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Department of Research Development

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TERMS OF REFERENCE (TORs) ERC SMBBIT

STANDARD 1: RESPONSIBILITY FOR ESTABLISHING THE RESEARCH ETHICS REVIEW SYSTEM

Senior doctors, sociologists, researchers and administration at the SMBBIT will ensure that ERC will adhere to the legal framework set forth in the WHO guidelines adapted from "Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants"

All research with human participants will be subject to ERC oversight.

Mechanisms must be developed to ensure that ERCs activities are coordinated with national regulatory authorities as well as with national and/or international clinical trial registries.

Mechanisms must be in place for obtaining community input into the ethics review system when required.

Types of research studies ERC may review different types of research studies, including clinical, epidemiological, social science research.

STANDARD 2: COMPOSITION OF RESEARCH ETHICS COMMITTEES

Ensure that ERC has a multidisciplinary membership with an understanding of the social and cultural diversity of the communities from which research participants are most likely to be drawn. Our ERC committee endeavors to have membership comprising of consultants, surgeons, public health specialist, epidemiologist, lawyer and a representation from civil society. The members will be retained by the committee for two years and consent from them will be taken to be onboard with the committee for the stated amount of time.

STANDARD 3: RESEARCH ETHICS COMMITTEE RESOURCES

SMBBIT administration is supportive to ERC and has 2 research officers on board, a spacious seminar room with multimedia facilities, and provision of stationary and other office supplies. ERC members will contribute to the committee on a voluntary basis.

STANDARD 4: INDEPENDENCE OF RESEARCH ETHICS COMMITTEES

ERC members (including the Chair) will remove themselves from the review of any research in which they or close family members have a conflicting interest.

ERC membership will include at least one person from outside SMBBIT.

Researchers may attend an ERC meeting to answer questions about their research protocols but they cannot be present when the ERC reaches decisions about their proposed research.

The director or CEO of SMBBIT should not serve as member or Chair of the ERC as this can lead to conflict of interest.

In order to protect ERC members from retaliation based on positions taken with respect to ERC-related matters or review of research projects, the following safeguards should be instituted:

- Disgruntled researcher will be encouraged to send an email to the committee regarding his/her grievances and it will be entertained as soon as possible and efforts will be done to resolve the issue.
- Request the researcher for additional literature to support his/her study proposal.
- Request an independent opinion from an outside institution who is an expert on the subject under review.
- Schedule second review with ERC as soon as possible, if study proposal is still under consideration.
- Employ strict disciplinary action in case of malice or harm to an ERC member

STANDARD 5: TRAINING THE RESEARCH ETHICS COMMITTEE

Training on the ethical aspects of health-related research must be conducted on a regular basis throughout the year. Some of the recommended online resources are listed below, and ERC members are required to complete these initial modules within 6 months of becoming members. These mandatory courses are:

https://bioethicsresearchreview.tghn.org/elearning/
https://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/

Other highly recommended courses include:

https://about.citiprogram.org/en/series/bioethics/

STANDARD 6: TRANSPARENCY, ACCOUNTABILITY, AND QUALITY OF THE RESEARCH ETHICS COMMITTEE

Mechanisms must exist to make ERC operations transparent, accountable, consistent, and of high quality.

Yearly internal (within SMBBIT) audits to be conducted by knowledgeable and unbiased people in administration or faculty regarding:

- Maintenance of confidentiality of data by ERC members
- Number or proposals received, reviewed and approved by ERC.
- Review of complaints against ERC.
- Review of the minutes to assess:
    - Attendance of members.
    - Contribution of members to the meetings.
- Training and educational activities of the members.

External audits should be conducted every 3 to 5 years or earlier if internal audits are not satisfactory. These audits should be conducted using a pre-defined format

ERC decisions, excluding confidential information, are made publicly available, through mechanisms such as clinical trial registries, web sites, newsletters, and bulletin boards, when feasible.

