the community’s values, customs, traditions, and culture.

All IRB members should at the minimum take one basic training on research ethics within one year of appointment.

## 6.2. Mandates and Functions of IRBs

The purpose of IRBs is to contribute to safeguarding the dignity, rights, safety, and well-being of all actual or potential research participants, by making an independent scientific and ethical review of research before commencement of research activities. Therefore, the major responsibility of IRBs is to safeguard the rights, safety, and well-being of research participants. The goals of research, while important, should never be permitted to override the health, well-being, and care of research participants.

IRBs should provide independent, competent and timely review of the research ethics of study protocols. The composition and decision-making procedures of the IRB should be independent from political, institutional, professional and market influences. Equivalently, they should demonstrate competence and efficiency in their review process and overall performance. They also need to ensure that there is regular evaluation of the ethics of ongoing studies that received a positive decision. Therefore, the functions of the IRB are

## 6.3. Independence of IRB

The review and decision making process of the IRB should be independent from the influence of appointing authority, hosting institution, investigators, sponsors and any other stakeholders.

IRB members that have any conflict of interest in a particular type of research proto­col must declare their conflict of interest and excuse themselves from the review process of the protocol.

IRB members who have a conflict of interest related to any research protocol must not participate in any stage of the review process (initial, continuing review) of that specific protocol or related matters. However, he /she should provide relevant and factual information which may be needed by the IRB.

COI can be declared at the time research protocols are submitted, upon receiving the IRB agenda prior to the meeting and at the beginning of each meeting.

The IRB member or invited expert who has conflict of interest must declare excuse himself/herself from the meeting during discussion and decision making process.

An IRB member or invited expert assigned to carry out an expedited review on a protocol (or related matter) for which a conflict has been identified must notify the IRB Chairperson or Secretary so that the pro­tocol may be reassigned to another person.

## 6.4. Duties and Responsibilities of IRB Members

### 6.4.1. Chairperson

The Chairperson should not be affil­iated with MoSHE in order to maintain and enhance independence of the ERERC . In other IRBs, the Chairperson can be a member of the institution.

The Chairperson should be selected by the IRB members through a process of nominations followed by secret ballot voting; the committee is obliged to inform the appointing authority.

The Chairperson should have the power to sign official IRB documents such as approval certificates.

The Chairperson should decide to step down as Chairperson of the IRB, he/she should inform the board in writing at least one month in advance; the commit­tee is obliged to inform the appointing authority.

### 6.4.2. Vice Chairperson

The Vice Chairperson should be selected using the same process as for the Chairperson.

The Vice Chairperson should Chair meetings and sign official IRB documents and approval certificates when the Chairperson is not available.

In the absence of both the Chairperson and Vice Chairperson, the IRB members should select an Acting Chairperson to chair the current meeting provided.

The Acting Chairperson should not have authority to sign official IRB documents such as approval certificates but may sign minutes confirmed during his/her Chairpersonship.

The process of resignation should be the same as that for the Chairperson.

### 6.4.3. Members and Responsibility

Membership becomes effective upon accepting an invitation from the appoint­ing authority. Acceptance must be indicated by the member’s dated signature.

A member should be willing to have his/her full name, profession and affilia­tion(s) published in the public domain.

Members are responsible for reviewing research protocols to safeguard the environment and its entities.

Members are obliged to read protocols, including supplementary documents (e.g, informed consent forms, project reports and SAE reports given to them by the IRB Secretariat in advance preparation of IRB meetings.

Members are obliged to keep IRB documents secure, private and confidential.

Members should attend IRB meetings regularly and participate fully and actively in deliberations.

Members should participate in continuing education activities in environmental research ethics.

Members must declare any conflict of interest for any research protocol, and withdraw from the review process of the protocol.

Members must maintain privacy and confidentiality of documents and deliber­ations of IRB meetings.

Orientation Training of Members

New members should be familiarized with basic of environmental research ethics upon joining the IRB through short term training. The training should be organized by the IRB Secretariat, the host institutions and/or any other players involved in such training.

Continuous training of IRB members on environmental research ethics and other rel­evant sciences areas such as Environmental biology, Environmental Chemistry, Environmental geology, Environmental physics, Ecology, should be conducted as necessary.

The IRB Secretariat should be kept the current CVs and records of training of all members in the IRB office.

## 6.5. Termination of Membership

The member who needs to terminate membership voluntarily should write a resig­nation letter to the appointing authority giving at least a one-month notice.

The Chairperson who needs to resign should send resignation letter to the appointing authority after notifying the committee.

* The authority upon advice of the IRB should terminate membership if a member;
* going away for more than one year.
* absent from five consecutive meetings without offering an explanation.
* make misconduct that tarnishes the credibility of the IRB.
* convicted of a criminal offence.
* suffer with chronic incapacitating illness and death.

## 6. 6. Terms of Office

One term membership should be for a period of two (2) years.

Membership may be renewed for only two terms and at least one-third of the former members should be retained.

The IRB Secretariat may serve up to a maximum of five (5) terms, which translates to a maximum of fifteen (15) years.

## 6.7. Committee Meetings

### 6.7.1. Scheduled Full (Convened) IRB Meetings

The calendar dates and time of scheduled full (convened) IRB meetings should be agreed upon and confirmed by the committee and made public.

The frequency of the scheduled full (convened) IRB meetings should depend on the workload and the availability of IRB members.

The meeting will be held if more than 50% of the total numbers of IRB members are available.

The quorum should include members with the relevant expertise to the research ideas of the protocols.

The IRB Secretary should send an agenda; minutes of the previous meeting; notice about the date, venue and time of the next scheduled meeting; expedited reviews performed; continuing review applications and amendments to all IRB members at least ten working days before the meeting.

Review applications should be submitted to the IRB Secretariat at least three (3) weeks before the scheduled meeting.

The general conduct of the meeting should be as follows:

Meeting called to order by the Chairperson

Adoption of the agenda, with or without changes

Call for a vote to approve the minutes of the previous meeting

Declaration of COI

New business (new protocols)

Other business

Adjournment of the meeting by the Chairperson

### 6.7.2 Ad Hoc /Extraordinary IRB Meeting

Ad hoc/Extraordinary IRB meetings should be held if there is an urgent issue or issues that do not qualify for expedited review but require a full (convened) IRB meeting.

The Secretariat should circulate a notice giving the date, venue, time, and agenda of the ad hoc/extraordinary meeting at least 48 hours be­fore the meeting.

The general conduct of the meeting should be as follows:

Call meeting to order by the Chairperson

Adoption of the agenda

The issues for which the ad hoc meeting was convened

## 6.8. Registration and Accreditation

All IRBs in the country must be accredited by the ERERC , and registered and licensed by the Secretariat of the ERERC at MoSHE.

Registration and renewal of all IRBs shall be done every two years from the date of registration or renewal of the IRB.

When IRB members are replaced for any reason, these outgoing members shall be notified in writing. The reason for termination of membership shall be clearly described in the letter.

Review procedures, TORs, and the review forms should be standardized.

IRBs shall have members with a varied professional mix and thereshould be at least, animal welfare, cultural heritage and conservation, environmental sciences, toxicologist community representation by a lay person. No IRB can be composed entirely of a single profession, similar gender, or without a community representative.

Following registration, a letter of accreditation shall be given to IRBs by the Secretariat.

## 6.9. External Reviewers

If a protocol requires expertise that is beyond the competence of the IRB mem­bers or the IRB need additional opinion in the review process, the IRB may engage independent experts to review and give their opinion.

The Secretariat should keep an updated list of experts along with their CVs, which should be reviewed annually by the IRB.

Independent experts must sign privacy and confidentiality agreements and con­flict of interest (COI) forms to ensure that the information in the protocol is protected and that consultants do not have any conflicts.

The IRB may ask questions that could guide the review of the experts.

The expert may be invited to attend or consult by telephone an IRB meeting but he/she cannot vote in the meeting.

## 6.10. Dissolution of IRB

The IRB should automatically cease to exist when the institution at which it is based ceases to exist.

# 7. Review Mechanisms

The IRB must have written procedures including procedures to be followed in their review mechanism.

## 7.1. General Requirement

The following are the minimum requirements for an IRB review mechanism.

The IRB shall review research protocol in meetings at which more than 50% of the members of the IRB are present including at least one member representing the community.

The research protocol shall be approved when majority of those members present at the meeting support the approval (not include expedited review).

IRB shall informin writing the outcome of the research protocol review toinvestigators within 15 days from the date of IRB review protocol. The notification should also present a detail reasons for unapproved research protocols.

## **7.2. Exempted Review Procedures**

Environment related research activities which will be done in one or more of the specific categories stated below can be considered as exempt:

Agriculture: Research conducted in established or commonly accepted agricultural settings, involving normal agricultural practices.

Natural conservation: Research involving to the protection and well-being of rare and endangered animal and plant species.

Emergency conditions of national or regional importance, such as environmental epidemics.

All research classified under exempt categories must meet environmental ethics principles outlined in section 3. The determination exemption other than mentioned above will be based on regulatory and institutional criteria and documented.

The investigator must complete the appropriate exempt application and submit the application along with (if appropriate):

Questionnaires, surveys, assessments, interview questions, and tools.

Consent statements.

Advertisements and letters of permission.

### 7.2.1. Assessment of the research

The following points should be assessed to determine whether or not the proposed research is ethical sound.

### 7.2.2. Quality of the Research

Whether the research has a sound research design:- appropriateness of methodology; sufficiency of the statistical power to establish the answers sought; competency of the researcher and access to resource to conduct the research

Assuring there is minimal risk to the environment and participants:- the potential private, ecological and social benefits or risks associated with the research

The potential direct, indirect and cumulative impacts of the research including the temporal and spatial scales of this impact

The level of confidence in the impact assessment including all levels of biodiversity, geodiversity, geomorphology, cultural heritage and aesthetic considerations, and potential or actual commercial resources such as fisheries.

The research effect on the interests of traditional/religious community, other legitimate users of the area or the wider community

### 7.2.3. Animal welfare considerations

The assessment of information on species present in the research site should include:

The risk of disease transmission; the effects of a series of stressors (disturbance, trapping and handling); the effects on non-target animals; and the effects on resources of target and non-target species.

### 7.2.4. Transportation impact

The research sites may need the use of off-road vehicles, air or sea transport. These may have theirown impacts on sensitive area (the damage to soil or vegetation, damage from anchors on coral reefs and disturbance to wildlife by vehicular noise).

The level of impacts on transportation of researchers or equipment to the study site(s) and the possible remedial measures in case of such effects.

What measures are planned to avoid inadvertent introduction of seeds, spores, insects or marine larvae into the sensitive area?

## 7.3. Approval Period

Study protocol which fulfill all the requirements stipulated in this guideline shall be approved for period of one year

The researcher needs to inform the IRB for any changes in the study. The investigator may close the study when data collection has ended.

## 7.4. Notification for Investigator and IRB members

• The investigator will be notified by appropriate medium of the exempt determination.

• Each month claims of exemptions will be listed on the IRB meeting agenda.

## 7.5. Expedited Review Procedures

The expedited review of a protocol will be made by only one or two members of the IRB who are assigned by the chairperson.

### 7.5.1. **Eligibility Criteria**

For the review to be expedited the proposed research must involve negligible risk in the environment and its component, meaning that the probability and magnitude of harm on the environment must not greater than those ordinarily encountered during the performance of routine physical or chemical examinations. In addition, research activity which appropriately protects the well-being of the environment.

Research fall into one of the following categories:

Research employing survey, observation, interview, focus group or human factors evaluation.

Research involving materials (data, document, records, or specimens) that were originally collected for non-research purposes.

Collection of data from voice, video, digital or image recordings previously made for research purposes.

Follow-up on changes, amendments and annual renewals:

Follow-up on changes or information requested by the Review Committee as a condition of approval.

Minor amendments to previously approved research.

Annual renewals, if the original approval was through expedited review.

The only remaining activities involve long-term follow-up of previously accepted research.

The only remaining activities involve data analysis.

The review committee has determined and documented at a convened meeting that the research involves no greater than minimal risk.

### 7.5.2. Applying **for an Expedited Review**

Application for an expedited review can be submitted to the Secretariat any time.

The investigator should submit an application including the reason(s) for the eligibility of the protocol for expedited review.

The IRB Secretary/Administrator in consultation with the Chairperson/Vice Chair makes the initial assessment on the study protocol to determine eligibility for expedited review.

The IRB chairperson shall assign one or more experienced reviewers from among the members of eligible research protocol. If the review involves a study amendment, the selected member should be a member who reviewed the previous version of the protocol.

Upon approval of the protocol, the Secretariat will notify the investigator(s).

A summary of the protocols reviewed through the expedited process should be submitted to the full (convened) IRB at its next meeting.

A decision arising from an expedited review will be provisional pending approval from the Chair/Vice Chair or the IRB. Such decisions should be communicated to the investigator in writing.

The full (convened) IRB has the power to endorse, modify or reverse a decision of the expedited reviewer. Decision contrary to the expedited review should be supported with detail explanation of the reasons and should also record minutes.

The applicant should be informed any modifications that the full (convened) IRB recommends and the ethical justification for such a decision.

## 7.6. Review Procedure

The review process of both expedited review and full (convened) review are covered the same issues. The reviewer in expedited review has the same decision options as the full (convened) review committee (i.e., to approve, request modifications or rejection of the protocol).

Exempt and expedited research: The chairperson should inform the decision made on the protocol to the IRB members using aappropriate medium (full board meeting, internet, post, telephone). In this stage, the committee or any member may request a re-review of the approved protocol at the full (convened) committee meeting. The researcher will also be informed and asked to suspend the research pending full review.

## 7.7. Decision Making Procedures

The decision of the review process can be made if and only if the quorum is met. The review process must be conducted without involvement of a member who has conflict of interest. In addition, non-members like PIs of the project and independent experts may be consulted as part of the review process, but do not vote. The decision can only be made with IRB members who involved in the review process. The decision shall be either unanimous or by consensus where there is a majority decision. If the decision is by voting the number for and against should be recorded in the minutes.

The IRB may decide either of the following decisions after reviewing the research protocol:

**Approved:** if a protocol fulfills all requirements as stipulated in this guideline or

**Approved on conditions**: if a protocol needs modifications.

**Not approved**: if a protocol is found to be unscientific and/or unethical.

## 7.8. Communication of the Decisions of the review process

The decision made in review process of the protocols should be officially communicated within 10 working days of the meeting to the applicants. The communication format of the IRB decision should include but not be limited to the following:

The name of the applicant including the title and address.

The title of the research protocol.

The name of the study site(s) or study area.

The names and identification numbers (versions numbers/dates) of the reviewed documents.

A clear statement of the IRB decision on the study protocol.

The name of the IRB making the decision (letterhead of the IRB suffices),

The date of the decision made and the signature of the Secretary/Administrator or Chairperson/Vice Chairperson.

The IRB requirements or suggestions on conditionally approved should be explained clearly in writing to the researcher

The IRB decision for approved protocol should also describe the applicant responsibilities and any requirements.

The protocol approval validity period.

Chairperson/ Vice Chairperson shall countersign the final approval certificate/letter

## 7.9. Recording

### 7.9.1. Documentation

All activities of the IRB should be documented and the documentation processes maintain the following:

File of written procedures for the IRB.

File of each protocol, containing all versions of protocol submitted and accompanying documents such as consent, approved versions, approval letters, progress reports submitted by investigators, reports of harm to the environment, and other relevant documents.

Agenda of IRB meetings, minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution.

Records of continuing review activities.

Updated member files with CVs, training documents, etc.

SAE reports submitted by investigators.

Final reports from investigators.

### 7.9.2.**Archiving**

All closed files shall be retained for, at least, five (5) years after completion of the research project. All documents should be kept under a proper system that ensures confidentiality. All records shall be accessible for inspection by authorized personnel.

