

**Tribhuvan University**

# **Ethical Review Guidelines**



**Ethical Review Board/Committee**

**Tribhuvan University**

**Kirtipur, Kathmandu**

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# **Tribhuvan University**

## **Ethical Review Guidelines**

### **I. Introduction**

Tribhuvan University (TU) embraces ethics as the core component of research. At the same time, TU is committed to promoting good research practice by maintaining ethical standards and strengthening research integrity through training and ethical review of the research activities carried out under the TU constituents. This research ethics review policy sets the principles of ethical conduct that are expected of all research students, faculty members and staff and elaborates on how they are put into practice. This document informs researchers about how to maintain research integrity and minimize mental, physical, legal, and financial risks for research participants, or anyone associated with the research. The guideline will also address the need for ethical approaches for different disciplines ranging from social sciences to biological, physical, environmental, and medical sciences, at multiple levels from local to global, in ways that are respectful of all partners, participants and affected parties in a different environmental and socio-cultural context, on issues that are dynamic, often contested and sometimes sensitive.

It applies to all academic subjects/disciplines and programs of TU. Everyone including visiting professors and researchers who are planning to conduct research at TU, whether within or outside the university premises or facilities or in different parts of the country must follow this policy and guidelines. An appropriate level of ethical approval must be secured from the concerned research ethics review committee of TU by the principal researcher before conducting any research. These guidelines are designed in line with the other research ethical guidelines including Nepal Health Research Council (NHRC), and it does not duplicate or overlap with the functions of the NHRC and other similar systems. The university is responsible for ensuring that its research is conducted in line with principles of research ethics and legal as well as regulatory requirements. All researchers including teachers, visiting researchers, Masters, Master of Philosophy (M.Phil.) and

Doctoral students as well as staff of the university are required to conduct their research work with principles and procedures of research ethics that are set in this policy.

## **II. Purpose**

The purpose of this research ethics review is to safeguard the dignity, respect, independence, rights and freedom of the participants involved in the research and ensure the integrity, transparency and honesty in the research.

## **III. Objectives**

The main objectives of this policy are to:

- a) Defend the physical, social, mental and emotional well-being of the individuals involved in the research work and defend the values of human beings, other organisms and the environment.
- b) Safeguard the freedom and rights of the individuals involved in the research carried out by TU teachers, students and staff.
- c) Assess the risks and benefits of the proposed research and suggest strategies to minimize the risks so that the research addresses the equity fairness.
- d) Ensure the confidentiality of the information and response received from the research participants.
- e) Ensure that participants are pre-informed about the research in detail using the appropriate measures and the required consent is received from them.
- f) Coordinate between the researcher and the research-related governing bodies to facilitate research processes.
- a) Foster the culture of ethical research in TU, and promote these values in the high-level research carried out by TU.

## **IV: Guiding Principles**

The review shall be guided by the following principles:

#### **4.1. Principle of Respect**

Every individual shall be given their right to make their independent decision by treating them as unique individuals with due respect to their culture and value system. Anonymity and confidentiality have to be maintained throughout the research process and beyond. Obtaining informed consent and ensuring voluntary participation of individuals ensuring the right to withdraw at any point of time are must for the research work. Research participants' safety and protection must be ensured without coercing and deceiving them at any point.

#### **4.2. Principle of Beneficence**

Research activity should not harm individuals, society and the environment. Maximizing the benefits and minimizing the potential risks and harm should be the core principle of the research. It should not disturb social harmony and community relationships.

#### **4.3. Principle of Justice**

Researchers should ensure fairness and follow the equity principle in the distribution of benefits and risks to all the participants. They should neither exploit the region/community/people from the vulnerable groups, nor exclude or discriminate against from the research without justifiable scientific reason(s). Vulnerable groups and marginalized communities should not be systematically ignored merely as a matter of convenience.

#### **4.4. Respect for the Environment**

Environmental awareness and responsibility to protect the environment should be one of the key principles of research. The environment might include biophysical, socio-economic, cultural, natural, historical components. The principle of no-harm-to-environment should be strictly maintained throughout the research.

