

Ethiopian Health Research Ethics Application and Review Process

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Introduction

Health research involving human participants requires the application of ethical principles (autonomy, beneficence and justice) during and after the completion of a study or project. The purpose of ethical consideration in health research is to protect research participants from injury, disability and to ensure human respect and autonomy to be realized through out the study lifetime and thereafter. To this effect, internationally recognized code of ethics, declarations and guideline were formulated since late forties and institutional review boards (IRB) or ethical review committees were organized to review research protocols.

In Ethiopia, the National Health Science and Technology Council was established to advise the Ethiopian Science and Technology Commission on health, science and technology issues, research and development in particular. The Council has different standing committees of which the National Health Research Ethics Review Committee (NERC) is one. NERC is mandated to review research protocols based on its guidelines and report to the council all its activities three or four times per year.

Although NERC functions at the national level, regional and institutional ethics review committees are being organized. To this effect, capacity building in research ethics to researchers and reviewers are given due attention. According to the revised guidelines, the following procedures are currently utilized.

1. Application

All applications for review of research protocols are submitted primarily to either institutional or regional ethics review committees (IERC/RERC) depending on the location of the research site.

IERC/RERC shall give final official approval for projects stated under their mandates. However, if an applicant has complaint(s) against the decision of IERC/RERC, the project shall be considered by NERC.

IERC or wherever appropriate the RERC shall also review projects stated under NERC's mandates, and send the projects with recommendations and remarks to the NERC for final approval.

Secretariat/Health Department of ESTC receives applications from IERC/RERC for final ethical approval of projects stated under NERC's mandates.

Upon receipts of complete application, preliminary screening is done by the Secretariat. Proposals with all necessary documents shall be forwarded to NERC members for **individual ethics review**. Each member of NERC does review the protocol independently and come up with her/his views and comments to the meeting called for review.

2. Review

NERC ensures that its terms of reference regarding frequency of meetings, decision-making procedures and communicating decisions, follow-up and monitoring, documenting and archiving, etc. known by all users.

Documents and information that reach the National Ethical Review Committee are confidential.

Special attention is given when clearing proposals involving vulnerable groups such as children, pregnant women, mentally disabled, subordinates, prisoners, communities unfamiliar with clinical concepts, etc. NERC ensures that projects sponsored by external donors obtain ethical approval from the initiating country (ies).

The primary task of NERC is reviewing the proposals and supporting documents by giving emphasis to the principles of Beneficence, Justice and Respect to persons. Generally, the following fundamental ethics principles are given serious attention:

- a) The appropriateness of the study design in relation to the objective of the study.
- b) The justification of predictable risks and inconveniences weighed against anticipated benefits
- c) The adequacy of provisions made for monitoring and auditing the conduct of the research.
- d) Safety procedures if drugs, vaccines and other biological products are administered, establishing data safety and monitoring committee (DSMC).
- e) How the study participants are selected without discrimination
- f) Full details of the informed consent process
- g) The suitability of the investigator(s)'s qualifications and experience for the proposed study.
- h) The measures taken to ensure confidentiality.
- i) Signatures of all investigators will be checked.

These and few additional points are prepared in a checklist (form) so that each reviewer would note to these while reviewing. She/he would be required to come up with the following options for each important item inclusion or presence as: a) yes b) no c) requires revision d) not applicable in this particular study

3. Decisions

After in depth deliberation on the protocol, the National Ethics Review Committee (NERC) may reach at the following decisions:

- i. **Approved:** if a project fulfils all requirements as stipulated in this guideline or
- ii. **Approved on conditions:** if a project does need meet certain requirements of not major ethical issues to be fulfilled.
- iii. **Not Approved:** if a project is found unethical.

4. Follow up

- 4.1. The first ethical approval is valid only for one year. Renewal application thereafter is possible.

4.2 Any change and amendment in the protocol is subject for renewal application. This further needs approval by NERC. Commencing health research without obtaining approval is unethical.

4.3 Investigators are obliged to report all adverse events to the secretariat (NERC) and DSMC.

If investigators decide to prematurely suspend or terminate a study, the Secretariat (NERC) should be notified with a document that include justification (reasons) and summaries of results obtained.