MSI Ethics Review Committee
Member Terms of Reference (TOR)

MSI has established an Ethics Review Committee (ERC) to provide independent, thorough and expeditious reviews of all research conducted by MSI, or under its auspices, that involves human participants and/or draws on secondary data that carries personal identifiers. The aim of such review is to ensure that before any research is conducted by MSI, the formulated research protocol is ethically sound, and appropriately safeguards the dignity, rights, safety and well-being of all actual or potential research participants.

MSI’s ERC adheres to The Federal Wide Assurance, which is positioned as the highest set of global assurance standards and guidelines for the protection of human subjects within research. In compliance with the FWA, the ERC and MSI have agreed to be guided by the principles laid out within the World Medical Association’s Declaration of Helsinki; the Council for International Organisations of Medical Sciences International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS 2016)\(^1\); and The Common Rule. Recognising that as the nature and methods of research continuously evolve, so too do the associated risks. Consequently, MSI’s ERC draws its mandate from the following specific frameworks:

1. The Nuffield Council on Bioethics Report on ethics of research in healthcare within developing countries\(^2\). This report helps to operationalise the Helsinki Declaration and other frameworks, considering practical issues and challenges for research in low resource settings. It is particularly focused on those designing or conducting ‘externally sponsored’ research in the developing world, which is applicable to MSI;

2. The 2016 version of the CIOMS International Ethical Guidelines for Health-Related Research Involving Humans;

3. MSI’s ERC review of the principles and procedures of the following five IRB’s:
   a. NGO IRB’s: Medecins Sans Frontieres; Family Health International; and Population Council
   b. Academic institution IRB’s: John Hopkins University; and LSHTM; and
   c. The NHS

In compliance with Standard 4 of WHO’s Operating Guidelines for Ethics Committees (2000) and the Declaration of Helsinki, the ERC’s committee members are individual suppliers, whom are independent of the researcher, donor, and any other undue-influence by any individual or entity of whom could impact decision-making.

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ERC Member Deliverables

All committee members must commit to completing the following services for MSI. Failure to fulfil the above commitments may result in forfeit of ERC membership:

Agree to the following:

a. Review of new protocols submissions, resubmissions, amendments, and reports of adverse events, protocol deviations and violations, as requested by ERC Chair, to be completed by specified deadlines;

b. Attendance at scheduled monthly meetings by teleconferences, with a maximum of three (3) formal apologies/year;

c. Participation in additional non-review activities (e.g. global goods and training webinars), as requested by MSI or ERC Chair, to be completed by specified deadlines;

d. Attendance at all MSI ERC annual meetings in person or by teleconference;

e. Ensure accuracy of availability on shared calendar

f. Respond promptly to communications from the ERC Chair, Ethics Officer, and anyone else responsible timely management of workflow and deadlines.

ERC Member Specific Tasks and Objectives

1. Training

Upon commencement, and whenever requested, undertake ethics training including FHI training\(^3\), MSI ERC E-Learning Module training, etc. All training certificates of completion must be submitted to the Ethics Officer for record keeping.

2. Conflict of Interests

Committee members have an obligation to disclose to MSI and the ERC Chair any actual, potential, or perceived conflicts of interest that could arise from any protocol review or in any undertaking of other work as an ERC member. This includes but is not limited to:

- Personal involvement or participation in activities undertaken and/or the research to be reviewed;
- Financial, material, institutional, social or other interest or affiliation in activities to be undertaken and/or research to be reviewed; and/or
- Involvement or participation in competing activities and/or research.

Where it is deemed that the ERC member has a conflict of interest in a given research proposal, measures must be adopted to manage the conflict. Such measures may include but are not limited to:

- Exclusion from some or all of the ERC’s deliberations concerning the research to be reviewed; and/or
- Exclusion from all meetings and correspondence in relation to the research.

A record of disclosed conflicts and the chosen management strategy will be maintained by MSI.

\(^3\) FHI Training. [https://www.fhi360.org/sites/all/libraries/webpages/fhi-retc2/index.html](https://www.fhi360.org/sites/all/libraries/webpages/fhi-retc2/index.html)
3. **Protocol Reviews**

Committee members are expected to conduct reviews of research protocols put forward by MSI to ensure that the research is ethically sound, and safeguards the dignities, rights, safety and well-being of actual or potential research participants.

Dependent on the research protocol’s categorisation of risk (see below), the ERC Chair will either convene a small team of committee members to conduct the review, or, following an initial review conducted by the Lead and Second Reviewer (overseen by the Chair), the protocol will be put to the full committee for review at the ERC Live Meeting.