#### **4.5. Principle of Integrity**

The research should respect integrity and maintain trustworthiness. Any kind of fabrication, falsification, plagiarism, unethical academic behaviors and deceptive practices shall not be tolerated.

#### **4.6. Principle of Responsibility, Transparency and Accountability**

The responsible conduct of the research should maintain transparency and accountability both in the research process and the outcomes right from the inception of the research to the dissemination of findings. Role clarity and disclosure of the research plan, database, results and publications

should be made explicit. Conflict of Interest (CoI), if any, should be disclosed. Research should be conducted in an unbiased, honest, ethical, justifiable and transparent way to assure accountability.

## **V. Review Types**

The ethical review shall follow three routes; exempted review, expedited review and full review.

### **5.1. Exempted Review**

Research with no risks to the participants may qualify for the exempted review. Examples of the exempted reviews might include systematic reviews and meta-analyses, research using the published secondary data, and research being conducted in natural and commonly accepted educational settings. The ethical review board/committee shall decide whether the research falls under the category of the exempted review.

### **5.2. Expedited Review**

Research that involves low or minimal risks and does not involve any vulnerable populations may qualify for the expedited review. Non-invasive research, studies that do not require biological samples, descriptive studies, observational studies, and research based on unpublished secondary data might fall under this category.

### **5.3. Full Review**

A full review shall be carried out for the research that include vulnerable and disadvantaged population, minors, procedures that might cause physical and mental harms, invasive research, research that requires biological samples, experimental research, action research, collaborative research, archival resource-based research, and any other research that do not fall under the category of exempted and expedited research.

## **VI. Risk and Harms**

Risks and harms in research are categorized as no risk, low risk and high risk.

### **6.1. No Risk**

Instances with no foreseeable risk of harm or discomfort to the participants are included under the no risk category.

## **6.2. Low Risk**

If the risk is very minimum to the researcher, participants, environment, socio-economic, cultural and educational settings, and there is a moderate amount of discomfort, they are included under the low risk category.

## **6.3. High Risk**

The high risk research category includes all other studies with the possibility of severe harm to the psychological, physical, and socio-economic condition of the individuals and harm to the community, environment and national interest. Similarly, research carried out on socio-economic, geo-political and culturally sensitive issues that may affect social harmony are subject to high risk.

## **VII. Informed Consent**

It is the right of a research participant to be informed about the research and the research process. Researcher must obtain informed consent from all the participants involved in the study and this must be ensured in the research process. Such a consent must be obtained as per the template attached in the appendix.

A detailed description of how consent will be obtained should be mentioned in the proposal. It should include the process of obtaining informed consent, the individual responsible for obtaining the informed consent, the mode of communication about the research, and strategies to get consent from the vulnerable population, such as children, elderly, disabled, and prison population. It should clearly inform research participants about the risks and benefits and provision for participants to ask questions and file complaints during the research if required.

Consent document should include

- a) the **information sheet** that includes information of the research, research procedures, risks, benefits, what the research participant should be aware of in making their decision; and
- b) the **informed consent form** indicating that the research participant has agreed to voluntarily participate. Language of the consent form should be in the local language or the language that the research participants can understand.

All the consent forms used in the research need to be duly signed by the participants. In case of the minors and vulnerable population, the consent form should be signed by the parents/legal guardians or caretakers. If the children are participating in the study, their assent and parents' consent should be secured. If the research participant is unable to decide and sign the consent form, an eyewitness must sign on the consent form.

Electronic informed consent (E-consent) could be used in case of online/telephonic research and when participants need to be approached remotely and difficult to reach physically. Such an e-consent could be received by email or on website with digital signature.

Approval of the gatekeepers that include the institutions, local governments, community organizations and establishments is required before approaching the field for data collection and this will be done during the research process should be submitted to the ERB/ERC.

## **VIII. Institutional Arrangement**

There are two levels within the TU system for the ethical review of the research: Ethical Review Board (ERB) and Ethical Review Committee (ERC).

### **8.1. Ethical Review Board**

ERB is established at the Research Directorate of TU, Office of the Rector, consisting of seven members appointed by the TU Executive Council. The board is responsible to review the research that addresses the national priority areas, innovative and excellence research grants, national and international collaborative research and any research with the total budget exceeding Rs. 5,000,000/- (five million rupees). ERB will also review all the research grants administered by the Research Directorate and the Research Centers of TU.