# 8. Requirements for submission of proposal to IRB

IRB approval must be obtained prior to initiating any research activity involving human participants, animals, endangered species, protected areas, endemic species to eliminate hazard to the research entities.

There are requirements that must be fulfilled in order for the research protocol to be accepted by the IRB Secretariat for IRB review and approval. The requirements are administrative and research protocol related issues. Special categories of research entail fulfillment of particular requirements inherent in the type of research, such as staff thematic research, PhD and MSc thesis research and funded grant research.

## 8.1.Administrative Requirements

The applicant must be the principal investigator (Pi) or co-PI of the proposed research study

A protocol application form should be completed signed, and dated by the PI/co-PI or his/her designee.

A signed cover letter and CVs of the PI or co-PI and the institutional/school/department details where the investigator is based (which should include a physical ad­dress, fax number, telephone number, mobile number and email ad­dress) also must be submitted.

The applicant should submit hard copies and an electronic version of the full research protocol.

All materials and chemicals list to be used in the research study should be submitted along with the protocol.

Upon receipt of complete applications, preliminary screening is done by the Secretariat.

The IRBs shall give final official approval for studies under their man­date. However, if an applicant has a complaint(s) against the decision of the IRBs, the study should be reviewed by the ERERC .

## **8.2. Protocol Requirements**

All research protocol and related documents submitted to the IRB for review and approval must at the least include the following information:

**Research protocol:** title of the study, purpose of the study, objective of the study, sponsor of the study, background of the project, a rationale with full justification of the study and that there is no other alternative and less risky way of obtaining the data, descrip­tion of the environmental settings, participants, precise description of all proposed procedures, chemicals and interventions, including the duration of the study, provisions for protecting privacy and confidentiality, provisions for managing adverse events, plans for data management including plan for statis­tical analysis and publication, and budget.

Vulnerable/affected environments or population involvement requires further explanation to justify that without these vulnerable or affected entities involvement there is no other way of ob­taining the relevant data.

All materials to be used (including toxic and hazardous chemicals, advertisement mechanisms) for the research must be attached to the protocol.

Data collection tools such as sampling, sample transport and storge, questionnaires, interviews /discussion guides, checklists and other forms must also be submitted.

In studies that need transport of animal, plant and human and any biological material, a request for a material transfer agreement, how it is going to be processed and stored, how the material is intended to be analyzed, intent for possible future analysis, if there is one, as well as how and when it will be disposed of, must be included in the study protocol.

A dissemination and community involvement plan should be developed.

## 8.3. Types of research with special Consideration

Environmental research involving human subject, animal studies, certain types of biological materials and chemical substance requires special attention to ethical and safety considerations. Proposals must meet the requirements set by NEREB guideline. An investigator must provide adequate summery of all safety procedures during sampling, analysis, study product and disposal for the following research types:

**Climate research:** human related and animal related researches

In order to reduce the effects of increasing Climate research such as greenhouse gas concentrations, led to proposals for empirical tests of hypothesized climate research techniques, which raise serious ethical concerns; applicable in the event that CE research progresses beyond computer modeling.

Field experiments that might affect humans or ecosystems in significant ways should not proceed until a full discussion of the ethics of CE research occurs and appropriate institutions for regulating such experiments are established.

**Nanotechnology researches**

Nanotechnology researchers must always bear in mind that:

an element used in the research should be safe the nano-scale

avoid taking prohibited procedures that could jeopardize safety

Introduction of nano-particles to the environment could not affect the biodiversity and public welfare

effects on non-target animals;

**Air quality Monitoring researches:**

measuring toxic smog exposure using human participants

outdoor meteorological parameters- using human participants

**Animal Research**

Animal welfare considerations Observational and manipulative studies of free living animals, or habitats, have the potential to cause adverse effects because of interference with the normal behavior of animals, particularly reproductive behaviors and the rearing of young. Information on the potential impact of research on species present in the research site could be presented. This information should include:

the risk of disease transmission;

the effects of a series of stressors, e.g. disturbance, trapping, handling, etc;

the effects on non-target animals;

the effects on resources available to target and nontarget species.

**Environmental biotechnology researches:**

Genetic researches including recombinant DNA (or RNA)

Introduction of engineered Microorganisms to the environment for pollution remediation

Aquatic and soil Bioremediation applications

Exposure or risk assessment researches: human and animal related researches

Research on protected and environmentally sensitive areas

Research on endangered and endemic species

Water and sanitation research

Environmental Geology research

# 9. Biological and soil Materials

## **9.1. Definition**

Biological materials that may include, but not limited to any substance obtained from a plant, microorganisms(GMOs) and animals (such as: animal body parts, plant parts and microorganisms) and other associated bio-products obtained from plant, animal and human research entities. Soil material includes, but not limited to: soil, compost, and semi-processed compost and rock type.

## 9.2. Acquisition, Storage, Secondary use and Transfer

The acquisition, storage, and transfer of biological material and soil samples for research in Ethiopia shall be guided by the following procedures:

Researchers should know the purpose of sample storage, quantities of samples to be stored, place where samples will be stored, duration of storage, measures to protect confidentiality, potential risks and benefits of storing samples for future re­search and any other information deemed necessary by the Investigators, IRBs.

The researcher should also know policies that will govern use of the samples transfer to other countries for lab research.

Beyond examining the samples outside the country, the researcher should be confident enough that the biological material or samples should not be used for other purposes.

The researcher should bring a confidential letter from the host institute, stating that the biological materials should not be used for other purposes.

# 10. Regulatory Oversight of Research

Regulatory oversight of research involving environmental research is exercised at two levels. At the country level, the ERERC , which is established by MoSHE, is the primary responsible organ for oversight for larger research projects. At the institutional level, IRB, oversees all research being conducted under its jurisdiction. For research involving experiments on protected and environmentally sensitive areas, an additional investigation and approval should be solicit from the Ethiopian Environmental Protection Authority (EPA).

The legal obligations in research shall be overseen by MoSHE and EPA. IRBs, and Data and safety Monitoring Boards (DSMBs) are primarily responsible for safeguarding and ensuring environmental rights and safety. If present, the Institutional Biosafety Committee (IBC), and Community Advisory Board (CAB) shall ensure environmental wellbeing.

## 10.1. Ministry of Science and Higher Education (MoSHE)

MoSHE is established by the ‘Definition of Powers and Duties of the Executive Organs of the FDRE (Amendment) Proclamation No. 1097/2011. Under the Proclamation, MoSHE took over the rights and obligations research Ethics with the powers and duties to forward recommendations based on studies for adopting and revising policies, strategies, laws and directives on the development of science.

## 10.2. Environment forest and climate change commission (EFCCC)

The Environment, Forest and Climate Change Commission (EFCCC) is the Federal institution for managing the Environment of Ethiopia. EFCCC is responsible to ensure the realization of the environmental rights, goals, objectives and basic principles enshrined in the Constitution. It is also responsible for Environment Policy of Ethiopia through coordinating appropriate measures, establishing systems, developing programs and mechanisms for the welfare of humans and the safety of the environment.

## 10.3. Environmental Protection Authority (EPA)

Environmental Protection Authority (EPA) was established as an autonomous government agency at the Federal level by Proclamation 9/1995 in 1995. EPA as environmental regulatory and monitoring body has become independent institution and re-established by proclamation no. 295/2002.The institution was accountable to the prime Minister. Along with EPA, the Environmental Protection Council was also established to oversee the tasks and activities of EPA as well as the activities of sartorial environmental agencies and units responsible for environmental management. The proclamation establishing EPA also stipulated the need for the establishment of environmental organs by regions.

Under the Proclamation no. 295/2002 EPA took over the rights and obligations to put in place an environmental management system that could support the national development efforts by avoiding duplication of efforts among stakeholders, promoting sustainable utilization of environmental resources and strengthening coordinated but differentiated responsibilities through:

• Preparing the State of Environment Report;

• Development of environmental strategic plan;

• Formulation of environmental laws and standards;

• Provision of support for environmental regulatory bodies and implementers; and

• Undertaking monitoring and effectiveness evaluation of the environmental system in place

## 10.4. Institutional Review Board (IRB)

IRBs are established by institutions whose mandate includes carrying out research.

The primary function of IRBs is initial and continuing review, monitoring research to ensure adherence to the approved protocol in order to safeguard the rights of the environment and human health, train faculty on research ethics, accredit, register, and monitor other IRCs, and develop guidelines applicable to all environmental researches in Ethiopia.

# 11. Monitoring and Reporting

Monitoring essentially encompass four activities: continuing review, review of the consent process, review for adherence to an approved protocol and review to identify unapproved activities. Continuing review is the most common, conventional, and fundamental aspect of monitoring of an IRB.

The primary function of monitoring is ensuring safety through assuring compliance with regulations and adherence to approved research protocols and to keep the environment, social or cultural implication of the research. Moreover, analysis of risks and benefits should be a component of monitoring to ensure safety, whenever applicable.

In multi-center research, monitoring at each of the research centers should primarily be carried out by the local IRBs. However, the ERERC is also responsible for oversight at selected, representative research centers, as deemed necessary.

Based on monitoring and reporting that includes Adverse Events (AEs) as applicable, the IRB may allow continuation, suspension, or termination of the research or recom­mend an amendment (a change) in the research procedure.

In cases of emergency, all reasonable steps should be taken to consult with the responsible investigator and the chairperson of the IRB.

## 11.1. Adverse Events (AE): Definition, Grading, Follow-up, Reporting

**Definition Grading of an Adverse Event**

Adverse events are considered to be serious when they are fatal, life threatening, cause serious impact on the environment and its components, or lead chronic diseases or death.

An AE is considered to be related with the research procedure, or an investi­gational product based on temporal association with and response pattern to the proce­dure, to the research activities.

An adverse event is graded as:

**Mild**: if the event does not interfere with day-to-day activities and does not require mitigation/treatment.

**Moderate**: if the event marginally affects the environment and its components but can be recovered by natural means.

**Severe**: if the event significantly the environment and its components (human, animal and biodiversity)

**Follow-Up on an Adverse Event**

Once an AE has occurred, the investigator shall:

Monitor the AE closely

Provide a standard care to manage the AE and follow the AE until complete resolution of the AE.

Thoroughly investigate the likelihood and extent of relationship of the AE with the research procedure, or its product.

The details of the AE, from occurrence to complete resolution, must be recorded and reported to responsible person or office (IRB, EPA).

**AE Reporting**

A serious adverse event and the measures taken to manage the AE must be reported by the investigator, in writing, to the IRB Secretariat.

The IRB examines the AE report and the appropriateness, or otherwise, of the measures taken, and whether the measures are in accordance with the ap­proved protocol. Measures beyond the approved protocol shall be documented in the participant’s file and reported to the IRB. The IRB ultimately decides the need for additional action.

The medium for reporting should be according to the communication means/ channel described in the approved protocol.

## 11.2. Compliance Monitoring

Ethics approval is valid for one year. For research that takes more than a year to complete, a renewal (continuation) application should be submitted to the Secretariat with a full progress report and justification for IRB approval.

Any amendment in the protocol at any time should be reported to the Secretar­iat and approval secured from the IRB.

Serious and unexpected AEs shall be reported to the Secretariat as stated above in AE reporting

## 11.3. Types of Monitoring Oversight Visits

**Types of Monitoring**

**Passive monitoring** – The IRB receives information about the research that it ap­proved and uses that information to assess the study’s progress.

**Active monitoring** – IRB members should physically visit the research site(s) in order to assess the conduct of the studies.

Approved research should be actively monitored to ensure adherence to ethics principles, as considered necessary by the IRB.

IRB members should use the IRB’s oversight checklist in order to ensure appro­priate issues are assessed during the visit.

The number of IRB members needed to conduct an oversight visit depends on the workload of the monitoring team.

**Types of Oversight Visits**

The type and frequency of oversight visits should depend on the level of risk and complexity of the research. The IRB can make the monitoring visit announced or unannounced.

**IRB –initiated announced oversight visit**: the IRB informs the PI the date of the visit in advance.

**IRB-initiated unannounced oversight visit**: the IRB does not inform the PI in advance of the visit.

## 11.4. Report to EREB

The IRB must report in writing at least annually to the governing body of the agency or MoSHE (**EREB),** on its activities, on:

numbers and types of projects considered;

administrative or other difficulties being experienced;

any requirements for training EREAC staff;

report to management agency on adequacy of EREAC budget;

recommendation to improve procedures as required.

# 12. Research Misconduct

All researchers are obliged to respect the requirements set in this guidelines and the law and regulations related to research. Research misconduct occurs where an individual deliberately, dangerously or negligently deviate from accepted practices that the MOSHE expects to be followed ( i.e. unacceptable practices). Researchers/investigators must ensure that they do not commit any of the following acts, but is not limited to:

**Fabrication** - creation of false data or other aspects of research, including documentation and participant consent.

**Falsification** (inappropriate manipulation or selection of data) - inappropriate manipulation and/or selection of data, images and/or other contents.

**Plagiarism** - misuse of others idea’s work or intellectual property (written or otherwise), without the permission or acknowledgement. it includes self plagiarism – reusing or recycling your own work without appropriate disclosure and/or citation.

Failure to meet **ethical, legal and professional standards** may also comprise failure to declare competing interests; misrepresentation of involvement or authorship; misrepresentation of interests; breach of confidentiality; lack of informed consent; misuse of personal data; and abuse of research subjects or materials.

**Misrepresentation and unethical acts**includes:

Failure to comply with legislative, regulatory and ethical requirements

Conducting in environmental related research which poten­tially affects humans, animals, plants, water bodies, and soil without first obtaining ethical approval.

Collecting samples or information from human participants without first ob­taining valid, voluntary informed consent except in conditions where waiver of informed consent is applicable.

Sharing with other investigators samples collected from human participants or institutions without ethical approval and without a signed Material Transfer Agreement.

Sharing samples collected prospectively from human and animal with other investigators or institutions without the informed consent of the participant.

In appropriate behavior in relation to suspected misconduct- failure to cooperate with any claims of misconduct and against the researcher, failure to report known or suspected misconduct, destruction of any evidence related to any claim of misconduct, retaliation against any persons involved in a claim of misconduct, knowingly making false claims of misconduct.

Failure to support validation of the research – by refusing to supply complete datasets of research material needed to facilitate validation of the research results through a replication study.

Failure to respond to known cases of unsuccessful validation attempts- published research that is found to be retracted from the journal that published it.

# 13. Responsibilities of Investigators, Host Institutions, Sponsors/Donors

Responsible conduct of an environmental research requires that all stakeholders discharge the duties expected from them according to this guideline and the law and regulations of Ethiopia.

## 13.1. Investigators

The diverse origins of research proposals influence how their designs emerge and how the protection of the research participants is ensured. The investigator is responsible for overall conduct of the research according to the approved research protocol/procedures. More specifically, the investigator:

Shall maintain adherence to basic ethics principles,

Shall possess appropriate scientific and environmental ethics standards,

Shall ensure the highest possible standard of environmental protection care and follow-up, within the limit of the investigator’s and the sponsor’s capacity, available to research areas; the available care shall be provided for variable period even after the completion of the research based on the researched condition; shall open an investigator’s file where all documents related to the research are kept.

The investigator shall ensure that hard data is kept in locked cabinets and electronic data is password protected accessible only to appropriate personnel.

Monitor research staff to ensure the research is done according to the approved research protocol/procedures.

Periodically submit a progress report to the IRB. The frequency of the report is to be determined according to the level of risk inherent in the research, i.e., the higher the risk the shorter the reporting interval.

Shall promptly investigate serious adverse events and take appropriate measures to safeguard the environment and human health. The investigator shall inform such adverse events and measures taken, if any, to the IRBs and the sponsor.