### 3.1 Review Classifications and Timeframes

Applications will be classified as requiring one of three types of review, depending on the magnitude, likelihood and type of risk involved. Risk classification determines the type of review, the reviewers and associated review timelines. Review classifications are detailed below:

#### 3.1.1 Full Review

**Criteria for Full Review:**

- Any study involving greater than minimal risk\(^4\) of harm to participants
- Or, if the study involves any of the following:
  - Administration of drugs, placebos or other substances to participants;
  - Involves taking or storing samples of tissue or bodily fluids;
  - Potential harm or repercussions due to disclosure of sensitive topics (e.g., coerced sex); or possible pain or discomfort to participants;
  - Protocols proposing verbal consent;
- Or, if the study involves participants from any of the following groups who will experience constraints on their capacity to give full informed consent:
  - MSI People (collectively referring to MSI employees, trainees, volunteers, MS Ladies, Social Franchisees, agency staff, and any other partner or individual who provides services on behalf of MSI) whose contracts don’t specify that they consent to undertake research;
  - Illiterate people;
  - Children and adolescents under 18;
  - People with a health condition where a treatment isn’t available;
  - People experiencing a public health or humanitarian emergency;
  - Mentally disabled/cognitively impaired people;
  - People involved with criminal activities

**Reviewed by:**

Full Reviews will be conducted by the full committee at the monthly Live Meeting, led by a Lead and Second Reviewer.

**Review process and deadlines:**

1. Chair allocates a Lead and Second Reviewer to conduct the initial review of the protocol.
2. Reviewers liaise between themselves to clarify roles and internal deadlines. Protocol to be returned to ERC Chair no later than 9 working days before Live Meeting. Reviewer roles:
   - Lead Reviewer: Conducts the initial protocol review and shares Protocol Review Form with the Second Reviewer
   - Second Reviewer: Adds note of additional ethical concerns to review and shares with the ERC Chair

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\(^4\) Minimal risk means 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.” See the Common Rule [https://oprs.usc.edu/files/2019/01/PI-ed_New-Rule-1.9.19.pdf](https://oprs.usc.edu/files/2019/01/PI-ed_New-Rule-1.9.19.pdf)
3. Protocol discussed at the convened Live Meeting. Engagement of all committee members present at the Live Meeting is required for decisions to be made by consensus. Live Meeting reviewer roles:
   - Lead Reviewer: Provides a summary of the protocol’s research aims, methods and their assessment and recommendation for the ERC response. Engages the committee in discussion on areas of concerns which require their reflection and input.
   - Second Reviewer: Takes note of comments and additional concerns raised at the Live Meeting; collating comments into the Protocol Review Form and sharing with the ERC Chair within 3 working days.

4. The Chair and/or Lead Reviewer collate a formal written response to be reverted back to the researchers a maximum of 5 working days from the Live Meeting

5. ERC Chair finalises the formal written response and shares with Ethics Officer to be reverted back to the researchers a maximum of 5 working days from the Live Meeting.

Resubmissions reviewed by either:
   - The Chair (reviewed and responded to within 5 working days)
   - The Lead and Second Reviewer (reviewed and responded to within 10 working days)
   - The Full Committee (reviewed and responded to within 5 working days after the Live Meeting)

3.1.2 Expedited Review

Criteria for Expedited Review:
1. The study involves no more than minimal risk of harm to participants;
2. The study does not involve any of the risks listed in criteria for Full Review;
3. All studies involving human participants, or secondary analysis of data with personal identifiers.

Reviewed by:
Expedited Reviews will be conducted by the Chair and a small team of reviewers.

Review process and deadlines:
1. Chair convenes a small team of reviewers
2. Team of reviewers conduct the initial review, arriving at a decision made by consensus within specified deadlines
3. Chair and/or Lead Reviewer collate a formal written response to be reverted back to the researchers within 20 working days from submission

Resubmission reviewed by either:
   - The Chair (reviewed and responded to within 5 working days)
   - The Lead and Second Reviewer (reviewed and responded to within 10 working days)
3.1.3 Fast-Track Review

Criteria for Fast-Track Review:
Protocol adheres to one or more of the following criterial:

- Protocol has already received approval from an FWA-approved (or similarly accredited) ethics body such as FHI360, Population Council, or the WHO, and approval is included in the submission;
- Protocol is an amendment of a previously approved protocol by the ERC; and approval is included in the submission. This is inclusive of a country adaptation of a global protocol;
- Protocol is seeking an extension to the existing ERC approval, which has been included in the submission. This is for research studies continuing for more than 12 months;
- Studies that are low risk in which the most serious foreseeable negative consequence for participants taking part is discomfort (physical or psychological) e.g. minor side-effects of medication or anxiety or embarrassment induced by an interview.