### **8.2. Ethical Review Committee**

ERCs are established in each Office of the Deans of TU. The committee consists of five to seven members appointed by the respective Dean. The committee is responsible to review research proposals other than those specified in Article 8.1. Additionally, the committee shall review all the research work of M. Phil. and Ph.D. research, mini-research, faculty research and institutional research implemented by the respective Dean's Office and any other research with the total budget

less than Rs. 5,000,000/- (five million rupees) under the jurisdiction of the Dean's Office. The committee shall also review the proposals submitted by the students of bachelors and masters programs.

## **IX. Roles and Responsibilities of ERB and ERCs**

### **9.1. Responsibilities of ERB**

The main aim of ERB is to review and evaluate research proposals to ensure ethical research practices. It also acts as an advisory body to the Research Coordination and Development Council (RCDC) of TU. The board is chiefly responsible on matters related to research ethics and integrity that include;

- Ensuring the appropriateness and effectiveness of the research process with reference to the ethical approval mechanisms for research;
- Reviewing and, if necessary, recommending revisions to the research proposal to ensure ethical standards;
- Granting ethical approval of the research proposals after the review process.
- Advising on policy issues related to research ethics as determined and requested by the Research Committee;
- Advising on policy issues related to research integrity as determined and requested by the Research Committee;
- Maintaining records and documenting research activities for future reference;
- Building capacity of reviewers, researchers and staff of the university on research ethics.
- Monitoring of the approved research to maintain ethical standards.
- Review and update the existing ethical guidelines and review process.
- Ensure consistency and uniformity of the ethical review process of the ERC.
- Coordinate with the other research bodies, agencies and councils, including NHRC for health related research, if needed.

### **9.2. Responsibilities of ERCs**

The main aim of ERCs is to review and evaluate the research proposal and monitor the research activities of the students, teachers and staff under the Dean's office as stated in the research ethics guidelines. The committee is chiefly responsible for;

- Ensuring the appropriateness and effectiveness of the research process with reference to the ethical approval mechanisms for research;
- Reviewing and, if necessary, recommending revisions on the research proposal to ensure ethical standards;
- Granting ethical approval of the research proposals after the review process.
- Advising on policy issues related to research ethics as determined and requested by the Research Committee;
- Advising on policy issues related to research integrity as determined and requested by the Research Committee;
- Maintaining records and documenting research activities for future reference;
- Building capacity of reviewers, researchers and staff of the university on research ethics.
- Monitoring of the approved research to maintain ethical standards.
- Delegating authority to the concerned central departments, programs, research management cells and campuses to assess the ethical issues and recommend for ethical approval to the ERC.
- Reporting the status of approved research proposals to the ERB on quarterly basis.

#### **X. Responsibilities of Institutions (Campuses, Departments, Schools)**

All institutions of TU that include the campuses, central departments, departments, schools, programs and centers are responsible to maintain and promote ethical conduct of the research by following Ethical Review Guidelines of Tribhuvan University. For this, they should disseminate this Ethical Review Guidelines to their faculty, students and staff. All the research proposals developed by their students, faculty members and staff need to be reviewed locally to make sure that ethical standards are maintained and then they should be recommended to the ERB/ERC for ethical approval, if necessary. They should also sensitize the community to promote ethical culture of research in their respective institutions.

## **XI. Supervisor's Responsibilities**

It is the responsibility of all thesis/dissertation supervisors to ensure the ethical conduct of the research by informing their researchers about the ethical conduct and advising them to ensure research ethics in their research.

## **XII. Researcher's Responsibilities**

Researchers should ensure that their research adheres the principles and follows the ERC ethical guidelines with full honesty and integrity. No researcher should engage, personally or professionally, in discriminatory, harmful or exploitative practices, or any perceived form of harassment. Nor should the researcher impose views/beliefs on or try to seek personal, sexual or economic gain from anybody, including other researchers, juniors, assistants, trainees and students. In case of collaborative research, the principal researcher is responsible for obtaining ethical approval of the research. All individuals involved in the research are responsible for ethical conduct and observance of ethical guidelines.