Shall inform the IRB and obtain approval for any changes or amendments in the approved protocol/procedures except in circumstances where an apparent immediate hazard or danger to the research environment. Any amendment shall be appended to the approved research protocol.

Shall inform the IRB and the sponsor and the participants if the study is terminated or suspended at any time during the research process.

Shall be responsible for periodic assessment of the quality of data management as well as reporting on interim analysis whenever appropriate.

Shall ensure beneficial investigational outcomes are available to the community after the research is completed.

In collaborative research, the investigator shall consider the cultures and ethnic diversities and should make the research objectives particularly clear and remain aware of the concerns and welfare of the human health and environment to be studied.

Shall provide adequate information in all publications to the reader, and to colleagues to permit the methods and findings to be properly assessed. Limits of reliability and applicability should be made clear.

Shall submit final report and findings to the IRBs.

## 13.2. Host Institution

The institution’s culture in which research is conducted strongly influence whether ethical conduct of research is supported or valued. The host institution must work closely with the investigator. The host institution shall monitor the investigator(s) research activities via IRBs. More specifically, the host institution shall:

Ensure that the study design is scientific and ethical.

Ensure ethical implementation of the research.

Comply with legal requirements and ethics regulations as stipulated in this guideline.

Ensure that the investigators conducting the study are scientifically qualified and competent to carry out the research at the institution.

Facilitate and provide support for smooth and ethical implementation of the research.

Make sure that the results of the study are properly and publicly disseminated.

Ensure that guidelines, ethical principles, and related materials reach theend users and the investigators.

Provide periodical reports of ethical implementation of the study to the IRC’s Secretariat.

Take disciplinary action on the investigators for breach of any of this guidelines, regulatory and legal requirements.

## 13.3. Sponsors/ Donors

Sponsors/Donors are responsible for providing an environment that promotes integrity, objectivity and the highest ethical standards of research, including standards for design, implementation and reporting. Particularly, sponsors must commit to protect the environment in all research. Besides, sponsors are expected to ensure research subjects are not made worse off during or after completion of the research. Sponsors can accomplish these goals in the following ways:

Ensure appropriate review and approval by appropriate IRBs. If the sponsors is based outside of Ethiopia, the sponsor must in addition produce approval from an appropriate IRB where the sponsor is based. If the sponsors is/are an international organization, the review of protocol must maintain rigorin accordance with its own independent IRB.

Monitor the research according to a plan approved by the IRB.

Select qualified investigators and institutions as collaborators, sponsors.

Provide ethical guidelines to all investigators.

Complying with the local ethical, regulatory and legal requirements related with environmental protections.

Promoting research integrity.

Ensuring the local relevance of the research by involving local partners in the developmental stages.

Financing the study.

Ensuring safety and efficacy of investigational products, if applicable; the sponsor shall ensure investigational products are manufactured following good manufacturing practice

Updating investigators’ brochure as significant new information is made available.

Providing special forms for recording and reporting of serious adverse environmental events and ensure these adverse events are appropriately investigated and managed until resolution or stabilization.

Informing the IRB if it suspends or terminates a research with detailed explanation for the termination or suspension.

Ensuring the community where the research is conducted is informed about the research findings.

# SECTION V. ENGINEERING RESEARCH ETHICS REVIEW GUIDELINE (1ST EDITION)

# Introduction

## Background

Engineering and technology play pivotal roles for nations’ technological, industrial and socio-economic developments. Engineering is a systematic and iterative approach to design and develop objects, processes, and systems using scientific and mathematical principles to meet human needs. Engineering also involves modeling, operation, maintenance, diagnosis, prediction of behavior or improvement of objects, processes, and systems based on knowledge of basic engineering principles. Engineering activity often also involves the application of other bodies of knowledge, including economic, social, ergonomic and behavioral knowledge. In general, there are four majorly recognized branches of engineering; namely, **chemical engineering**, **civil engineering**, **electrical engineering** and **mechanical engineering**. These branches further lead to multiple specific disciplines and fields.

Technology, on the other hand, is deﬁned as any modiﬁcation of the natural or designed world developed to fulﬁll human needs or desires. Technologies, therefore, are products and processes resulting from application of engineering design processes. Technologies also often function as tools and processes used to support engineering design.

**Research** in engineering and technology, afterwards called *'****engineering research'***, is essential for gathering new knowledge, advancement of engineering knowledge, to fill gaps in knowledge and development of new products and improve organizational efficiency and growth. Engineering research, like any research in other domains, involves engagement with fellow experts, ordinary human beings, involvement with private data and opinions, and sometimes animals, among many other things.

Engineering researches shall be conducted in an ethical manner (or shall follow ethical principles) to ensure protection of research participants and the environment in every aspect, thereby enhancing the quality and morality of research. Especially, researches that involve human participants, animals, industry and environment require *ethical review* to solicit funding and publish research findings. However, all researches (academic, collaborative and industry) shall adhere to good *research practices* from idea inception until disseminating the research findings. The entire research process shall be monitored to make sure the research is conducted in an ethical manner.

In a broader definition, ***ethics*** is the norms for conduct that distinguish between acceptable and unacceptable behavior [6]. The same source defines ethics as a method, procedure, or perspective for deciding how to act and for analyzing complex problems and issues. In the case of research, responsible disciplines, institutions and researchers shall adhere to certain **ethical principles** to establish trustworthiness of the research and its outputs. Ethical issues in the field of engineering involve scientific integrity, data integrity, institutional integrity and social responsibility, the protection of human subjects’ research, animal welfare, and environment.

## Ethics and Engineering

There are three divisions while discussing the ethical aspect of engineering: ***engineering ethics, ethics of technology,*** *and* ***research ethics.*** Each of them is briefly described below.

**Engineering *ethics*** *is* professional ethics for engineers. It focuses on assisting engineers in shaping their *professional* responsibilities through formulation of general ethical principles and *professional codes*. Usually, professional engineering organizations and associations are responsible in developing ethical principles of engineering for each discipline. Ethical codes typically specify that professional conduct by engineers is bound by virtues such as honesty, integrity, competence, dignity, and objectivity. Ethical codes explicitly spell out rules, duties, and obligations.

**Ethics of technology** focuses on ethical issues involving technology that concerns society as a whole. Ethical issues concern with ways in which the development or use of a technology may threaten the realization of particular values, how technologies may be designed, used or regulated to better realize our values, and how to deal with conflicting values and principles in the development, use and regulation of technologies. Ethics of technology is typically governed by values such as justice, autonomy, freedom, privacy, dignity, and general welfare.

**Engineering *research ethics*** is a professional ethics for and by researchers, and is aimed at addressing ethical issues in various scientific fields, such as engineering research. It is largely subject to the same ethical principles that are relevant to (non-applied) research in other disciplines. The relevant principles of research ethics include: scientific integrity, collegiality, data integrity, institutional integrity and social responsibility, the protection of human subjects, and animal welfare in cases in which human subjects or animals are involved in the research process. Based on these principles, many different professional associations, government agencies, and universities worldwide have adopted specific codes, rules, and policies for research ethics.

This document focuses on ethical aspects of research conducted in engineering and technology disciplines.

## Purpose of the Document

Due to the massive public investment to the education sector in Ethiopia, a large number of HIEs have been opened in the last few years. Some of the HIEs currently running engineering and technology related programs in their respective Institute of Technologies (IoTs). To fulfill demands from industry and non-academic government institutions, and increased partnership with global universities, most of the IoTs in Ethiopia are opening new graduate programs (i.e., MSc and PhD) in various disciplines. Research, both basic and applied, is one key expectation from such graduate studies. Moreover, several researches are conducted in research institutes and industries, be it alone or in partnership with local and global academic institutions. There are also encouraging initiatives to support local research, an example of which is the annual research grant by the National Research Council of Ethiopia. While acknowledging the great efforts for strengthening the local research activities so far, giving more attention to ethical aspects of research is of paramount importance.

Ethical standards are needed to guide how researches in engineering and technology are conducted. This document is written to create awareness on ethical dimensions while conducting research in engineering and technology disciplines.

## Objective of Research Ethics Guideline

The main objective of this document is to create awareness and provide guidance to researchers involved in the area of engineering and technology regarding the research ethics principles, processes and procedures to ensure ethical compliance.

# Stages in Conducting Scientific Research

The entire scientific research process - from defining a research question to drawing conclusions – among other requires the researcher to think critically, be objective (to avoid errors and personal biases) and operate in an ethical manner. There are common stages universally accepted by the scientific community in conducting research. With the intention of highlighting ethical considerations in each stage, this section provides a brief overview of these stages.

## Defining the Research Problem

This stage involves identifying a problem or developing a research question. Identifying a problem can be the most challenging part of a research, as it requires experience, exposure and consultation with others. There are multiple ways for selecting a research problem. *Please note that originality of idea in the identified problem is one key requirement for academic research*. On the other hand, industry researches focus more on finding solution to existing problem using known scientific principles.

## Literature Review

Once the research problem is defined, the next stage is review of the existing research evidence to determine if it has been answered or the types of conclusions other researchers have drawn.

The review puts the research in the context of similar research that has been done in the past. For a given literature, this part identifies what has been done before? How it was done, i.e., methodology used? What are the major achievements (conclusions) and limitations of the reviewed paper?

In this stage, the researcher shall insure that the *selected literatures are from credible/reputable sources, are available on the Internet via research database, are actually related or relevant to the identified problem, and objectively (or fairly) evaluate the literature (to avoid erroneous or out of context conclusions)*. *Moreover, the reviewed papers should be cited properly*.

## Statement of the Problem

Many times the initial problem identified in the first stage of the process is too large or broad in scope. In this stage, the researcher clarifies the problem and narrows the scope of the study. This can only be done after the literature has been reviewed. The statement is actually a refined version, based on the literature review, of the identified problem. In this part (or even in the literature review part and others), terms and concepts (i.e., words or phrases used in the research), need to be specifically defined as they are applied in the research. Terms or concepts often have different definitions depending on who is reading the study. To minimize confusion about what the terms and phrases mean, the researcher must specifically define them for the study. *An ethical researcher would restate the problem taking into account his/her own identification of the problem and what others have done so far*.

## Research Objectives

This is a part that concerns with defining the general and specific objectives of the research. Stating the objectives should be in line with the problem formulation. Moreover, the objectives should have original component, achievable and clearly verifiable by the results.

## Research Methodology and Actual Research

Research methodology part determines how the research will be conducted. This requires consolidating knowledge via reviewing literatures, collecting (or even generating) appropriate and sufficient data (e.g., via survey and interview), formulating the right/proper model, required infrastructure, experimental setup, required staff and/or financial resources. Each activity shall be conducted following ethical normal as explained in the subsequent sections.

Once clear idea is established on how to conduct the research, the research proceeds with the research. Practical difficulties may arise in this stage. For example, the research method may not suit properly or the interviewer might be unwilling to let carry out the research as planned. *The researcher shall follow the right research approaches to respond to the changes instead of following shortcuts or trying to falsify the experiment*.

## Research Results, Conclusion and Future Outlook

After conducting an experiment or running a computer model, the results are analyzed and conclusions are drawn. In these stages, the researcher shall validate (or check correctness of) the results, establish the achievements as compared to previous work, and conclude on what the results mean and how to view them in the context of the research field or real-world environment, as well as making suggestions for future research. *The researcher shall avoid using overarching statements and conclusions, avoid falsification, report only what has been found (thought it may not be in line with previous hypothesis), care about confidentiality and proprietary issues.*

## Reporting the Research - Dissemination

The final stage of the research process is disseminating the research findings, in the form of reports, thesis/dissertation documents, conference proceeding and journal publications, and even in oral presentations. Research findings should be written and presented in a proper way. *Proper attention should be given to authorship, citation, acknowledge of others contributions, copyright and data sharing issues*. Also note that *more journals are demanding proof of research ethics clearance, i.e. research were conducted under the supervision and approval of ethical committees.*

# Good Research Conducts

Institutions engaged in research shall emphases the importance of integrity and rigor in all research carried out at and in partnership with the other institutions. Moreover, research requires the involvement of students, researchers, other research institutes, partners and funding entities. Complex relationships and expectations exist among collaborating entities that researchers be aware of. Below, some of the good practices/conducts to be followed in conducting a research are presented.

## General Research Conducts

### Reporting Research Misconduct

Institutions and individual researchers have the responsibility to report any incident of research misconduct, whether this has been witnessed, or is suspected. Institutions shall be committed to ensuring that allegations of misconduct in research are investigated with all possible thoroughness and vigor. Moreover, recognizing the broad nature of misconduct, institutions shall devise legislations, rules and procedures to handle any reported research misconduct. Researchers shall be aware of in advance, and if need be provided with the right training, on ethical ways of conducting research.

### Impartiality and Conflict of Interest

Both researchers and research institutions should declare and manage any real or potential conflicts of interest, both *financial* and *professional*. Researchers should ensure that they abide by any conflict of interest requirements of funders or that are otherwise relevant to their research. All researchers are obliged to respect the requirements regarding their own impartiality and that of others. Partiality can make research less reliable and independent, for example by leading to biased publication or selective reporting. Researchers may not take part in processes that involve approving, funding or judging their own research or the consequences of that research. Nor may researchers take part in evaluating measures that they have been involved in developing or implementing, or which are the result of their own research

### Promote Openness

Increasing knowledge and understanding is the main objectives of conducting research. Whilst recognizing the need for researchers to protect their own intellectual property rights (IPR) and confidentiality of personal and industry data, researchers shall be as open as possible in discussing their work with other researchers and with the public.

### Institutional Approval

Researchers should provide accurate information about their research proposals and obtain the required approval prior to conducting the research. Researches should also follow national ethical guidelines as well as be responsible and conduct in the global research enterprise where the research plan, review of research proposals, social, carrying out research, responding to irresponsible research practices, handling issues of responsible conduct of international research, reporting research results, peer review, authorship and referencing.

### Informed Consent to Research

When obtaining informed consent as required in Standard, the researcher shall inform participants about (1) the purpose of the research, expected duration, and procedures; (2) right to decline to participate and to withdraw from the research once participation has begun; (3) the foreseeable consequences of declining or withdrawing; (4) reasonably foreseeable factors that may be expected to influence their willingness to participate such as potential risks, discomfort, or adverse effects; (5) any prospective research benefits; (6) limits of confidentiality; (7) incentives for participation; and (8) whom to contact for questions about the research and research participants' rights.

### Good Leadership and Cooperation

Heads of research institutions and their senior colleagues should ensure that a research climate of mutual cooperation is created in which all members of a research team are encouraged to develop their skills and in which the open exchange of ideas is fostered.

Research institutions must create conditions for research cultures that are conducive to good research. They must strive to maintain a culture based on constructive discourse and management of collegial disagreement.

Efforts should also be made to foster an environment where research is conducted in accordance with good research practice and to ensure that all those involved in research are made aware of existing guidelines and related policies.

Senior researchers should make particular efforts to help new members of the scientific community understand and adopt best practice. Within a research group, responsibility to ensure that good research practice is maintained throughout the research process ultimately lies with the group leader.

### Responsibilities of Supervisors and Project Managers

Supervisors and project managers must assume responsibility for the research ethics problems faced by students or project team members. Supervisors and project managers are also responsible for taking account of participants and others who are affected by the projects of students and project team members. They must assume responsibility for dealing with the problems that may arise for those conducting the project, especially if conducting the research becomes particularly stressful or problematic for them. Supervisors and project managers also have a shared responsibility for disseminating the results of projects. This responsibility also involves dealing with challenges presented by research ethics.

### Right Training and Supervision

Research institutions shall provide appropriate training and direction on research and supervision of researchers. Training for supervisory skills and guidance for supervisors[[1]](#footnote-1) (or principal investigators) on existing legislation, laws and rules shall be provided by research conducting institutes. Supervisors should supervise all stages of the research process, including outlining or drawing up a hypothesis, preparing applications for funding, the design of experimental or research protocols, data recording and data analysis, and writing the thesis. Moreover, students and research assistants should be offered courses that provide them with the right skill to understand and adopt best practice in research as quickly as possible.

