

<p style="text-align: center;">Ethics Review Board Instituted by <i>Médecins Sans Frontières</i></p>	Revision Number:	1
<p style="text-align: center;"><u>STANDARD OPERATING PROCEDURE No 1</u></p>	Date:	November 2016
<p style="text-align: center;">REVIEW PROCESS FOR NEW PROTOCOLS</p>	Issued by: MSF ERB	
	Page 1 of 4	

I. Purpose

This document aims to standardize the process of submitting and receiving new protocols for review, assigning reviewers, consolidating reviews and providing approvals by the MSF Ethics Review Board.

II. Definitions

- A. Delegated review – ethics review requiring a minimum of two ERB reviewers.
- B. Full review – ethics review conducted by at least eight ERB reviewers.

III. Abbreviations

ERB	Ethics Review Board
MSF	<i>Médecins Sans Frontières</i>
OC	Operational Centre

IV. Responsible person for the submission

All requests for review of protocols must be submitted to the Chair of the ERB through the Operational Centre's Medical Director or the Director General of Epicentre (in case the research is carried out by Epicentre without MSF). The Medical Director or the Director General will be the contact person of the ERB regarding the protocol.

V. Documents required at the time of submission

Submissions should include the following:

- A. Duly completed MSF ERB Research Review Template¹.
- B. Complete study protocol² and annexes. The annexes may include documents related to but not incorporated in the protocol, such as:
 - 1. Information sheets for the community leaders, household heads, prospective participants, as applicable. Please note that separate information sheets for child participants may be needed to adapt the information to their level of comprehension.

¹ In filling out the template, please refer to the guidance document

² Online resources such as: WHO http://www.who.int/rpc/research_ethics/format_rp/en/; ICH GCP <http://ichgcp.net/6-clinical-trial-protocol-and-protocol-amendments/>; and EQUATOR <http://www.equator-network.org/> may be used for guidance.

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REVIEW PROCESS FOR NEW PROTOCOLS	Issued by: MSF ERB	
	Page 2 of 4	

2. Consent and assent forms for prospective participants, consent forms for parents/guardians, assent forms for child participants, other consent forms as needed.
 3. Data collection tools – questionnaires, question guides, observation guides, case report forms, etc.
 4. Risk identification and mitigation plan.
 5. Research staff training plan.
 6. Study SOPs.
 7. Other documents pertinent to the submission.
- C. Short (2 pages) curriculum vitae of all study investigators.
- D. Disclosure of previous and current reviews by other ethics or scientific boards or committees and copies of the approvals or conclusions and/or recommendations³.
- E. Data sharing agreements, material transfer agreements, memoranda of understanding, if already available at the time of submission⁴.
- F. Insurance certificate (for clinical trials), if already available at the time of submission⁵.

VI. Submitting the protocol

The research protocol, annexes and other documentary requirements must be sent electronically by the Medical Director/Director General to the MSF ERB Secretariat at msferb-secretariat@msf.org. The ERB Executive Officer will confirm the documents received and inform the Medical Director/Director General the assigned MSF ERB Identification Number of the protocol. The ERB will not review incomplete submissions. The review will only commence once all required documents are received.

The Executive Officer shall record details of the protocol in the ERB database and upload the protocol and other accompanying documents to the MSF ERB online repository.

VII. Pre-ethics review

The Executive Officer, in collaboration with the Chair / Vice-Chair, shall conduct a pre-ethics review. The aim of this pre-ethics review is to evaluate the

³ This includes any reviews or advice provided by individual MSF ERB member(s) consulted independently.

⁴ This may be submitted on a later date / once available.

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	Page 3 of 4	

submission so that all required documents and protocol elements are complete and, as much as possible, all necessary information may be clear and available for the ERB members to make a sound ethics review of the protocol. Protocols may be sent back to the Medical Directors/Director General for completion and/or revision prior to the ethics review.

VIII. Ethics review

The Executive Officer, in collaboration with the Chair and/or the Vice-Chair, will conduct an initial assessment to ascertain the level of risk posed by the proposed research and whether to conduct a delegated or a full review, and to determine attribution to reviewers. The MSF ERB Risk Matrix shall be used as a guide in the risk stratification of protocols; attribution will be based on the expertise and workload of the ERB members.

The evaluation of research protocols by the Board shall be guided by the MSF ERB Ethics Framework for Review and various international reference documents for ethics review, as mentioned in the MSF ERB Terms of Reference.

The Executive Officer will compile individual reviews. The Chair or Vice-Chair shall facilitate discussion between the different ERB members in case of disagreement. A consolidated ethics review will be prepared by the Executive Officer usually within six weeks of initial reception of the research protocol, and will be revised as needed and validated by the Chair and/or Vice-Chair. Reviews typically include clarification questions and suggestions or requirements for improving the ethical aspects of the protocol.

The ERB's review of the protocol shall be sent by the Chair or Vice-Chair to the Medical Director of the MSF OC concerned or to the Director General of Epicentre. All ERB members who participated in the review will receive a copy.

The Medical Director/Director General shall submit the investigators' replies and the revised protocol to the Chair through the ERB Secretariat. Any revisions made to the protocol should be in tracked changes.

Several cycles of ERB comments and MSF replies and protocol revisions may be needed before a decision is reached by the ERB.

IX. Decisions of the ERB

Decisions of the ERB are made by consensus.

The review of a research protocol will result in one of the following actions:

- A. **Approved:** The submitted version of the research protocol is approved.

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REVIEW PROCESS FOR NEW PROTOCOLS	Issued by: MSF ERB	
	Page 4 of 4	

- B. **Conditionally approved:** The research protocol has not yet been approved; it requires the completion of one or more requirements before approval can be granted. When the requirements are met, a letter of approval will be issued.
- C. **Not approved:** The research protocol cannot be approved due to continuing serious ethical concerns.

The ERB has an advisory role and has no enforcement powers with regards to any decisions to implement the research. It is the responsibility of the Medical Director of the MSF operational centre concerned or the Director General of Epicentre to decide about this. The ERB would like to be informed if MSF or Epicentre acts contrary to its recommendations. The ERB cannot be held accountable for any research carried out against (or without) its advice.

The Board will not retrospectively review any research that has been started or that has taken place without prior ERB approval.

X. Interfaces

- A. MSF ERB Risk Matrix, version 1 2016 and further updates
- B. MSF ERB Research Review Template and Guidance Document, version 1 November 2013 and further updates
- C. MSF ERB Ethics Review Approval Form

XI. Revision history

SOP NUMBER	TITLE	REVISION VERSION	DATE
1	Review process for new protocols	1	November 2016

XII. Approved:

Doris Schopper, Chair Person

Date: November 2016

Please make sure you have the most current version
You may direct your inquiries regarding versions of this SOP and interfaces to the MSF ERB Secretariat at msferb-secretariat@msf.org