## **XIII. Time Frame for the Review of Proposals by ERB/ERC**

The initial screening is done on the first day of the receipt of the proposal to ensure that all the documentation has been submitted. A more detailed technical screening at the Secretariat level is carried out within 15 working days.

### **13.1. Expedited review**

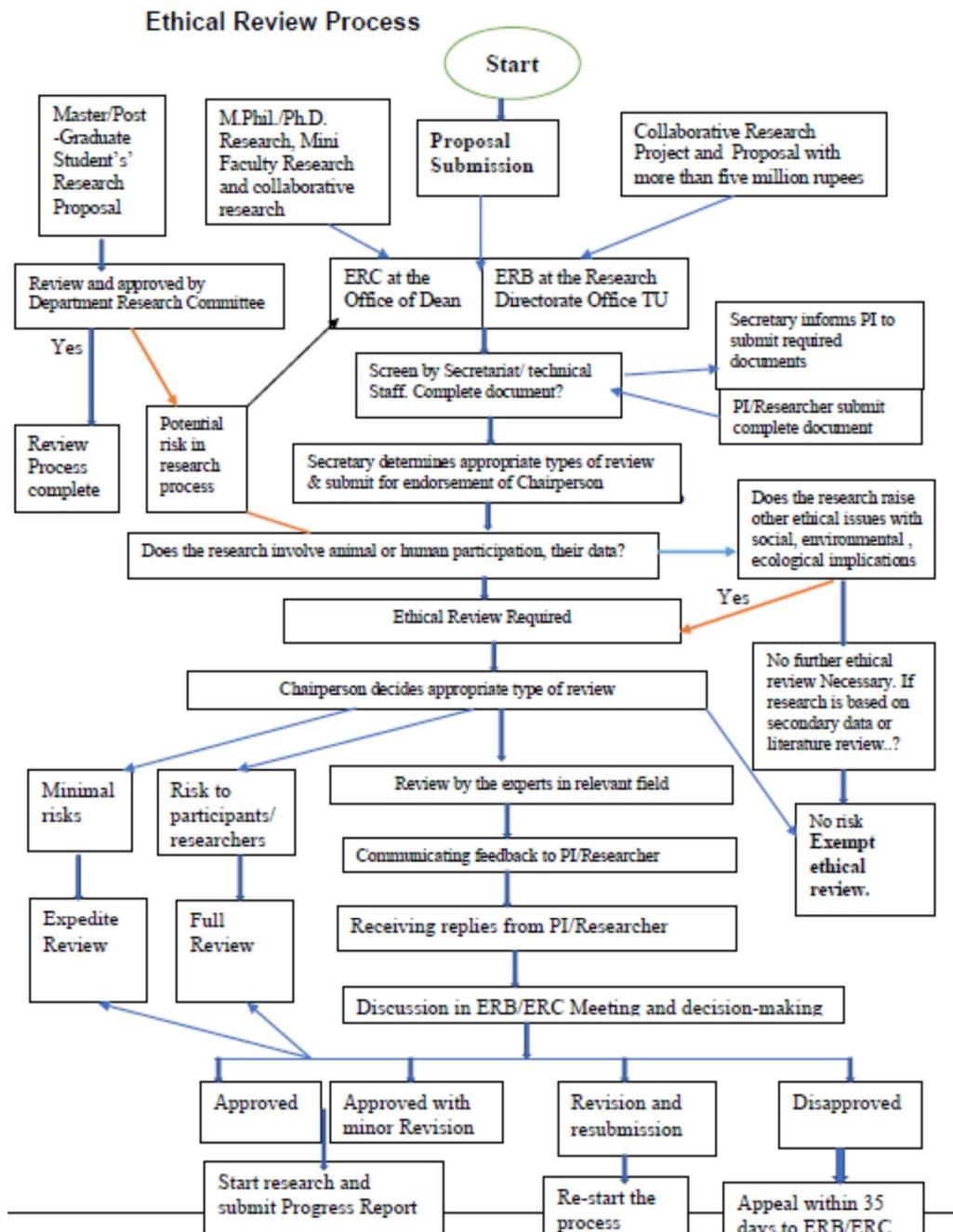
A proposal submitted for the expedited review with adequate reasons is reviewed within 21 days. The ERB/ERC will make the decision on the proposal within a month of the initial submission.