### Avoid Contract Cheating, Collusion and Fabrication

Contract cheating is contracting a third party to provide work, which is then used or submitted as part of the research undertaking. Collusion, on the other hand, is working with others and using the ideas or words of the joint work without their acknowledgment, as though it is the researchers' own work, or allowing others to use the ideas or words of joint work without acknowledgment. Fabrication refers to falsification or misrepresentation of data, results or other outputs or aspects of research, including documentation and participant consent, or presenting or recording such data, etc, as if they were real. *Contract cheating, collusion and fabrication are bad research practices that shall be avoided at all cost.*

### Offering Inducements for Research Participants

Researchers should make reasonable efforts to avoid offering excessive or inappropriate financial or other inducements for research participation when such inducements are likely to coerce participation. When offering professional services as an inducement for research participation, all staff members and students should clarify the nature of the services, as well as the risks, obligations, and limitations.

### Deception in Research

Researchers should:

Not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's significant prospective scientific, educational, or applied value and that effective non-deceptive alternative procedures are not feasible.

Not deceive prospective participants about research that is reasonably expected to cause physical pain or severe emotional distress.

Explain any uncertainty and ambiguity that is an integral feature of the design and conduct of an experiment to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the data collection, and permit participants to withdraw their data.

### Debriefing

Researchers should provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research, and they take reasonable steps to correct any misconceptions that participants may have of which the psychologists are aware;

If scientific or humane values justify delaying or withholding this information, staff members and students should take reasonable measures to reduce the risk of harm; and

When staff members and students should become aware that research procedures have harmed a participant, they take reasonable steps to highly minimize and totally avoid the harm.

### Meet Legal, Ethical and Professional Obligations

Researchers shall meet legal, ethical and professional obligations in carrying out research. This includes failure to follow agreed protocol if this failure results in unreasonable risk or harm to humans, other sentient beings or the environment, and facilitating of misconduct in research by collusion in, or concealment of, such actions by others. It includes any plan or conspiracy to attempt to do any of these things.

### Record keeping

Researchers should keep clear and accurate records of the procedures followed and the approvals granted during the research process, including records of the interim results obtained as well as of the final research outcomes . This is necessary not only as a means of demonstrating proper research practice, but also in case questions are subsequently asked about the conduct of the research, the results obtained, or inventor-ship on patentable inventions.

### Encourage Collaboration

Research is increasingly collaborative, involving individuals from different disciplines and from institutions, from local and abroad. In establishing research collaborations researchers should be mindful of existing policies and guidelines, as well as funder, legal and regulatory requirements, and ensure that research partners and their employing institutions are able to meet the required standards of research conduct. There needs to be clear agreement on and articulation of the standards and frameworks that will apply to collaborative work. This is particularly important in relation to the provenance of intellectual ideas and ownership of research outcomes as well as the specific conditions under which these may be shared. All parties should be clear about their respective roles and responsibilities within the collaboration, which should be set out in any formal collaboration agreement.

## Publication Related Good Practices

### Co-authorship

Researchers must observe good publication practice, respect the contributions of other researchers, and observe recognized standards of authorship and cooperation. Co-authorship is recognizing contributions from the involved parties. In general, below are some of the requirements to qualify as co-author of publications :

All researchers should take responsibility and credit, including authorship credit, only for work they have actually performed or to which they have substantially contributed;

All researchers should note that principal authorship and other publication credits accurately reflect the relative scientific or professional contributions of the individuals involved. Minor contributions to a research or to the writing for publications are acknowledged appropriately, such as in footnotes or in an introductory statement; and

All researchers shall have substantial contribution to the research (from conception and design or the data acquisition or the data analysis and interpretation).

Only those who have actually contributed to the analysis and writing of a scientific work may be credited as co-authors.

### Good Citation Practice

All researchers are obliged to follow good citation practice. Researchers are under an obligation to provide accurate references to the literature they use, whether this is primary or secondary literature. This must be accounted for explicitly, also when re-using text from one’s own publications (so-called «duplication» or more misleadingly referred to as «self-plagiarism») in the form of proper citation. When researchers obtain information from sources outside their research – such as public documents or the internet – they must provide accurate references that make it possible to trace the information back to the source.

### Avoid Plagiarism and Self-Plagiarism

Plagiarism is the act of using someone else’s idea, work, data or other material produced by them without acknowledgement. Self-plagiarism, on the other hand, is using the researchers' own ideas, words, data or other material produced by the researchers and submitted for formal assessment at the institute or another institution, or for publication elsewhere, without acknowledgement, unless expressly permitted by the assessment.

Self-plagiarism is unacceptable and constitutes a serious breach of recognized norms of research ethics. A plagiarist undermines not only his or her own reputation as a researcher, but also the credibility of the research. Both researchers and research institutions are responsible for preventing plagiarism. Researchers who build on the work of others must cite their sources in accordance with good practice.

### Establish Data Ownership, Recording and Sharing

As data is an integral part of a research, there should be clarity at the outset on data ownership, recording and sharing.

*Ownership and responsibilities* – Clarity shall be established about to the ownership and use of data and samples used or created in the course of the research, results of the research, patient questionnaires, equipment procured as part of the project and the like. The responsibilities and procedures for the storage and disposal of data and samples (including compliance with the requirements of any ethics committee) should be made clear at the commencement of any project. Any research collaboration agreement relating to the research should contain clauses describing any necessary arrangements.

*Researchdata generation and recording -* Research data should be generated using sound techniques and processes and accurately recorded in accordance with good research practices by those conducting the research. When collecting personal data, data from the industry, and environment related data researchers must comply with existing data sharing and protection agreements. This will include explaining to any participants in their research what they will be doing with their data, who will have access to it, and who (if anyone) they intend to pass it to outside their institute.

All research data must be managed effectively throughout its lifecycle to ensure integrity, security and quality and where possible to support new research and research data sharing.

Data stored locally on a computer should be backed-up. Electronic files containing personal data should be encrypted or password protected and access to them should limited to as few people as possible.

Data shall be retained after the completion of a project for an appropriate period. The exact period is to be determined in agreement with all stakeholders.

*Data Sharing* - Research material should be made available to other researchers for secondary analysis and further use. Sharing of research data is often a prerequisite for building up knowledge, comparing results and critically testing the work of others. Improved openness and quality assurance can be achieved by sharing data. At the same time, data sharing gives rise to ethical challenges relating to privacy and confidentiality. Therefore, the norm of transparency and data-sharing, particularly in large-scale registry research, should be balanced against other considerations and requirements of research ethics. Generally, those responsible for collecting material have the priority right to use it in analyses and in publications. Data acquired with the aid of public funding must be made publicly available after a short period.

### Dissemination and Publication of Results

Publication of and dissemination of results of high quality research shall be encouraged and researchers must do their responsibilities to ensure high quality research.

Researchers and research institutions are obliged to disseminate scientific knowledge to a broader audience outside the research community. Dissemination of research involves communicating scientific results, methods and values from specialized research fields to researchers in other disciplines, or at a broader audience. It may be a matter of disseminating established insights into the discipline, or results from more recent research.

Researchers shall check funders’ willingness for dissemination and aware them researchers’ academic freedom for publication. Funding agreements will normally require funders to be informed of any potential publication or dissemination of the research findings.

Arrangements and responsibilities for the publication of results should be taken into account when planning a research and should ideally be agreed by all investigators at the outset.

Researchers should take into account the following guidance when publishing or disseminating their research or research findings including any plans they may have to publish or publicize research at conferences or on websites.

Research should normally be peer reviewed prior to it being published, publicized or disseminated. If research is placed in the public domain before peer review has been undertaken, it is good practice to make this clear in any publicity.

Funding sources should normally be acknowledged in any publication or publicity.

Results of research should be published in an appropriate form.

Anyone listed as an author on a paper should accept responsibility for ensuring that he or she is familiar with the contents of the paper and can identify his or her contribution to it. Honorary authorship is not good practice.

The contributions of formal collaborators and all others who directly assist or indirectly support the research should be both specified and properly acknowledged.

Researchers should make every effort to ensure that research is disseminated in a responsible manner, in such a way that results are not overstated. The Research Communications team can provide advice on research dissemination.

### Intellectual Property and Patient

Researchers should consider and be aware of the active involvement of patients and intellectual property in research and in the dissemination of research findings.

### Reviewers

Parties who review material submitted for presentation, publication, grant, or research proposal review respect the confidentiality of and the proprietary rights in such information of those who submitted it. Reviewers should maintain the responsibility bestowed on them to participate in the review of research proposal and not to abuse the trust on which the review process is based. They should disclose conflict of interest and treat colleagues fairly in reviewing their ideas, proposals and manuscripts.

# Governing Principles in Engineering Research Ethics

There are common research ethical principles that are applicable in all disciplines. This document adopts these principles with a focus on engineering and technology. Engineering researches are required to maintain and promote high ethical standards and challenge unethical behavior. Below is a list of fundamental principles of ethical research.

## Beneficence and non-malfeasance

Research is conducted to provide value and must be sufficiently meaningful, that outweighs any harm and risk. Maximum *benefit* of the research should be aimed by researchers while, at the same time, minimizing *potential risk* of harm to participants and researchers.

Researchers shall strive to benefit those with *whom they work* and take care to do no harm; seek to *safeguard* the welfare and rights of those with whom they interact professionally and other affected persons, and the welfare of animal subjects of research; and potential risk and harm of all types must be robustly mitigated through appropriate precautions. At the same time potential risk of harm to participants and researchers must be minimized. Preferences such as *anonymity* of individuals or groups as research must be respected, especially those concerning the confidential nature of information and all types of personal data must be respected.

## Integrity and Honesty

All researchers should seek to promote accuracy, honesty, and truthfulness in research. Researchers at all cost should not steal, cheat, or engage in fraud, subterfuge, or intentional misrepresentation of fact. Both researchers and research institutions must promote norms for good scientific practice. Scientific integrity is about maintaining and complying with good scientific practice. Misconduct is serious breach of good scientific practice associated with the collective commitment to the pursuit for truth. Researchers have an obligation to truthfulness, and scientific misconduct implies misleading others through lying concealment or distortion.

Honesty is needed in all aspects of research including: presentation of research goals, intentions and findings; reporting on research methods and procedures; gathering data; using and acknowledging the work of their researchers; conveying valid interpretation and making justifiable claims based on research findings.

Appropriate information about methods, purpose and research intention should be provided to the research personnel and participants – specifically about the role of their participation in the research, and what benefits and risks are involved (if any);

A good researcher strives to keep his/her *promises* and to avoid unwise or unclear commitments;

Researchers should aware themselves on recognized *standards of integrity* while designing, conducting and disseminating research;

Research must be conducted with a high degree of rigor and accuracy. Quality and transparency should be reflected in research design.

In addition to these core principles, researchers should ensure that their research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards. This includes:

Seeking ethical approval for research where appropriate;

Avoid research misconduct, conflict of interest (both professional and financial (aware of rules and regulations from funders and existing regulations));

Researchers are also expected to treat colleagues with integrity, honesty and collegiality, including the fair provision of references and peer review.

## Transparency and Open Communication

Whilst recognizing the need for researchers to protect their own intellectual property rights (IPR), it is encouraged that researchers to be *as open as possible* in discussing their work with other researchers and with the public. The aim in conducting research is to increase knowledge and understanding; and hence, research’s purpose should not be primarily to seek *publicity* for the researcher or the funder. So, transparency shall be established in:

Declaring possible conflicts of interests;

Reporting of research data collection methods;

Analysis and interpretation of data;

Making research findings widely available, including sharing negative results as appropriate; and

Presenting the work to other researchers and to the general public.

## Fidelity and Responsibility

All researchers should:

Establish relationships of trust with those with whom they work;

Be aware of their professional and scientific responsibilities to society and to the specific communities in which they work;

Uphold professional standards of conduct, clarify their professional roles and obligations, accept appropriate responsibility for their behavior, and seek to manage conflicts of interest that could lead to exploitation or harm;

Consult with, refer to, or cooperate with other professionals and institutions to the extent needed to serve the best interests of those with whom they work.

## Justice

All researchers should:

Recognize that fairness and justice entitle all persons to access to and benefit from the contributions of academic profession and to equal quality in the processes, procedures, and services being conducted by students and staff;

Exercise reasonable judgment and take precautions to ensure that their potential biases, the boundaries of their competence, and the limitations of their expertise do not lead to or condone unjust practices.

All conflicts of interest or partiality must be explicitly spelled out, and the independence of research should be clear from the proposals.

## Respect for People’s Right and Dignity

All researchers should [2]:

Volunteer participation of research participants should be ensured, free from undue influence or any coercion, and their dignity, rights, dignity and autonomy (when possible) should be respected and protected appropriately.

Respect the dignity and worth of all people, and the rights of individuals to privacy, confidentiality, and self-determination;

Be aware that special safeguards may be necessary to protect the rights and welfare of persons or communities whose vulnerabilities impair autonomous decision making;

Be aware of and respect cultural, individual, and role differences, including those based on age, gender, gender identity, race, ethnicity, culture, national origin, religion, sexual orientation, disability, language, and socioeconomic status and consider these factors when working with members of such groups; and

Try to eliminate the effect on their work of biases based on those factors, and they do not knowingly participate in or condone activities of others based upon such prejudices.

Care and respect for:

All participants in and subjects of research, including humans, animals, the environment and cultural objects;

The stewardship of research and scholarship for future generations.

# Research Ethics Committee

## Roles and Responsibilities of Committee

Research Ethics Committees (RECs) (also known as Research Ethics Boards (REBs) or Institutional Review Boards (IRBs)) are charged with ensuring that research is planned and conducted in accordance with prevailing *laws* and *regulatory standards* . Most research conducted inresearch conducting institutions, and researches conducted using *publically available data* do not require approval from this committee. However, in the case that the research involves human participants, data, industry partners, animals and the environment, the REC shall review applications for research and approve.

In HIES setting, a university will set-up (if not yet available) it’s main REC and, sub-committees will be set-up in each colleges/institutes running engineering and technology researches. The sub-committees will directly reports to the main REC. In an industry or research institute setting, these institutions can establish their own REC following internal procedures. In either case, aim of the REC is to ensure that ethical considerations and issues are appropriately addressed in the conduct of research. Specific roles of the ERC are:

To encourage and support ethically conduction of research;

The ERC should provide independent, competent and timely review of the ethics of the proposed studies.

To provide *ethical review* for research on human participants and/or data, which is not publicly available or when no other system for formal ethical review is available/appropriate.

To review the ethics of research involving industry partners, animals and the environment.

Ethical clearance/approval is needed for research conducted outside of the institute and in partnership (e.g., because of project grants) with local and global partners. Researchers working on projects granted research at another institution require ethics approval and should inform their college research ethics committee of this. This will enable the committee to record the researcher’s involvement in the project, and ascertain whether any formal review process is necessary.

The REC has the overarching institutional responsibility for research integrity.  The committee also provides policy direction to ensure that appropriate structures, groups, and processes are in place in research institute for conducting ethical reviews of research.

## Organization of the REC

The REC shall be comprised of competent/experienced professionals from the university and academia, have balanced gender composition, and with a limited term of service. Each IoT (or college conducting technology-related researches) is expected to establish ERC. Depending on the size of the IoT and graduate researches conducted, the Committee may also be instituted at school or department level. The following shall constitute as members of the REC.

Director for Research and Technology Transfer and Industry Linkage of each IoT – Chairperson of the committee;

Deans/heads of Engineering Schools/departments or their representatives;

Representative from a research journal concerning the IoT;

One internal faculty member, preferably female, working at least as Associate Professor’; and

One external member from the industry.