STANDARD 7: ETHICAL BASIS FOR DECISION-MAKING IN RESEARCH ETHICS COMMITTEES

ERC must make clear the specific ethical guidelines on which its decisions were made and the rationale for either rejection or approval must be readily available to researchers and the public. These decisions will be communicated through emails to the corresponding researcher.

Scientific design and conduct of the study

Research is ethically acceptable only if it relies on valid scientific methods. Research that is not scientifically valid exposes research participants or their communities to risks of harm without any possibility of benefit.

Therefore, scientific community must be established that will review the scientific aspects of the proposal. Those proposals that are approved by SRC, will be forwarded to ERC, preferably within 1 month time from when proposal received by ERC.

ERC will then further evaluate the ethical implications of the chosen research design or strategy.

Risks and potential benefits

In ethically acceptable research, risks have been minimized (both by preventing potential harms and minimizing their negative impacts should they occur) and are reasonable in relation to the potential benefits of the study. The nature of the risks may differ according to the type of research to be conducted. REC members should be aware that risks may occur in different dimensions (e.g. physical, social, financial, or psychological), all of which require serious consideration. Further, harm may occur either at an individual level or at the family or population level.

Selection of study population and recruitment of research participants

Ethically acceptable research ensures that no group or class of persons bears more than its fair share of the burdens of participation in research. Similarly, no group should be deprived of its fair share of the benefits of research; these benefits include the direct benefits of participation (if any) as well as the new knowledge that the research is designed to yield. Thus, one question for research ethics review to consider is whether the population that will bear the risks of participating in the research is likely to benefit from the knowledge derived from the research. In addition, ethically acceptable research includes recruitment strategies that are balanced and objectively describe the purpose of the research, the risks and potential benefits of participating in the research, and other relevant details.

Inducements, financial benefits, and financial costs

It is considered ethically acceptable and appropriate to reimburse individuals, if funds are available, for any costs associated with participation in research, including transportation, child care, and lost wages or for time spent in research. However, payments or inducements should not be so large that prospective participants are tempted to consent to participate in the research against their own better judgment.

Protection of research participants' privacy and confidentiality

RECs should therefore examine the precautions taken to safeguard participants' privacy and confidentiality.

Informed consent process

ERC will review the consent form and examine the following:

- The process through which informed consent will occur, as well as the information that will be provided.
- That the Language is appropriate for the participants.
- Medical terminology is adequately explained based on the likely knowledge of the study participants.
- Research participants are competent to fully understand the consent and make informed decisions.
- Competent individuals are entitled to choose freely whether to participate in research, and that there is no hidden compulsion to do so.
- Decisions for children or adults who lack the mental capacity to provide informed consent should be made by an authorized surrogate decision-maker.

ERCs may waive the requirement of informed consent only when doing so is consistent with international guidelines and national standards.

Community considerations

ERC should ensure that, as far as possible, any negative effects on communities such as stigma or draining of local capacity, has been minimized.

STANDARD 8: DECISION-MAKING PROCEDURES FOR RESEARCH ETHICS COMMITTEES

During meetings of the REC, members engage in discussions to elicit all concerns and opinions related to the protocols and the associated documents under consideration. The Chair is responsible for the decision-making process, in particular for determining when consensus is needed to achieve the decision. Researchers, funders, or others directly associated with the protocol in question are not present during committee deliberations.

ERC members should recognize the limitations of their knowledge and seek external input when necessary.

Decisions are arrived at through a consensus. Consensus does not require that all ERC members support the decision, but that all members consider the decision at least acceptable and no member considers the decision unacceptable. Decision is communicated to the researcher through email.

STANDARD 9: WRITTEN POLICIES AND PROCEDURES

Written policies and procedures will specify:

Membership of the committee

ERC members will be required to serves tenure of at least two years, which may be staggered, allowing continuity of some members when other members are newly appointed.

Committee governance

The Chair is not a person who has a supervisory relationship toward other members of the committee.