### **13.2. Full review**

The full ethical review of the proposal will be completed within three months. The length of time for approval of regular reviews depends on the promptness of the response from the responsible officers, reviewers and the researcher's response.

#### **XIV. Ethical Review Process**

Recipients of the research grants provided by the Research Directorate of TU including national and international collaborative research must apply to ERB for ethical approval. Individual researchers and institutes with the total research budget less than Rs. 5,000,000/- should apply to the respective ERCs of the Deans' Office. Ph.D. research proposals approved by the respective research committees of the Dean's office must be submitted to the ERC for ethical approval. M. Phil., Masters and Bachelor level research proposals recommended by the respective research committees/RMCs shall be reviewed by the ERC, if necessary. Applications to ERB/C should provide sufficient information for an ethical judgment to be reached by the Board/Committee.



### 14.1 Submission of the Application

Individuals or an institution planning to conduct research in their Department, Campus, Schools, Faculties/Institutes and Research Centers of Tribhuvan University are required to submit their research proposal to the ERB/ERC for ethical review. The Principal Investigator (PI) and/or the one responsible for the proposed research will submit the full research proposal for review. The proposal must include the key components of the research that include:

- 1) The title of the research
- 2) Summary of the research proposal
- 3) Background/context of the research
- 4) Aims/objectives/research questions/hypothesis
- 5) Review/conceptual/theoretical framework
- 6) Methodology/Methods/Materials: approach, design, sample/research participants, method of data collection, data analysis procedure
- 7) Data management and storage
- 8) Expected outcomes of the research
- 9) Ethical considerations (risks, benefits, consent taking, approval, etc.)
- 10) Research plan and budget

Other documents that should be submitted with the application are as follows:

- 1) Information sheet and informed consent form
- 2) Declaration of conflicting interests
- 3) Research instruments
- 4) Approval letter
- 5) MoU/agreement, in case of collaborative research grants and sponsored/funded research
- 6) License/permission to use copy-righted research tools
- 7) CVs of the principal investigator and co-investigators

The application form should be submitted with the signature and date of submission.

#### **14.2. Application Requirements**

The application requirements are as follows:

- i. Cover letter: A cover letter addressing the Chair of ERB/C
- ii. Application format: Applications should be submitted in the format provided by ERB/C. The prescribed format can be accessed from the TU website or a hard copy can be obtained from ERB/C office.
- iii. Language: All Applications should be submitted in English except the research proposals of the Nepali language and Nepali literature.
- iv. Applications must include the recent curriculum vitae of the principal investigator and co-investigators along with their academic qualifications and research experiences.

- v. The application should include one hard copy and an electronic copy of the research proposal.
- vi. A copy of informed consent form with information sheet should be included in the application. In addition, this can include a translation copy, in a local language. The form should also include a detailed description of the process of giving the information to the research participant and its content, process of obtaining the consent, the person responsible for obtaining the informed consent and documentation of the signature of the researcher/research participant and /witness if applicable.
- vii. Any compensation to be given to the research participant should be clearly mentioned. (e.g. any transportation costs, food, free health care or insurance coverage etc. that is to be borne by the researcher)
- viii. In case of clinical trials, description about the study design, the trial phase, and a detailed description of the safety of the product or procedures must be mentioned. It should include the pharmacological, pharmaceutical, and toxicological data available and also include the investigators brochure.
- ix. A declaration of the conflict of interest, if applicable, should be mentioned in the application.
- x. Application fee: Applications should be submitted along with a processing fee of Rs. 2,000/- (two thousand rupees). After the proposal is approved, the applicant should pay 1% of the total research budget to TU. Likewise, the processing fee is Rs. 2,000/- (two thousand rupees) for Ph.D. and Rs. 1,000/- (one thousand rupees) for M. Phil., Masters and Bachelors level research proposals.

Only those applications fulfilling these requirements will be accepted for review. Deficits in the application shall be informed to the applicants within one weeks of submission. Incomplete applications will have to be resubmitted. ERB/C can request the applicant for supplementary documents/or changes to the proposal during the review which will be communicated to the applicant and the application will be considered in the subsequent meeting after those changes are made by the researcher.