*Note that for research projects conducted by undergraduate and taught postgraduate students that involve human participants or other possible ethical considerations can be reviewed by the concerned academic unit*.

## Operating Principles of the Committee

The committee follows the following principles during its operation.

The quorum of the meeting shall be *one-half*, fraction being counted as one.

The committee shall meet as per the *need of reviews*.

All research projects involving human participants, data, industry partners, animals and the environment, whether as individuals or communities, shall be reviewed by the ERC before a study can begin.

The Committee shall review ethical considerations for submitted applications based on the ethical guidelines, ensuring the principles defined in this document are adequately and appropriately met. Specifically, the ERC will rest its decision based on the following:

Respect for an individual's capacity to make reasoned decisions, and protection of those whose capacity is impaired or who are in some way dependent or vulnerable.

The risks of the proposed research in respect of expected benefits, the research design and competence of the investigators having been assessed.

A proposal must state the purpose of the research; the reasons for using humans as the subjects; the nature and degree of all known risks to the subjects; and the means for ensuring that the subjects' consent will be adequately informed and voluntary.

The subjects of research should be clearly aware of the nature of the research and their position in respect of it.

Consent must be valid. The participants must be sufficiently informed and have adequate time to decide without pressure. Consent must be obtained from the subjects, preferably written.

Subjects must be able to easily withdraw from a research protocol without giving reasons and without incurring any penalty or alteration in their relationship with providers of services.

Specify procedures, including periodic appraisal of the progress of approved projects, for ensuring that subjects of research are protected from harm, their confidentiality is maintained, and their rights are respected.

The tasks of the ERC shall be executed free of bias and influence. The ERC has the authority to request research protocol modifications, enforce and monitor all informed consent or participants/animal rights issues and to suspend or stop any research that doesn’t conform to the protocol approved by the ERC.

The ERC shall also be involved in the on-going monitoring of conduct of research projects that are approved by it, in case necessary.

The ERC is responsible for acting in the interests of potential research participants and the concerned communities, taking into account the interests and needs of the researchers.

ERC may call for the proposal to be externally reviewed.

All proposals needing approvals from ASRB, shall have their ERC decisions prior to being submitted to ASRB (if applicable).

Working papers shall be circulated at least seven working days before the meeting and the minutes shall be issued within seven working days.

If no observations on minutes are received within three days, Secretary ASRB shall communicate ERC decision to the applicant, copy of which shall be sent to Registrar for record.

Appeals to the ERC, can be made to the Vice-Chancellor, within two weeks of the ERC decision. The Vice-Chancellor may take expert opinion as per his/her discretion. The decision of the Vice-Chancellor shall be final.

## Additional Considerations for the Committee

Ethics committee should have:

Office administrator – The committee should have administrative staff(s) that oversee the day to day activity of the committee;

Term of Office – Committee members shall serve for a period of 3 years.

Conditions of appointments – Members are appointed by the Director of the institute;

The committee shall document all its functions and activities.

Office space - The ethics committee should have an office space with necessary equipment and staff for good functioning

Continuous training - The provisions available for ethics committee members to receive introductory as well as continuous education need to be stated and observed.

## Stakeholders in Ethical Review Process

There are four main stakeholder groups in the research ethics review process: researchers/research teams, research ethics unit administrative staff, REB members, and the institution. Each plays a role in the transit of an application through the process and how well they undertake their role responsibilities affects the time that the application takes to move through.

### 5.5.1. Researcher

The researcher initiates the process of research ethics review by developing a proposal involving human participants and submitting an application. Here are some of the key issues requiring considerations.

Across standards, the principal investigator is accountable for the conduct of the study, including adherence to research ethics requirements.

Developing a sound proposal where ethics requirements are met at the outset places the application in a good position at the time of submission.

Researcher are required to have an understanding of legal and ethical standards, possess scholarly integrity, must be knowledgeable about the relevant scientific literature and present proposals that are justified based on what is known and where knowledge gaps exist.

Researchers are advised to review and proof their applications prior to submission to ensure that all required components have been addressed and the information in the application and supporting documents (e.g. consent forms, protocol) is consistent. Missing or discrepant information is causal to application return and therefore to time lost.

### 5.5.2. Administrators

Administrators are responsible to manage and coordinate the entire ethical review process. They serve as a bridge among researchers, reviewers (subject-matter experts) and REC members. Some of the functions of the administrators are outlined below.

Contact point for researchers and share them application requirements, undertaking completeness check (or preliminary screening) of applications and assign the documents to reviewers, with the approval of REC members.

Administrative checklists are useful tools to help ensure consistent application of standards in this preliminary application review.

If possible, the administrators shall have good knowledge of both institutional application requirements and ethics standards.

Reviewers typically send their completed reviews back to the administrators. In turn, the administrators either forward the applications to the Chair to consider (i.e. for delegated approval) or to a Board meeting agenda.

When reviews are delayed or incomplete for any reason, administrators may need to reassign the file to a different reviewer.

### 5.5.3. REC Members

REC members have the primary responsibility of evaluating the substantive ethics issues in applications and how they are managed. The committee is comprised of a body of staff members within the IoT with relevant expertise representing core domains of the IoT. The committee also includes a dedicated administrator to the committee who receives all applications and communications.

The Board may approve applications, approve pending modifications, or reject them based on their compliance with standards and regulations.

Shall prepare and utilize review templates, intended to guide reviewers and Board members to address a consistent set of criteria.

REC members are expected to undertake training and education, yielding consistent, efficient application of ethics principles and regulatory standards.

REC members shall understand ethical principles and regulatory standards and that they maintain awareness of previous decisions.

Membership: Chair, Vice Chair, Members (at least one from each teaching discipline with relevant academic and professional/research experience), and administrator.

Meetings are held monthly. Applications received by 5pm one week before each meeting will be considered. Where less than 5 applications are to be reviewed the meetings may take place electronically.

[Research governance and research conduct complaints](https://www.swansea.ac.uk/engineering/research/research-ethics-committee/#research-governance-and-research-conduct-complaints-contents) -

### 5.5.4. Institutions

Where research ethics review takes place under the auspices of academic institutions, the institutions must typically take responsibility to adequately support the functioning of their REC and promote a positive culture of research ethics.

Supporting the financial and human resource costs of participating in ongoing education (e.g. retreats, speakers, workshops, and conferences) is therefore the responsibility of the institution;

Institutions shall set a modal target turnaround time of 6 weeks;

Recognize contributions from REC members using possible forms e.g., allowance, supporting/recognition letters.

# Standard Operating Procedure

The REC shall take decisions in a short period of time. That requires receiving complete application documents, sufficient administrative support, well trained REC members with the right commitments, and the volume of applications received. Systemic improvements of the review process include standardization of review practices, enhanced training for REC members, and requiring accreditation of review boards.

The research review process is composed of document submission, review and decision stages.

## Documents Submission Guidelines:

All documents required for a thorough and complete review of the proposed research project should be submitted by the applicant on prescribed application format (sample shown in Annex 1) to Secretary of ERC. As per applicability, this includes, but not limited to:

Complete application form containing title of the proposal, investigator and co-investigator, research institution, sponsor (or funding entities, and others)

Project Proposal

The data management and ethics protocol for the proposed research project, clearly identified and dated, together with supporting documents and annexes:

A project summary or synopsis in non-technical language (containing Title of the Protocol, Principal Investigator, Sponsor, Abstract, Type of protocol, Objectives, Anticipated outcomes, Inclusion/Exclusion criteria, Withdrawal or discontinuation criteria, … Modes of treatment, Study design or methodology, Methods of analysis, Activity plan/ Timeline, Schedule and duration of treatment, Efficacy or evaluation criteria, Safety parameters criteria (toxicity), study budget, study agreement, CV of investigators, investigator’s brochure, …

A description (which may be included in the protocol) of the ethical considerations involved in the proposed research

Background information on previous research in the same area of work that justifies and/or supports the proposal

When the research involves an experimental product (such as a pharmaceutical or medical device under investigation), an adequate summary of all safety, pharmacological, pharmaceutical, and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g. recent investigator’s brochure, published data, a summary of the product’s characteristics)

All forms, documents, advertisements to be used in recruitment of potential participants.

Informed consent form(s) (with date and version number) in languages understood and at a reading level appropriate for the potential research participants and when required, in other languages

A description of the process that will be used to obtain and document informed consent

A description of measures that will be taken to ensure the protection of participants’ privacy and the confidentiality of data i) Electronic data acquisition and management plan

A statement describing any remuneration or other goods or services to be provided to study participants, including in-kind provisions.

Current curricula vitae of the principle investigators.

Disclosure of all previous decisions (including those leading to a negative decision or modified proposal) by other ERCs or regulatory authorities for the proposed study, whether in the same location or elsewhere, and indication of the reasons for previous negative decisions and modification(s) to the proposal made on that account

A signed statement that the researcher(s) agree to comply with ethical principles during the course of research

## Review Process

From the time of document submission, reviewers should be given enough time to review protocols and make comments. Ethics committee should have a process to determine which protocols are exempt, reviewed expedited and what happens after such review and reviewed by a full board. Review element should include:

Value of research, scientific design and conduct;

Ethics (risk, benefit, informed consent documents and processes, care and selection of participants etc.);

A complete documentation of all aspects of the meeting including time allocated for review is important as this will reveal how the ethics function, its adherence to their stated procedures and how transparent the committee is;

Management of conflicts of interest - Ethics committee should have a policy to address conflicts of interest and obligations;

Decision making - In other for the ethics committee to function fully they should have a procedure for decision making and members should be free to participate fully in discussion, debate and voting where the need arises.

## After Review Process - Communicating decision

Ethics committee should have an effective and timely way of communicating a decision.

REC should issue approval/disapproval letters with the conditions of approval or reasons for disapproval clearly stated

Documentation and archiving - All documentations and communication of the ethics committee should be properly filed and archived for easy access. A retrieval procedure should be indicated and complied with the minimum period of archive should also be stated and complied with.

## Terms of Reference

The Research Ethics Committee (REC) to be established in each research institute of technology (IoT) or college is a sub-committee of the Research Ethics Committee of the main university. Establishment of the committee is to recognize and support the values and principles: Research merit and integrity, Justice, Beneficence, Respect. The Committee reports to the IoT Directors or college deans.

An application for research ethics approval must be completed by researcher (staff or students) who are

Conducting research with human participants;

Or data derived from research with human participants which is not publicly available;

Research which is being conducted by staff or students overseas will still require approval by the committee. The appropriate permissions including where necessary ethical review should also be sought from the relevant institutions in the host country.

Where applications concern research with patients or medical devices, an external review may be required.

### Role or Objective

Some of the functions of IoT or college level Research Ethics Committee are:

Provide ethical review of research which involves human participants and/or data derived from such research that are not publicly available when no other system for formal ethical review is available.

Protect the mental and physical welfare, rights, dignity and safety of human research participants, their data and/or human tissue.

Promote compliance with the national codes of conduct applicable to the specific disciple and all applicable legislation.

Provide independent, competent, timely review and monitoring of human research projects with respect to their ethical and scientific acceptability for as long as the projects are active.

Protect the privacy and confidentiality of research participants by ensuring that researchers appropriately manage the security, storage and disposal of confidential data collected during the conduct of research involving humans.

Review proposals for human research projects with the intent to identify potential risk and/or harm to persons undertaking the research

Take decisions on submitted applications, which could be either (a) approved, (b) recommend for revision and re-submission, (c) not approved.

Handle appeals by a staff or student members.

Prepare an annual report.

### Scope of responsibility

Develop and provide input on policies and guidelines for research ethics.

Receive, review and monitor proposals for research projects to determine whether they meet all relevant ethical standards.

Provide education and training for individuals undertaking research.

Provide advice to the institute (IoT/college) on strategies to promote awareness of the ethical conduct of research and on ethical issues including the ethical aspects of complaints against researchers or research projects.

### Membership/composition

The committee will initially be comprised of a body of staff members within the IoT or college, including administrative support of the committee. The committee may co-opt external members and administrative support where special expertise is not present within the committee. Sub-committees may be formed with membership from the main committee where particular courses/domains of research give rise to large numbers of applications.

The current membership of the committee is as follows:

A chairperson, with suitable experience, whose other responsibilities will not impair the REC’s capacity;

Vice Chair;

Members –at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.

Administrator.

### Membership

The Chairperson, Deputy Chairperson, and all members will be appointed by director/dean, and will receive a letter of appointment including the date of appointment, length of appointment, and responsibilities as committee member.

Members are required to sign a declaration of interest and confidentiality statement undertaking:

That all matters of which he/she becomes aware during the course of his/her work on the REC will be kept confidential; and

That any conflicts of interest, which exist or may arise during his/her tenure on the REC, will be declared;

Members are appointed for an initial period of one year. Thereafter, members may be appointed for a two year term, and may then be re-appointed for a consecutive 3 year term. All appointments are renewable at the discretion of the REC Executive and the Deputy Vice-Chancellor (Research).

Members are required to attend at least 80% of the meetings held during each year of their appointment and to provide written comments on the majority of the ethics applications being reviewed.

Lay members and non-institutional members will be reimbursed for their travel costs.

A formal induction session and support will be provided to all new members in accordance with the requirements of the National Statement.

During their membership on the HREC, members will be provided with opportunities to attend training and professional development relevant to their work on the committee.

### Meetings

The committee will meet monthly and the dates announced at the start of each academic year. Applications may be considered at committee after review, reviewed at committee, or reviewed and approved prior to a committee meeting should the application be deemed of sufficiently low risk.

The Chairperson, Deputy Chairperson and the Ethics Secretariat shall form an Executive. The Executive is responsible for conducting the business of the HREC between meetings.

Meetings will be held if at least 51% members are present, including the Chair, Co-chair, or a Chair’s nominee.

All meetings will be minuted and the minutes stored for 5 years (or more, subject to the requirements of relevant legislation).

Where appropriate the review process may be conducted electronically, rather than in person at meetings, and the decision ratified at the meeting.

### Committee Decisions

Decisions are made by majority vote with the Chair having the casting vote.

### Expedited Review Committee (ERC)

A subcommittee called the Expedited Review Committee (ERC) will review amendment applications, ratifications of external ethics approval, transfer of research from another institution, applications for noting, program approval applications, evaluation of teaching and learning activities, and any urgent matters.

The Membership of the ERC will be as follows: Chairperson of the HREC, Deputy Chairperson of the HREC, and the Human Research Ethics Manager.

The decisions of the ERC will be noted on the Agenda at the next meeting of the HREC.

### Appeals

Applicants have a right of appeal against committee decisions. Such appeals should be directed to the university research ethics committee.

### Terms of office:

Committee members will normally serve for a 3 year period. There is no maximum tenure for members, but membership will be reviewed every three years to try to share the benefits and burdens of membership across the IoT/college. The Chair’s appointment will be reviewed every three years.

### Review of nil/negligible risk research applications

Research involving nil or negligible risk ‘where there is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience’. Nil or negligible risk applications will be noted on the Agenda at the next meeting of the ERC.

### Faculty review of low risk research applications:

Research involving low risk ‘where the only foreseeable risk is one of discomfort’ will be assessed via the risk assessment in Research Master.

The ethics review and approval process for low risk research is undertaken at the Faculty level.

Low risk applications will be noted on the Agenda at the next meeting of the ERC.

### Declaration of interest

An REC member must declare to the REC any conflicts of interest they have in relation to an application for ethical and scientific review or any other matter for consideration at the meeting. Conflict of interest includes financial interests, personal, professional or institutional benefits or advantages that depend significantly on research outcomes.

An REC member with a conflict of interest who is present at the meeting may be asked to withdraw from the meeting (by leaving the room) or may remain in the room at the HREC’s discretion.

The REC member with a conflict of interest will not participate in the discussions and will not be entitled to vote in the decision with respect to the matter.