Independent consultants

The ERC's policies and procedures define the circumstances under which an ERC may call upon independent consultants to provide special expertise.

Policy towards research Proposals from outside institutions

This involves specifying:

- At this stage of our ERC, which is in its infancy, we will not be providing ERC review for outside institutions. We will review this policy in two years.
- If an outside investigator wishes to conduct a study at the Trauma Institute, he/she will be obligated to include a co-principal investigator from the faculty from the Institute. ERC of the Trauma Institute will be required for outside investigators, even if they have approval from the ERC of their institution for that study
- International or national registry that wishes to include data from Trauma Institute will need to present their TORs to the SRC. It can be further referred to ERC, if deemed necessary.

Submissions, documents required for review, review procedures, and decision-making

The ERC must have developed and/or request the following documents:

- ERC form
- Consent form guidelines
- Signed form for permission to review medical records within institution
- Letter for permission to conduct study from concerned department if outside institution.

Policies must describe the requirements for submitting an application for review. This is as follows:

Submit proposal with above documents to Department of Research Development.

These proposals will be forwarded to members of Scientific Review Committee, which will meet on a monthly basis or less frequently, depending on the volume of proposals.

If approved by SRC, research proposals will be forwarded to ERC.

ERC meetings will be held on a monthly basis. The process for setting up meetings involves invitation through emails. These meetings will be held last Thursday of every month, unless gazette holidays or unavailability of the required quorum members. Emails will be used for circulating documents for the meetings, for inviting non-members of the ERC, approving the meeting minutes, and any related process issues.

Communicating a decision

Communicating the decisions taken by ERC will be accomplished within a maximum amount of one week.

Follow-up reviews and monitoring of proposed research

ERCs will follow up the progress of all approved studies—from the time that the approval decision is taken until the termination or completion of the research at a quarterly interval.

Documentation and archiving

All of the ERC's documentation and communication will be dated, filed, and archived electronically with back up files, all of which are password protected. Documents submitted by researchers will be kept in locked cabinets for hard copy files. ERC will ensure that it will maintain confidentiality

STANDARD 10: RESEARCHERS' RESPONSIBILITIES

Research is performed only by persons with scientific, clinical, or other relevant qualifications appropriate to the project, who are familiar with the ethical standards applicable to their research, who submit the necessary information to the ERC for review (including both the research protocol and disclosures of any conflicting interests), and who carry out the research in compliance with the requirements established by the REC.

Student applications are submitted under the responsibility of a qualified advisor / faculty member involved in the oversight of the student's work or in the student's name, co-signed by the qualified faculty supervisor.

Conduct of research

The research is conducted in compliance with the protocol approved by the ERC. No deviation or changes are made to the approved protocol or in following it, without prior approval of the ERC, except where immediate action is necessary to avoid harm to research participants. The ERC is informed of any changes at the research site that significantly affect the conduct of the trial, and/or reduce the protections or decrease the benefits provided or increase the risk to participants.

Safety reporting

All serious, unexpected adverse events related to the conduct of the study/study product or unanticipated problems involving risks of harm to the participants or others are promptly reported to the REC

Ongoing reporting and follow-up

The researcher submits written summaries of the research status to the ERC annually, or more frequently, if requested by the ERC. Researchers inform the ERC when a study is completed or prematurely suspended/terminated. In the case of the early suspension/termination by the researcher or sponsor, the researcher notifies the ERC of the reasons for suspension/termination.

Information to research participants

Researchers have a responsibility to keep the research participants and their communities informed of the progress of research by appropriate means, at suitable time-frames in simple and non-technical language.

Response to SRC and ERC feedback

The PI should respond to comments, reservations and recommendations within a 3 month period. If no reply is received by that time, the proposal will be set aside and placed on hold.

Outside Investigator

An outsider investigator/PI, who needs to conduct study in SMBBIT trauma center, needs to collaborate with faculty of SMBBIT trauma center.