### **14.3. Screening of Submitted Proposal**

The secretariat will initially screen the submitted documents and ensure that all the required documents are included in the designated formats. The application will then be forwarded to the review Board/Committee for further processing.

### **14.4. Review of the Proposal**

Consistency should be maintained among the various components of the research proposal such as research topic, objectives, methodology and expected outcomes. An ethical review of the proposal encompasses the following aspects:

- 1) Research design, approach, conduct and procedures
- 2) Population and sample selection criteria (inclusion/exclusion) and sampling strategies
- 3) Approach, methods, and tools
- 4) Data management, protection, safety and analysis plan
- 5) Potential risk assessment and mitigation strategies
- 6) Measures to ensure confidentiality and privacy of the research participants
- 7) Description about who has access to data including biological samples
- 8) Plan for the dissemination of findings or publication of research results
- 9) Infrastructure and other facilities in the institutions conducting the research, as relevant
- 10) Plan to share the research outcomes to the community/stakeholders

### **14.5. Communicating Feedback to PI/Researcher**

The Board/Committee will compile the feedback from the reviewers and communicate it to the researcher with the deadline for the amendment in the application.

### **14.6. Amendments/Revision of Research Proposal**

If any amendments are recommended by ERB/C, the PI/Researchers will make the necessary amendments/revisions and submit the revised proposal to the ERB/C secretariat. The proposal will be reviewed again in ERB/C, taking the amendments into consideration for the approval process.

### **14.7. Meeting of the ERB/ERC**

Generally, ERB/ERC meetings take place on a monthly basis. The Member-Secretary of ERB/ERC with the permission of the Chairman will call the meeting as per necessity. In case of the ERC, Assistant Dean responsible for the research will work as a Member-Secretary.

The followings conditions are considered as applicable for an ERB/C meeting:

- The Secretariat of ERB/C will plan the meeting in accordance with the workloads and number of proposals received for review.
- ERB/C members will be informed about the meeting at least 72 hours prior to the scheduled date.
- If felt necessary by the ERB/C, the applicant researcher can be invited to present the proposal or elaborate on specific issues of the proposal. Similarly, if necessary, experts can also be invited to the meeting for expert opinion about the research.
- Minutes will be kept of all decisions and procedures of the meeting.
- All the members and invitees present in the meeting should sign the minutes to indicate their presence.

#### **14.8. Decision Making**

Based on the recommendations made by the proposal reviewers, ERB/C will make a decision about the research proposal and provide the ethical approval letter. In case of negative decisions, ERB/C will provide reasons for rejection and provide feedback for re-submission. For the purpose of grant application, a provisional ethical approval letter can be issued on the condition that all the requirements are met before implementing the research.

As per the decision of the meeting, The ERB/C may give any one of the following recommendations on a proposal:

1. Approved as submitted: The proposal can be accepted as submitted and no modifications are required.
2. Approved conditionally: The proposal requires amendments and/or clarifications
3. Not approved: The proposal requires additional information and/or rewriting

#### **14.9. Communicating a Decision**

The Member Secretary of ERB/ERC will communicate its decision to the applicant in writing within two weeks after the meeting. The communication of the decision will include, but is not limited to the following information:

- 1) The title of the research proposal reviewed, sites of the research, date of the decisions, any suggestions made for the improvement of the proposal and the decisions made.

- 2) In the case of conditional decision, any requirements asked by the board, including suggestions for revision and the procedures for having the application re-reviewed.
- 3) In the case of a positive decision, the applicants will be informed with the following information:
  - i. A statement of the responsibilities of the applicant
  - ii. Confirmation of the acceptance of any requirements imposed by the ERB/ERC
  - iii. Deadlines for the submission of progress report(s)
  - iv. The need to notify the ERB/ERC in cases of protocol amendments (other than amendments involving only logistical or administrative aspects of the study)
  - v. The need to notify the ERCB/ERC in the case of amendments to the recruitment material, the potential research participant information, or the informed consent form
  - vi. The need to report serious and unexpected adverse events related to the conduct of the study
  - vii. The need to report unforeseen circumstances, the termination of the study, or significant decisions by other Ethical Committees
  - viii. The information the ERB/ERC expects to receive in order to perform ongoing review and deadlines for the submission of final report
  - ix. The schedule/plan of ongoing monitoring by the ERB/ERC
- 4) In the case of a negative decision, clearly stated reason(s) for the negative decision should be stated.
- 5) The decision letter should be signed by the Secretary (or other Authorized person) of the ERB/ERC and dated.