The minutes will record the declaration of interest and the decision of the HREC on the procedures to be followed.

### Confidentiality

HREC meetings are held in private. The agenda and minutes of meetings, applications, supporting documentation and correspondence are all treated confidentially.

### Record keeping and reporting

The Ethics Secretariat will maintain a record of all research proposals received and reviewed in accordance with the National Statement.

The Ethics Secretariat will prepare and maintain official records of the REC’s activities, including agendas and minutes of all REC meetings.

Files will be kept securely and confidentially in accordance with the requirements of the Institute.

Records shall be retained for a minimum of 15 years after action completed, then destroyed.

The REC will provide annual reports as required.

### Complaints

Any concern or complaint about the ethical conduct of a research project should be directed to the Research Ethics Manager.

Concerns or complaints from internal and external stakeholders received by email, telephone or in a face-to-face conversation are recorded in writing by the Research Ethics Manager and kept in a separate file to which only they will have access.

The Research Ethics Manager undertakes a preliminary investigation regarding the issues raised by the complainant.

The REC Chair is notified about the complaint and the results of the preliminary investigation and if necessary provides advice about the appropriate resolution of the concern or complaint.

Complaints relating to the ethical approval of a research project will be notified to the REC.

The Chair and the REC should endorse the resolution of the complaint.

The complaint and its proposed or actual resolution are notified to the REC (at its next meeting) and the Director for Research and Technology Transfer.

The Research Ethics Manager informs the complainant and the researcher to whom the complaint has been made of the outcome.

In exceptional cases, the REC Chair, Deputy Chair or Research Ethics Manager may place an immediate suspension on a project upon receipt of a complaint. The researcher will be notified immediately if this occurs.

Concerns or complaints about the REC’s review process and/or the decision of the REC should be directed to the Director, Research and Innovation Office, who will investigate the complaint.

**Appendix I: Material Transfer Agreement Form**

Ministry of Science and Higher education (MoSHE), National Health Research Ethics Review Committee

Address: Tel.: +251011-4-674353 P.O. Box: 2490 Fax: +251-011-4-660241 e-mail: Addis Ababa Ethiopia \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_

Annex #: Material Transfer Agreement

This Material Transfer Agreement (MTA) has been prepared for use by \_\_\_\_\_\_\_\_\_\_\_\_ and \_\_\_\_\_\_\_\_\_\_ in all transfer of research material (samples, derivatives, and specimens) related to the protocol. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Provider: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Recipient: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Provider agrees to transfer to recipient’s designated ( \_\_\_\_\_\_\_\_\_\_ ) the following research materials /specimen. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_The research material will only be used for research purposes as described in the protocol by recipient’s investigator in designated laboratory for the research project described below, under suitable containment conditions. This research material will not be used for commercial purposes such as screening, production or sale for which a commercialization license may be required. Recipient agrees to comply with all National and International guidelines rules and regulations applicable to the Research Project and the handling of the Research Material.

a) Are the research materials of human origin? Yes No

b) If yes, are they collected according to the details in the protocol and in adherence to National Research Ethics Review Committee (NRERC) and \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Ethics Review Committee recommendations and their approval. Yes No

2. This research material and its derivatives will be used by recipient’s investigator solely in connection with the following research project (“Research Project”) de- 90 National Research Ethics Review Guideline Fifth Edition scribed with specificity as follows \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3. In all presentations or written publications concerning the research project, recipient will seek agreement of provider and acknowledge provider’s contribution of this research material unless requested otherwise.

4. This research material represents a significant contribution on the part of provider and is considered proprietary to provider. Recipient therefore agrees to retain control over this research Material and further agrees not to transfer the research material to other people not under her/his direct supervision without advance written approval of provider. The research material will be disposed of as agreed upon per protocol at the end of completion of the project on \_\_\_\_\_\_\_\_\_\_\_\_\_.

5. The provider does not take any responsibility for loss, damage, wastage or spoilage of the research material during or after shipment to the address provided by the recipient under conditions agreed to in the protocol on shipment of the samples. This research material is provided as a service to the research community. IT IS BEING SUPPLIED TO RECIPIANT WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Provider makes no representations that the use of the research material will not infringe any patent or proprietary right of third parties.

6. The recipient shall notify the provider in witting of any intention, improvement, modification discovery or development to the material or the information made by recipient or parties, collaborating with recipient, here in after referred to as “invention”. Nothing in this agreement shall, however, be construed as conveying to the provider any rights under any patents or other intellectual property to such invention, other than as explicitly provided herein. At its option the provider shall be entitled to receive sample of any materials derived from the Materials for its own research and evaluation purposes only.

7. The under- signed provider and recipient expressly certify and affirm that the contents of any statements made here are truthful and accurate.

8. Any additional terms (use an attached page if necessary):

9. The provider maintains, ownership right of the research material and its derivatives unless stated otherwise.

The provider will retain a copy (aliquot) of every sample sent abroad as much as possible for local research needs.

**Material Transfer Agreement Signature page**

For Recipient:

Recipient’s Investigator

………………………………………………………..

Signature

…………………………………………………………

…………………………………………………………

Date

………………………………………………………….

Mailing Address for Material

………………………………………………………….

………………………………………………………….

Tel………………………………………………………

Fax……………………………………………………….

For provider

Provider’s Investigator

……………………………………………………………

Signature

Date……………………………………………………

Mailing Address:

P.O.Box \_\_\_\_\_\_\_\_\_\_\_

Tel: \_\_\_\_\_\_\_\_\_\_\_

Fax: \_\_\_\_\_\_\_\_\_\_\_

Duly authorized

………………………………………………………..

Signature/stamp

…………………………………………………………

…………………………………………………………

Date

………………………………………………………….

Mailing Address for notices

………………………………………………………….

………………………………………………………….

Tel………………………………………………………

Fax……………………………………………………….

Duly authorized

……………………………………………………………

Signature

Date……………………………………………………

Mailing Address for notices:

P.o.Box \_\_\_\_\_\_\_\_\_\_\_

Tel: \_\_\_\_\_\_\_\_\_\_\_

Fax: \_\_\_\_\_\_\_\_\_\_\_

**Appendix II: Health Research Ethics Review Application Form**

**APPLICATION FORM for INITIAL REVIEW**

|  |  |
| --- | --- |
| Protocol Title: | |
| Protocol number: | Total Participants to be included: |

STUDY TYPE: (Mark “✓“whichever apply to the study)

* Survey ⬜ Social ⬜ Medical ⬜ Community based ⬜ Individual based
* Screening ⬜ Observational ⬜ Epidemiology ⬜ Intervention study
* Clinical Trial: ⬜ Phase I ⬜ Phase II ⬜ Phase III ⬜ Phase IV
* Genetic Study ⬜ Retrospective ⬜ Prospective ⬜ Others………………………………..

Study POPULATION: ⬜ Healthy ⬜ Patient ⬜ Vulnerable groups

CHARACTERISTICS of PARTICIPANTS:

Age Range: ⬜<1 month ⬜ 1 month- 12 years ⬜>12-17 yrs⬜ 18yrs & above

Impaired ⬜ None ⬜ Physically ⬜ Cognitively ⬜ Mentally

REQUESTED EXCLUSION OF PARTICIPANTS:

⬜ None ⬜ Male ⬜ Female ⬜ Children ⬜ Other (specify))

SPECIAL RESOURCE REQUIREMENTS (check all that apply):

⬜ Intensive Care ⬜ Isolation unit ⬜ Surgery

⬜ Pediatric Intensive Care ⬜ Transfusion ⬜ CAT/MRI scan

⬜ Gene therapy ⬜ Controlled substances (Narcotics/Psychotropics)

⬜ Prosthetics ⬜ Gynecological services ⬜Others, specify…………….

⬜ Organ transplantation, specify………………………… …………………………….

IONIZING RADIATION USE (X-rays, radioisotopes, etc):

⬜ None ⬜Medically indicated only

INVESTIGATIONAL NEW DRUG (IND) / DEVICE (IDE):

⬜ None ⬜IND ⬜ IDE

PROCEDURE USE: ⬜Invasive ⬜Non-invasive

MULTI-SITE COLLABORATION: ⬜ YES ⬜ NO

FINANCIAL DISCLOSURE: ⬜ YES ⬜ NO

INSTITUTE CONTACT

Name:……………………………………………………………………………………

Address: …………………………………………………………………………………

Telephone:…………………………………………

Fax:…………………………………………………

E-mail:……………………………………………...

**APPLICATION FORM for INITIAL REVIEW**

**INVESTIGATORS**:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **First / Last Name** | **License No.** | | **Institution** | **Telephone / Fax No.** |
| 1. |  | |  |  |
| 2. |  | |  |  |
| 3. |  | |  |  |
| 4. |  | |  |  |
| 5. |  | |  |  |
| 6. |  | |  |  |
| 7. |  | |  |  |
| 8. |  | |  |  |
| 9. |  | |  |  |
| 10. |  | |  |  |
| TYPE OF REVIEW: | | | | |
| Initial Review  Resubmission Review  Amendment Review  Expedited Review  Exempt review | | Emergency Review  Continuing Review  Report Review  Protocol Termination | | |
| SIGNATURES:  Date: ………………..  Principal Investigators  COMPLETION:  Date:…………………  Secretariat, NRERC | | | | |
| APPLICATION NUMBER : ⬜⬜⬜ / ⬜⬜ - ⬜⬜ | | | | |

## Appendix III. Research Ethics Review Form

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Protocol Number: | | | | | | | Date submitted: | | | | | |
| Protocol Title: | | | | | | | | | | | | |
| Principal Investigator: | | | | | | | | | | License: No: | | |
| Institute**:** | | | | | | Contact No**.** | | | | | | |
| Co – investigator(s): | | | | | | | | | | | | Contact No. |
| Total No. of Participants: | | | |  | | | | No. of Study site: | | |  | |
| Funding Agency: |  | | | | | | | | | Contact No. | | |
| Duration of the Study: | | |  | | Status: | | | | New Revised Amended | | | |
| Reviewer’s name: | | |  | | | | | | | Contact No. | | |
| Type of the Study: | | Intervention  Epidemiology  Observation  Document based Individual based  Genetic  Social Survey Others, specify……………………………… | | | | | | | | | | |
| Review Status: | | Regular  Expedited  Emergency | | | | | | | | | | |
| Description of the Study in brief: Mark whatever applied to the study.  Randomized  Stratified Randomized  Open-labeled  Double blinded  Placebo controlled Treatment controlled  Cross-over  Parallel Interim Analysis  Use of Tissue samples  Use of Blood samples Use of genetic materials  Multi-center study  Screening  Descriptive  Brief the study design and the statistic used:  Study Objectives:…………………………………………………………………….…………..  ………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………….. | | | | | | | | | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | Objectives of the Study  Clear Unclear | | What should be improved? | |
| 2 | Need for Human Participants  Yes  No | | Comment: | |
| 3 | Methodology:  Clear  Unclear | | What should be improved? | |
| 4 | Background Information and Data  Sufficient  Insufficient | | Comment: | |
| 5 | Risks and Benefits Assessment  Acceptable Unacceptable | |  | |
| 6 | Inclusion Criteria  Appropriate  Inappropriate | | Comment: | |
| 7 | Exclusion Criteria  Appropriate  Inappropriate | | Comment: | |
| 8 | Withdrawal Criteria  Appropriate Inappropriate | | Comment: | |
| 9 | Involvement of Vulnerable Participants  Yes  No | | Comment: | |
| 10 | Voluntary, Non-Coercive Recruitment of Participants  Yes  No | | Comment: | |
| 11 | Sufficient number of participants?  Yes  No | | Comment: | |
| 12 | Control Arms (placebo, if any)  Yes  No | | Comment: | |
| 13 | Are Qualification and experience of the Participating Investigators appropriate?  Yes  No | Comment: | |
| 14 | Disclosure or Declaration of Potential Conflicts of Interest  Yes  No | Comment: | |
| 15 | Facilities and infrastructure of Participating Sites  Appropriate  Inappropriate | Comment: | |
| 16 | Community Consultation  Yes  No | Comment: | |
| 17 | Involvement of Local Researchers and Institution in the Protocol Design, Analysis and Publication of Results  Yes  No | Comment: | |
| 18 | Contribution to Development of Local Capacity for Research and Treatment  Yes  No | Comment: | |
| 19 | Benefit to Local Communities  Yes  No | Comment: | |
| 20 | Availability of similar Study / Results  Yes  No | Comment: | |
| 21 | Are blood/tissue samples sent abroad?  Yes  No | Comment: | |

|  |  |  |
| --- | --- | --- |
| 22 | Does the study involve sample storage? If ‘No’, go to # 27  Yes No | Comment: |
| 23 | Is the duration of specimen storage specified?  Yes  No | Comment: |
| 24 | Separate consent for specimen storage sought  Yes  No | Comment: |
| 25 | Planned practice for storage, coding and further utilization of stored specimens  Appropriate  Inappropriate | Comment: |
| 26 | Institutional support/permit confirming adequate samples storage commitment for long term storage sought  Yes  No | Comment: |
| 27 | Are procedures for obtaining Informed Consent appropriate?  Yes  No | Comment: |
| 28 | Contents of the Informed Consent Document  Clear  Unclear | Comment: |
| 29 | Language of the Informed Consent Document  Clear Unclear | Comment: |
| 30 | Contact Persons for Participants  Yes  No | Comment: |
| 31 | Privacy & Confidentiality  Yes  No | Comment: |
| 32 | Inducement for Participation  Unlikely  Likely | Comment: |
| 33 | Provision for Medical / Psychosocial Support  Appropriate Inappropriate | Comment: |
| 34 | Provision for Treatment of Study-Related Injuries  Appropriate Inappropriate | Comment: |
| 35 | Provision for Compensation  Appropriate  Inappropriate | Comment: |

Review Date ……………………….Protocol number:…………….

|  |  |  |  |
| --- | --- | --- | --- |
| Protocol Title: | | | |
| Elements Reviewed (AA 01-008) | | Attached  Not attached | |
| Review of Revised Application  ⬜Yes  No | | Date of Previous review: | |
| DECISION: | Approved  Approved on condition  Not Approved | | |
| Comment: |  | | |
| Signature: |  | | Date: |

## Appendix VI: Risk Benefit Analysis Guidance



Adopted from : Rid A, Emanuel EJ, Wedler D. Evaluating the Risks of Clinical Research. JAMA, 2010, 304,13

**ANNEXES**

**Annex 1:** Member Confidentiality Agreement Form

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, agree to maintain full confidentiality in regards to any and all documentation received from researchers, Institutional Animal Care and Use Committee (NARERC) in matters related to ARSERC function.

Furthermore, I agree:

To adhere to the NARERC Procedures.

To ensure that all NARERC related documents are in a safe, secure location as long as they are in my possession.

To not make copies of any documents received at the NARERC unless specifically requested to do so by the committee.

To not to discuss, disclose, or reproduce any confidential information except when I carry out my functions as an NARERC Member.

To hold in strictest confidence the identification of any individual that may be reprimanded by the Committee.

To delete all electronic files containing NARERC-related documents from my computer hard drive and any backup devices when I leave the committee.

I am aware that I can be held legally liable for any breach of this confidentiality agreement and for any harm incurred by individuals as a result of the violation.