Reviewed by:
Fast-Track Reviews will be conducted by the either the Chair, or, the Chair and one other reviewer.

Review process and deadlines:
- Chair conducts the review, collating a formal written response to be reverted back to the researchers within 10 working days from submission.
  OR,
- Chair recruits one committee member to assist in the review;
- Chair and additional reviewer collate a formal written response to be reverted back to the researchers within 10 working days from submission.

Resubmission reviewed by either:
- The Chair (reviewed and responded to within 5 working days);
- The Lead and Second Reviewer (reviewed and responded to within 10 working days)

5 Minimal risk means 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.” See the Common Rule https://oprs.usc.edu/files/2019/01/PI-ed_New-Rule-1.9.19.pdf
3.2 Conducting Reviews and Deciding on Outcomes

ERC members will conduct their reviews based on a careful weighting of the benefits and risks involved. They are required to use The Ethics Review Summary Form (Annex 1) as a checklist that guides the review and decision-making. The small team of reviewers convened by the Chair will make decisions by consensus. Where small teams cannot reach a consensus decision, the protocol will be referred to the full committee for review within the ERC Live Meeting.

Where the full committee cannot come to a consensus, a majority vote will hold sway.

Decisions will be one of three types:

1. **Approved as submitted, conditional on the terms laid out within the approval letter**
   The protocol and accompanying documents are approved by the ERC as submitted without changes or modifications.

2. **Approved subject to satisfactory ERC review of resubmission based on specified conditions laid out within initial ERC review, and conditional on terms laid out within the approval letter**
   The ERC requires modifications or additions to the protocol or accompanying documents in the form of a resubmission. Human subjects shall not be recruited into, or involved in, the proposal until approval has been given. In some cases, ongoing review may be requested.

3. **Denial of approval**
   The research places the subjects at a risk that outweighs the benefit or value of the knowledge to be gained, or it raises such serious ethical questions that the protocol is unacceptable.

3.3 Communicating the Decision

The Chair or designated Lead Reviewer (oversighted by the Chair) is responsible for formally documenting and providing written explanation of the decision – as well as any subsequent clarifications or advice required – to the applicant and (where applicable) the relevant Research Advisor.

All effort will be made for decisions to be formally communicated in a letter from the ERC no more than 2 days after:
   a. The date that Fast & Expedited review teams are scheduled to submit their collated review to the Ethics Officer or
   b. The monthly Live Meeting of the full Committee for full Committee reviews

3.4 French Protocol Review

Some of MSI's research is conducted in French, and therefore, the ERC has made a commitment to ensuring it has the capacity to review French protocols through the recruitment of several francophone members.

In instances where the ERC Chair is unable to conduct reviews of French protocols the Chair will delegate the management of the French protocol to a francophone committee member.

In order to ensure transparency, consistency and record keeping Regional and Evidence Advisors will continue to submit the Protocol Submission Form in English, for classification by the ERC Chair. However, the protocol, instruments and appendices can be submitted in French. Internal reviews, ERC approval letters and the summary of the review within the ERC response letter will be provided in English. However, the details of the ERC review within the response letter will be provided in French. The ERC will also accept
replies from the researchers in French. This enables researchers to address concerns on a point-by-point basis within their resubmission along with the modifications they have made to the protocol.

4. **Additional Reporting and Monitoring Responsibilities**

4.1 **Continuing Review**

As part of its continuous monitoring obligations in compliance with the FWA, the MSI ERC is required to monitor and review both annual and final reports submitted by the researchers relating to ERC approved research protocols.

The ERC Chair may engage committee members in review of annual or final reports as necessary.

4.2 **Adverse Events, Protocol Deviations and Protocol Violations**

Reports related to adverse events, protocol violations and protocol deviations are reviewed by the ERC Chair and responded to, according to specified deadlines (set out within *Annex 2*). The purpose of this is to assist MSI in identifying and mitigating risks relating to study participants, MSI people (collectively referring to MSI employees, volunteers, partners and suppliers) and MSI’s reputation that could arise from such incidents. The ERC Chair may engage committee member in reviews where necessary, and will report back to the full committee on all reports of adverse events, protocol deviations and protocol violations.

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**Annexes**

1. MSI ERC Ethics Review Summary Form
2. MSI Reporting Adverse Events, Protocol Violations, Protocol Deviations Form
3. MSI ERC Invoicing Guidance.
4. MSI ERC Principles, Processes and Procedures