#### **14.10. Follow up of the ERB/ERC**

ERB/ERC may conduct follow-up monitoring during the research for the approved research proposals. Decisions of a follow-up review will be issued and communicated to the applicant, indicating a modification, suspension, or termination of the ERB/ERC's original decision or confirmation that the decision is still valid. The ERB/ERC can issue an approval letter for publication as per the need.

In case of any misconduct observed during the research, the PI/Researcher will be given suggestions for correction. In case the misconducts are not corrected, a warning will be issued and this might result into the termination of the approval.

## **XV. Documentation and Archiving**

All the documents received and prepared during the ERB/ERC will be dated, filed, and archived both in hard copy and in digital format. Research proposals, review related documents, decisions made, all the expenditures made during the process, meeting documents including the minutes, all the documents received from the researchers, reviewers comments and communications made at various levels will be achieved.

Documents that should be filed and archived include

- 1) The curriculum vitae of all ERB/ERC members
- 2) A record of all income and expenses of the ERB/ERC, including allowances and reimbursements made to the secretariat and IRC members.
- 3) The agenda of the ERB/ERC meetings
- 4) The minutes of the ERB/ERC meetings
- 5) All materials submitted by an applicant
- 6) All the agreements signed including the budget
- 7) The correspondence by ERB/ERC's Secretary and members with applicants or concerned parties regarding application, decision, and follow-up.
- 8) Ethical approval or non-approval or pending or in process with date
- 9) Approval or non-approval of any changes to the protocol
- 10) The terms and conditions, if any, of approval of any protocol
- 11) A copy of the decision and any advice or requirements sent to an applicant.
- 12) All written documentation received during the follow-up.
- 13) The notification of the completion, premature suspension, or premature termination of a study.
- 14) The final summary or final report of the study
- 15) Actions to be taken by the ERB/ERC to monitor/supervise the research

## **Appendix A: Template for the information sheet**

**Title of the Study:** .....

### **Principle Investigator**

[Name]

[Department]                      [Address]

[Phone]                              [Email]

**Name of Researcher:**

### **The Introductory Paragraph**

(Mention why you are doing this research, how you will do it and the contributions of the study. Also, mention that participation is voluntary and participants can ask questions and may withdraw at any time if they do not want to continue with the research)

### **Research Purpose**

(Mention the specific purpose of the research that you are doing)

### **Duration**

(Mention the duration of the research and the time that you expect from the different research participants)

### **Study Procedures**

(Elaborate how the research participants will be involved in the research and what kind of information you would like to receive from them)

### **Discomforts and Risks**

(Mention any potential risk or discomforts that are likely to arise from study procedures)

### **Potential Benefits**

(Explain the type of benefit the individuals, community and the society will receive during the research, if any)

### **Compensation**

(If you plan to give some compensation such as money, gifts, stationery items or anything, please mention them)

### **Confidentiality**

(Mention that all the private information obtained from the participants and their personal identity will be kept confidential. Also mention how you will do this)

**Voluntary Participation and Withdrawal from the Study**

(Mention that participation in your research is voluntary and they have their rights to refuse to answer any questions, if they decide to do so)

**Contact Information**

(Provide the contact details (phone number/email) of the research team and mention that participants can contact for emergency in the given contact details at any time during the study)

**Appendix: B: Consent Form**

[This section is mandatory]

I have read the information of this research, or it has been read to me and I understood it. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I understand that I will be given a copy of this form, and the researcher will keep another copy on file. I consent voluntarily to be a participant in this study.

Name of the Participant: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

[This section is mandatory]

Name of the Researcher : \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

If the participant cannot sign, a person selected by the participants and who can sign should sign it.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness : \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_