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Witnessed by the ARERC Committee Chairperson:***

Name: \_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Annex 2: Application review form

***Research title:*** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Principal Investigator/Co-PI’s Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |
| --- | --- | --- |
| **Evaluation criteria** | **Project assessment result** | **NARERC Recommendation** |
| Clear and Achievable objectives |  |  |
| Presence of any alternative to animal use |  |  |
| Originality |  |  |
| Technical competence (Suitability of study design and Appropriateness of Study Procedures |  |  |
| Invasiveness of the research (non-invasive/mild/invasive). Level of risk/harm the study presents:  a. Minimal risk/harm  b. More than minimal risk/harm  c. High risk |  |  |
| Identify and assess the risks and anticipated benefits. |  |  |
| Clarity of procedures/techniques to be involved |  |  |
| Mechanisms of reducing pain & distress |  |  |
| Biosafety and Biosecurity concerns (human/animal concern) |  |  |
| Environmental concerns |  |  |
| Is there provision for capacity building and/or technology transfer |  |  |

Urging the applicant to incorporate the above recommendations, Institutional Animal Care and Use Committee (NARERC) ***approved/Rejected*** the applicants request with ***minor or major modification.***

Annex 3: Ethical clearance certificate template

|  |
| --- |
| **Ethical Clearance Certificate**  Certificate Ref. No: **\_\_\_\_\_\_\_\_\_**  Date: \_\_\_\_\_\_\_\_\_\_\_\_  Name of applicant: **\_\_\_\_\_\_\_\_\_**  Address : **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  Title of the project: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  Nature of the project : **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  Animal species to be used: **\_\_\_\_\_\_\_\_\_\_\_\_\_**  Minutes No. and date of review: **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  The above indicated research project is found Scientifically and Ethically sound from relevance, originality and technical competence point of view.  Hence, the project is allowed to be executed provided that;  All procedures and conditions stipulated in the proposal are respected and any deviations, variations or changes may be made only in consultation between and reported to committee, any progress will be made with written agreement.  All the comments given by the committee should be considered and fulfilled by the Researchers.  The project activity be open for occasional supervision by the committee whenever this is deemed necessary. The PI will submit progress and final report to the review committee.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Chairman Signature  \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Center Director Signature |

Annex 4: Application registration logbook

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Name of the Applicant** | **Application number** | **Project/Research title** | **Name of Applicant** | **Signature of Applicant** | **Documents received** | | | | **Remarks** |
| **Completed Application form** | **CV of PI/Co-PI** | **Signed cover letter** | **Full research protocol** |
|  |  |  |  |  |  |  |  |  |  |
| **List of other Documents submitted for application** | | | | **Name and Signature of Application Receiver** |
|  | | | |  |

Annex 4: NARERC evaluation feedback distribution logbook

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Evaluation feedback provided date, time** | **Application number** | **Project/Research title** | **Certificate Reference Number** | **Certificate Receiver Name and Signature** | **Remarks** |
|
|  |  |  |  |  |  |

Annex5

Department/Unit: \_\_\_\_\_\_\_\_\_\_\_

Application No: \_\_\_\_\_\_\_\_

Animal Research Scientific and Ethics Review Committee (ARSERC)

APPLICATION FOR ANIMAL RESEARCH SCIENTIFIC AND ETHICS CLEARANCE FOR APPROVAL OF PROPOSED RESEARCH

(All applications are to be typed and presented using language that is free from jargon)

**SECTION A**

**Project Title…………………………………………**

Projected start date for data collection - …………………

Projected end date- ………………………………………

Applicant Details (Select either STAFF of the institute or STUDENT APPLICATION or Researcher from the outside and complete details)

|  |
| --- |
| STAFF of the institute APPLICATION (excluding staff who are also students) |
| |  | | --- | | Full name of Staff Applicant | |
| |  | | --- | | Department/Unit/Section | |
| |  | | --- | | Unit where you are based (name one only) | |
| |  | | --- | | Telephone and e-mail address: | |

|  |
| --- |
| STUDENT/Other Non-staff APPLICATION |
| |  | | --- | | Full name of student/non staff Applicant**-** | |
| Employer (if applicable)- |
| |  | | --- | | Telephone and e-mail address - | |
| |  | | --- | | Postal address | |
| Telephone and e-mail address: |
| Full name of local research supervisor – …………………………………………………. |
| |  | | --- | | Telephone and e-mail address of research supervisor –  …………………………….  ……………………………..  …………………………… | |

**Type of Project** (tick one only)

❍ Staff of the home institute research

❍Student/other non-staff Research (DVM, Masters or PhD)

If other, please specify:

**Summary of Project**

Please outline in no more than 200 words in lay language why you have chosen this project, what you intend to do, and the methods you will use. Be sure to name all the places in which you will gather data from live animals.

***. ……………………………………………………………………………………………***

Please indicate whether this application is for: Convened review 􀀀 Expedited Review 􀀀 Exempted 􀀀

5.1 a new project? Yes 􀀀 No 􀀀

5.2 a project which has (previously or simultaneously) been submitted to this or another ethics committee? Yes 􀀀 No 􀀀

If *yes*, provide reasons for re-submission or simultaneous submission.

5.3 a significantly revised current protocol? Yes 􀀀 No 􀀀

**List any attachments to your Application**

***Summary of the research proposal***

Applications that are incomplete or lacking the appropriate signatures will not be processed. This will mean delays for the project.

**SECTION B: PROJECT INFORMATION**

For staff research, is the applicant the only researcher? ❍ Yes ❍ No

If no, list the names and affiliations of all members of the research team.

State concisely the aims of the project

Give a brief background to the project to place it in perspective and to allow the project’s significance to be assessed. (no more than 200 words in lay language)

If the project repeats previously reported experiments, give the reasons for the experiments to be repeated.

How many animals will be required?

Explain, on the basis of experimental design, why this number of animals will be required.

Outline the research procedures to be used, including approach/procedures/manipulations for collecting data.

Where will the project be conducted? Include information about the physical location/setting.

Describe the experience of the researcher and/or supervisor to undertake this type of project?

Describe the process that has been used to discuss and analyze the ethical issues present in this project. Identify all factors and procedures that may have an impact on an animal's well-being. This may include handling, sampling, housing etc as well as specific experimental procedures.

**SECTION C: RISK OF HARM**

What discomfort (physical, physiological), incapacity or other risks of harm are the live animals being used in this research project likely to experience?

**The experimental animals will be subjected to infection with…………………………*,***

Describe the strategies you will use to minimize the discomfort identified in Q17?

………………………………………………………………………………………….

…………………………………………………………………………………………….,

Describe any circumstances that might give rise to biological safety and security concerns for researchers, the environment and experimental animal population during sample collection, laboratory analysis and during experimental procedures like inoculation of infectious agent and brief the waste management procedures.

**SECTION D: INVASIVE PROCEDURES/PHYSIOLOGICAL TESTS AND EUTHANASIA**

20. Does the project involve the collection of tissues, blood, other body fluids or physiological tests?

❍**Yes** ❍ No

21. Describe the material to be taken and the method used to obtain it. Include information about the training of those taking the samples and the safety of all persons involved. If blood is taken, specify the volume and number of collections.

***……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………..***

22. Describe the fate of live animals at the end of the research project. Give details (sequentially) on **what happens to the animal(s)** from the time you obtain them until the time the project is completed. A flow chart or sequence of events table may assist in making this information clear.

***……………………………………………………………………………………………………………………………………………………………………………………………………………..***

23. Describe each factor or procedure and detail how any adverse impact will be minimized. Explain precisely how sick or injured animals will be euthanized.

***……………………………………………………………………………………………………………………………………………………………………………………………………………***

DECLARATION (Complete appropriate section)

Home institute STAFF RESEARCH

**Declaration for home institute Staff Applicant**

I have prior understanding of animal ethics issues and I understand my obligations. I have advised my co-researchers and assistants of their obligations. I agree to undertake the research as set out in Animal Ethics guidelines available elsewhere. My Head of Division/Institute (delete as appropriate) knows that I am undertaking this research. The information contained in this application is to the best of my knowledge accurate and not misleading.

Staff applicant’s Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

STUDENT/or other non-staff RESEARCH

**Declaration for Student/or other non-staff Applicant**

I have prior understanding of animal ethics issues and discussed the ethical issues surrounding my project with my Supervisor. I understand my obligations. I agree to undertake the research as set out in Animal Ethics guidelines available elsewhere. The information contained in this application is to the best of my knowledge accurate and not misleading.

Student/or other non-staff applicant’s Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Declaration of Supervisor**

I have assisted the researcher/student in the ethical analysis of this project. As supervisor of this research, I will ensure that the research is carried out accordingly to the Animal Ethics principles employed elsewhere.

Supervisor’s Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Print name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**ANNEX 6: Material Transfer Agreement Form**

The RECPIENT and the RECIPIENT SCIENTIST should sign both copies of this letter and return one signed copy to the PROVIDER SCIENTIST. The PROVIDER will then forward the BIOLOGICAL MATERIAL.

Please fill in all of the blank lines below:

TITLE OF RESEARCH: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

- PROJECT IDNUMBER: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

ORIGINEOF MATERIAL (Enter description):  
\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PROVIDER (Organization providing the ORIGINAL MATERIAL)

Name of Organization: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Street Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

City/State: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone/Fax: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Head of Provider Institution/Date:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PROVIDER SCIENTIST

Name and Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Street Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

City/State: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone/Fax: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature/Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

RECIPIENT SCIENTIST

Name and Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Street Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

City/State: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Country: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone/Fax: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature/Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

RECIPIENT ORGANIZATION (Organization receiving the O MATERIAL)  
I hereby certify that the RECIPIENT organization has accepted and signed the Materials Transfer Agreement (this may be the RECIPIENT SCIENTIST if he/she is authorized by the RECIPIENT organization)

Name of Organization: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Street Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

City/State: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Country: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Phone/Fax: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of authorized official/Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name and Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

In response to the terms of the research Proposal entitled \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**ANNEX 7: Consent of the RECIPIENT SCIENTIST**

The PROVIDER asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following points:

I. The above BIOLOGICAL MATERIAL is being made available to the RECIPIENT for the sole purpose of research outlined in the protocol named in this letter only. Within the context of this research proposal only, the MATERIALS, their modifications and progenies are jointly owned by the parties to this agreement.

II. The BIOLOGICAL MATERIAL will not be further distributed to others without the PROVIDER's written consent.

III. Any BIOLOGICAL MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The RECIPIENT assumes all liability for damages which may arise from its use, storage or disposal of the BIOLOGICAL MATERIAL.

IV. The RECIPIENT agrees to use the BIOLOGICAL MATERIAL (animal subjects or recombinant DNA) in compliance with all applicable national statutes and regulations and also UN Convention on Biological Diversity.

V. The BIOLOGICAL MATERIAL is provided at no cost other than as specified in the research protocol.

VI. The BIOLOGICAL MATERIALS are to be stored at \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and used at the laboratories of the RECIPIENT SCIENTIST and collaborators under the RECIPIENT SCIENTIST’s direct or delegated supervision as specified in the research protocol approved by the Institutional review board

VII. Without written consent from the **PROVIDER**, the **RECIPIENT** and/or the **RECIPIENT SCIENTIST** may NOT provide **MODIFICATIONS** for **COMMERCIAL PURPOSES**.

VIII. If the **RECIPIENT** desires to use or license the **MATERIAL** or **MODIFICATIONS** for **COMMERCIAL PURPOSES**, the **RECIPIENT** agrees, in advance of such use, to negotiate in good faith with the **PROVIDER** to establish the terms of a commercial license.

IX. The**RECIPIENT AND PROVIDER** as joint owners are free to file patent application(s) claiming inventions made by the **RECIPIENT** through the use of the **MATERIAL**.

X. The **RECIPIENT** agrees to use the **MATERIAL (**animals or recombinant DNA) in compliance with all applicable statutes and regulations, including national, international and institutional regulations and guidelines.

XI. This Agreement will terminate on completion of the **RECIPIENT's** current research with the **MATERIAL**, after which full ownership reverts to the PROVIDER and the **RECIPIENT** will discontinue its use of the **MATERIAL** and will, upon direction of the **PROVIDER**, return or destroy any remaining **MATERIAL**.

**ANNEX 8: Checklist for primary Roles and Responsibilities of Ethics Committees and Community representatives**

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| **Measurable** | **Community Representatives** | **Ethics Committees** |
| To protect research participants by applying the principles of research ethics and any relevant guidelines and regulations |  | √ |
| To review the protocol |  | √ |
| To represent the interests of research participants | √ |  |
| To review the informed consent and other materials intended for research participants |  | √ |
| To provide input into the informed consent process; to review support materials for linguistic and cultural relevance | √ |  |
| To provide input into the development of recruitment and retention plans | √ |  |
| To review the recruitment and retention plans |  | √ |
| To approve the study |  | √ |
| To advocate for the study among the community | √ |  |
| To conduct ongoing review, at least annually, for all research studies |  | √ |
| To participate in community education and outreach activities. | √ |  |
| To review and approve any changes to approved research prior to implementation |  | √ |
| To alert the research team about rumors and assist in dispelling them. | √ |  |
| To advise the research team on how to best disseminate research results | √ |  |

APPLICATION FOR ETHICAL COMMITTEE APPROVAL OF A RESEARCH PROJECT [1]

All research with human participants or on data derived from research with human participants that are not publicly available, undertaken by staff or students linked with A-STEM or in the College of Engineering more widely must be approved by the College of Engineering Research Ethics Committee.

**RESEARCH MAY ONLY COMMENCE ONCE ETHICAL APPROVAL HAS BEEN OBTAINED**

The researcher(s) should complete the form in consultation with the project supervisor. After completing and signing the form students should ask their supervisor to sign it. The form should be submitted electronically to coe-researchethics@swansea.ac.uk.

Applicants will be informed of the Committee’s decision via email to the project leader/supervisor.

|  |
| --- |
| **1. TITLE OF PROJECT** |
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| **2. DATE OF PROJECT COMMENCEMENT AND PROPOSED DURATION OF THE STUDY** |
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| --- |
| **3. NAMES AND STATUS OF THE RESEARCH TEAM**  *State the names of all members of the research group including the supervisor(s). State the current status of the student(s) in the group i.e. Undergraduate, postgraduate, staff or other (please specify).* |
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| **4. RATIONALE AND REFERENCES**  *Describe in* ***no more than 200 words*** *the background to the proposed project.*  *In all sections below that detail your study and its aims please use language suitable for a lay audience.* |
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| **5. OBJECTIVES**  State the objectives of the project, i.e. one or more precise statements of what the project is designed to achieve. |
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| **6.1 STUDY DESIGN**  Outline the chosen study design (e.g., cross-sectional, longitudinal, intervention, RCT, questionnaire etc) |
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| **6.2. STUDY DESIGN**  *- state the number and characteristics of study participants*  *- state the inclusion criteria for participants*  *- state the exclusion criteria for participants and identify any requirements for health screening*  *- state whether the study will involve vulnerable populations (i.e. young, elderly, clinical etc.)*  *- state the requirements/commitments expected of the participants (e.g. time, exertion level etc)* |
|  |

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| **6.3. PARTICIPANT RECRUITMENT**  *How and where will participants be recruited? How will you ensure that these methods of recruitment do not compromise the ability of the research participant to freely consent to and withdraw from the study?* |
|  |

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| **6.4 DATA COLLECTION METHODS**  *- describe all of the data collection/experimental procedures to be undertaken*  *- state any dietary supplementation that will be given to participants and provide full details in Section 6.5*  *- state the inclusion of participant information and consent forms (and assent forms where necessary in appendices)*  *- Where you are asking research participants to undertake physical activity consider appropriate health screening processes. Note that the ACSM have updated their guidelines in a consensus statement dated 2015.* |
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| **6.5 DATA ANALYSIS TECHNIQUES**  *- describe briefly the techniques that will be used to analyse the data* |
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| **6.6. STORAGE AND DISPOSAL OF DATA AND SAMPLES**  *describe the procedures to be undertaken for the storage and disposal of data and samples*  *- identify the people who will have the responsibility for the storage and disposal of data and samples*  *- identify the people who will have access to the data and samples*  *state the period for which the raw data will be retained on study completion (normally 5 years, or end of award. But data should not be retained for longer than is necessary for the purposes of the research project.)*  *Please confirm that where data is being stored away from Swansea University (for example on cloud based services) that procedures are still in line with GDPR legislation.* |
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| **6.7 HOW DO YOU PROPOSE TO ENSURE PARTICIPANT CONFIDENTIALITY AND ANONYMITY?** |
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| **6.8 PLEASE PROVIDE DETAILS OF ANY DIETARY SUPPLEMENTATION (DELETE IF NOT APPLICABLE)** |
| *State the full name of the supplement to be used in the study, including proprietary names under which it is also known*  *Provide full details of the manufacturer and source of origin of the supplement that will be used*  *Provide details of the composition of the supplement, including details of any potentially active ingredients*  *State the quantity & frequency (dosage) of supplement administration*  *State the method/route of supplement administration (e.g. oral)*  *State the time of supplement administration relative to any form of physical exercise that participants will be asked to undertake as part of the proposed study*  *State the desired (or hypothesised) effects of the supplement in the context of the proposed study*  *Provide, with references, a list of known contraindications (i.e. conditions or factors that increases the risk involved in using the supplement) that have been associated with the supplement during resting and exercise indications*  *Provide, with references, a list of possible side effects (i.e. adverse or unintended, and undesirable, consequences of using the supplement) that might occur after administration of the supplement, during resting and exercise conditions* |

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| **7. LOCATION OF THE PREMISES WHERE THE RESEARCH WILL BE CONDUCTED.**  *- list the location(s) where the data collection and analysis will be carried out*  *- identify the person who will be present to supervise the research at that location*  - *If a first aider is relevant, please specify the first aider and confirm that they possess the first aid qualifications appropriate for this form of research* |
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| **8. POTENTIAL PARTICIPANT RISKS AND DISCOMFORTS**  *- identify any potential physical risk or discomfort that participants might experience as a result of participation in the study.*  *- identify any potential psychological risk or discomfort that participants might experience as a result of participation in the study.*  *- Identify the referral process/care pathway if any untoward events occur* |
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| **9.1. HOW WILL INFORMED CONSENT BE SOUGHT?**  *Will any organisations be used to access the sample population?*  *Will parental/coach/teacher consent be required? If so, please specify which and how this will be obtained and recorded?* |
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| **9.2 INFORMATION SHEETS AND CONSENT/ASSENT FORMS**  **Please ensure that your forms are written in clear, simple language enabling research participants to fully understand the project.** |
| Have you included a participant information sheet for the participants of the study? YES/NO  Have you included a parental/guardian information sheet for the parents/guardians of the study? YES/NO  Have you included a participant consent (or assent) form for the participants in the study? YES/NO  Have you included a parental/guardian consent form for the participants of the study? YES/NO |

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| **10. IF YOUR PROPOSED RESEARCH IS WITH VULNERABLE POPULATIONS (E.G., CHILDREN), HAS AN UP-TO-DATE DISCLOSURE AND BARRING SERVICE (DBS) CHECK (PREVIOUSLY CRB) IF UK, OR EQUIVALENT NON-UK, CLEARANCE BEEN REQUESTED AND/OR OBTAINED FOR ALL RELEVANT RESEARCHERS?.** |
| If appropriate please provide a list below including the name of the researcher, and confirming that they have an up to date DBS check. Please also confirm the type of check (i.e. basic/enhanced). |

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| **11. HUMAN TISSUE ACT**  **Does your research involve the collection or storage of human tissue samples?**  **Where not relevant please respond N/A. Where appropriate please provide further details.** Please note that University ethics committee approval is not sufficient to comply with legislation for the storage of relevant material for research. |
|  |

**12. STUDENT DECLARATION**

*Please read the following declarations carefully and provide details below of any ways in which your project deviates from these. Having done this, each student listed in section 2 is required to sign where indicated.*

“*I have ensured that there will be no active deception of participants.*

*I have ensured that no data will be personally identifiable.*

*I have ensured that no participant should suffer any undue physical or psychological discomfort (unless specified and justified in methodology).*

*I certify that there will be no administration of potentially harmful drugs, medicines or foodstuffs.*

*I will obtain written permission from an appropriate authority before recruiting members of any outside institution as participants.*

*I certify that the participants will not experience any potentially unpleasant stimulation or deprivation.*

*I certify that any ethical considerations raised by this proposal have been discussed in detail with my supervisor.*

*I certify that the above statements are true with the following exception(s):*

Student/Researcher signature: (include a signature for each student in research team)

Date:

Where submitted electronically we will accept the lead supervisor/researcher’s email of the application as confirmation that both they and other researchers on the project have discussed and are happy to adhere to the above.

**13. SUPERVISOR’S APPROVAL**

Supervisor’s signature:

Date

# REFERENCES

Abiy Zegeye, Alemayehu Worku, Daniel Tefera, Melese Getu and Yilma Sileshi, “Introduction to Research Methods - Preparatory module for Addis Ababa University graduate programs”, Graduate Studies and Research Office Addis Ababa University, September 2009.

A Guide to Research Ethics, University of Minnesota, Center for Bioethics, 2003

[Aceme Nyika](https://www.sciencedirect.com/science/article/pii/S0001706X09002009#!), 2009. Animal research ethics in Africa: An overview, [Acta Tropica](https://www.sciencedirect.com/science/journal/0001706X), [Volume 112, Supplement 1](https://www.sciencedirect.com/science/journal/0001706X/112/supp/S1), Pages 48-S52

Casarett, Karlawish, Sugarman. JAMA, 2000, 283 (17): 2275-80.

Code of Federal Regulations. TITLE 45 — PUBLIC WELFARE. Department of Health and Human Services. PART 46: PROTECTION OF HUMAN SUBJECTS. Revised June 23, 2005. Effective June 23, 2005.

Code of Practice For Research, Promoting good practice and preventing misconduct, 2009. UK Research Integrity Office.

“College Research Ethics and Governance Committee”, online resource available at<https://www.swansea.ac.uk/engineering/research/research-ethics-committee/> and accessed on March 18, 2020, SwanseaUniversity, College of Engineering, UK.

“CSET Research Ethics”, University of South Africa (UNISA), online resource available at <https://www.unisa.ac.za/sites/corporate/default/Colleges/Science,-Engineering-&-Technology/Research/Research-Ethics> and accessed on March 19, 2020.

Cowan DH. Scientific Design, Ethics, and Monitoring: IRB Review of Randomized Clinical Trials. *IRB: Ethics and Human Research*, 1980;2: 1-4.

David B. Resnik, “What Is Ethics in Research & Why Is It Important?” December 1, 2015, accessed on March 10. available at <https://www.niehs.nih.gov/research/resources/bioethics/whatis/index.cfm>

DeMets DL, Fost N, Powers M. An Institutional Review Board dilemma: responsible for safety monitoring but not in control. *Clin Trials* 2006; 3; 142.

Diane Blankenship, “[Applied Research and Evaluation Methods in Recreation](https://us.humankinetics.com/products/applied-research-and-evaluation-methods-in-recreation)”, available online at <https://us.humankinetics.com/blogs/excerpt/steps-of-the-research-process> and accessed on March 11, 2020

Dowie, M. (2009). Appendix B United Nations Declaration on the Rights of Indigenous Peoples. In *Conservation Refugees*. The MIT Press. https://doi.org/10.7551/mitpress/7532.003.0025

Edys Quellmalz, "Engineering and Technology: Assessing Understanding of Similarities and Differences Between Them", Encyclopedia of Science Education, 2021, Springer Netherlands, doi="10.1007/978-94-007-6165-0\_19-2"

Engineering Council Royal Academy of Engineering, “Statement of Ethical Principles”, accessed on March 4 and available at <https://www.raeng.org.uk/publications/reports/statement-of-ethical-principles>Frey, R.G. “Animals and Their Medical Use.” 2005.  Contemporary Debates in Applied Ethics. Cohen, Andrew and Wellman, Christopher eds. Blackwell Publishing. In this essay Frey puts forth a view where animals do matter, but human welfare is considered more important.

Environmental Research Ethics—National Principles And Guidelines, Australian Journal of Environmental Management, 5:sup1, 72-84, DOI: 10.1080/14486563.1998.10648443

Ethical considerations in protecting the environment from the effects of ionizing radiation, 2002. IAEA, VIENNA.

Ethiopian Science and Technology Commission. National Health Research Ethics Review Guidelines, Fourth Edition. Addis Ababa, Ethiopia 2005.

Ethical Guidelines for International Comparative Social Science Research in the framework of Management of Social Transformations, MOST. UNESCO, MOST Paris.

“Ethics and Alternatives”. Research Animal Resources. University of Minnesota. 2003.

Federal Negarit Gazetta of The Federal Democratic Republic of Ethiopia. 15th Year No 1 Addis Ababa, October 24 2008.

Federal Negarit Gazetta of The Federal Democratic Republic of Ethiopia. 16th Year No 51 Addis Ababa, August 23 2010.

Gómez-Castro, B., & Kipper, R. (2019). Nagoya Protocol on Access and Benefit-Sharing. *Microbiology Australia*, *40*(3), 103–106. https://doi.org/10.1071/MA19028

“Good Research Practice Guidelines,” University of Cambridge, available at <https://www.research-integrity.admin.cam.ac.uk/files/good_research_practice_guidelines_2018.pdf> and accessed on March 20, 2020.

Guidelines for the ethical use of animals in research and teaching, 2011. e Department of Primary Industries Biosecurity Victoria

Guidelines for Ethical Conduct in the Care and Use of Nonhuman Animals in Research, American Psychological Association, APA Council of Representatives on February 24, 2012.

Guidelines for Research Ethics in Science and Technology, 2016. The Norwegian National Research Ethics Committees, [www.etikkom.no](http://www.etikkom.no)

Guide to the Care & Use of Animals in Research & Teaching, 2016. Interfaculty Animal Ethics Committee University of the Free State.

Guidelines for Research Ethics in the Social Sciences, Humanities, Law and Theology, 2016. The Norwegian National Research Ethics Committees,

Guidelines for Conducting Clinical Trials. Drug Administration and Control Authority. Addis Ababa, Ethiopia.

Heath EJ. The IRB’s Monitoring Function: Four Concepts of Monitoring. *IRB: Ethics and Human Research*, 1979; 1: 1-3+12.

Hendriksen, C.F., 2005. The ethics of research involving animals: a review of the Nuffield Council on Bioethics report from a three Rs perspective. Alternatives to Laboratory Animals, 33(6), pp.659-662.

Hyder A, Dowson L, Bachani AM, Lavery J. Moving from research ethics review o research ethics systems in low-income and middle-income countries. Lancet 2009;37:862-65.

International Ethical Guidelines for Biomedical Research Involving Human Subjects. Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO). CIOMS Geneva 2002.

International Declaration on Human Genetic Data, UNESCO, 2003.

Karbwang J, Pattou C. Standard operating procedures for clinical investigators. UNDP/World Bank/WHO, special program for research and training in tropical diseases (TDR). TDR/TDP/SOP/99.1.

Karlawish, Hall *(1996).* Am J Respir Crit Care Med, 1996;153:499-5-6.

Koepsell, D., Brinkman, W.-P., & Pont, S. “*Human Research Ethics Committees in Technical Universities*”, Journal of Empirical Research on Human Research Ethics, 9(3), 67–73. doi:10.1177/1556264614540596.

*Local Food and Community Development - Google Books*. (n.d.). Retrieved February 26, 2020, from https://books.google.com.et/books?id=Q8noBAAAQBAJ&printsec=frontcover&source=gbs\_vpt\_buy#v=onepage&q&f=false

National Research Ethics Review Guidline: 2014. EFDRE Ministry of Science and Technology. 5th edition.

Nuremberg Code. 1948.

Ogueri, E. I. (2005). E Valuation O F a Gricultural E Xtension M Essages. *Agricultural Ethics*, *12*(29), 3–12.

Operational Guidelines for Ethics Committees that Review Biomedical Research. WHO, 2000.

Operational Guidelines for the Establishment and Functioning of Data and Safety Monitoring Boards, TDR-WHO, Geneva 2005.

PhD Programs Management Standard, document draft from AAU, ….

Philip Brey and Philip Jansen, “Ethics Assessment in Different Fields Engineering Sciences”, University of Twente, June 2015, accessed on March 10, available at <https://satoriproject.eu/media/2.b-Engineering.pdf>

“Research Ethics Policy”, NED University Of Engineering And Technology, accessed on March 4 and available at https://www.neduet.edu.pk/policies/EthicalPolicy.pdf

Review Mechanisms” Institutional Review Board (IRB). Loyola University, Chicago, 2020.

Richards HM, Schwartz LJ. Ethics of qualitative research: are there special issues for health services research? Family Practice 2002; 19: 135-139.

Roli Varma, “Technology and Ethics for Engineering Students”, June 2000, Bulletin of Science Technology & Society 20(3):217-224, DOI: [10.1177/027046760002000309](https://www.researchgate.net/deref/http%3A%2F%2Fdx.doi.org%2F10.1177%2F027046760002000309?_sg%5B0%5D=qRmofe_1DK7v_YImHruh6eNMnSc5oVc063MlsEcjaZwjj8ckZpQIF-mQQHAlMzQnRcm4oMxaGWYcfss5Z_gH_4EzHw.te6C4LdiP4x05l-fjnuELxxSufYowM3GIwa-dvm1H-jaDB68gl1_Lv7ssaKEXpbczF69x0lVHavwJEntDuJS4w)

“7 Steps Research Process Outline to Conduct a Research”, online resource available at <https://www.campuscareerclub.com/research-process-outline/>and accessed on March 11, 2020.

Stacey A. Page  and Jeffrey Nyeboer, “Improving the process of research ethics review”, online resource accessed on March 17, 2020 and available at <https://researchintegrityjournal.biomedcentral.com/articles/10.1186/s41073-017-0038-7>

Statement of WHO Expert Advisory Group on Ethical issues in Medical genetics. WHO, Geneva 1998.

Shapiro, Barry I. "Livestock Master Plan (LMP): Roadmaps for the Ethiopia Growth and Transformation Plan (GTP II—2015-2020)." (2015).

Standard Operating Procedures for Research Ethics Committees, 2018. UK Health Departments Research Ethics Service

The Royal Academy of Engineering, “Engineering ethics in practice: a guide for engineers”, accessed on March 4 and available at <https://www.raeng.org.uk/publications/other/engineering-ethics-in-practice-full>

The Norwegian National Research Ethics Committees, “Guidelines for Research Ethics in the Social Sciences, Humanities, Law and Theology”, 4th edition – June 2016, ISBN: 978-82-7682-077-5

The Constitution of the Federal Democratic Republic of Ethiopia. Addis Ababa, August 21 1995.

The Belmont Report. Ethical Principles and Guidelines for the Protection of Human Subjects of Research. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. April 18, 1979.

The Constitution of The Federal Democratic Republic of Ethiopia. Addis Ababa, August 21 1995.

The Ecosystem Services for Poverty Alleviation (ESPA), The Ethics Review Procedure

The Ethics of Research in Protected and other Environmentally Sensitive Areas, 1999, Article in Marine Pollution Bulletin.

Uganda National Council for Science and Technology, 2007. National Guidelines for Research involving Humans as Research Participants. Kampala – Uganda: UNCST.

WHO Library Cataloguing-in-Publication Data Research ethics committees: basic concepts for capacity-building

World Commission on the Ethics of Scientific Knowledge and Technology, 2009 The Teaching of Environmental Ethics

World Medical Association Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. Adopted by the 18th WMA General Assembly. Helsinki, Finland, June 1964, and amendments in 1975, 1983, 1989, 1996, 2000. Note of Clarification on Paragraph 29 added in 2002. Note of Clarification on Paragraph 30 added in 2008.

1. For funded research or projects, the term principal investigator is more appropriate while supervisor (adviser) is for academic research by graduate students. [↑](#footnote-ref-1)