I. Purpose & Scope

This document aims to standardize the process of continuing review of studies that were approved by the MSF Ethics Review Board, specifically the process of submitting and receiving end of study notifications by the MSF Ethics Review Board.

This SOP applies to ERB-approved studies which have been completed or terminated.

II. Definitions

A. ERB-approved protocol – a research protocol, identified by a version number and date, which has been reviewed and approved by the MSF ERB.

B. ERB-approved study – research carried out according to the ERB-approved protocol

C. End of study – a study is considered to have ended if the study is completed or has been stopped prematurely.

1. The ERB considers that a study is completed when there is no more contact with study participants and when all data are collected, cleaned and analysed, and, as applicable, all samples have been de-identified/coded and analysed.
2. A study is prematurely stopped when its implementation is discontinued earlier than what was planned in the ERB-approved research protocol.

III. Abbreviations

ERB	Ethics Review Board
MSF	*Médecins Sans Frontières*
MSF ERB ID	*Identification number* *(The identification number assigned to the protocol by the ERB Executive Officer)*
OC	Operational Centre

IV. Responsible person for the submission

All end of study notifications of ERB-approved protocols must be addressed 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 said ERB-approved protocol.

V. Documents required at the time of submission

Submissions should include the following:

A. Duly completed MSF ERB Declaration of End of Study Template[1]

B. Final report for completed studies

C. Any additional documents (for example: journal articles / manuscripts; copies of presentations).

VI. Submitting the end of study declaration

The filled-out MSF ERB Declaration of End of Study Template and other documents must be submitted electronically by the Medical Director/Director General to the MSF ERB Secretariat at msferb-secretariat@msf.org. The Medical Director/Director General should mention the MSFERB ID number of the originally approved protocol in the communication. The Secretariat, through the ERB Executive Officer, will acknowledge the Medical Director/Director General of the documents received.

The Executive Officer shall record details of the request in the ERB database and upload the completed MSF ERB Declaration of End of Study Template and any accompanying documents to the MSF ERB online repository.

VII. Evaluation

The Executive Officer will evaluate the end of study declaration, final report and publications / presentations submitted. The ERB may require other documents to be submitted, as warranted. The end of study declaration and any related documents will be provided to the ERB members who reviewed the original protocol.

In circumstances where the end of study declaration and/or the final report and/or the publications/presentations related to the research are assessed to be divergent with the ERB-approved protocol or should noncompliance and/or violations and/or research misconduct be noted, the ERB may conduct a review of the end of study documents. Decisions regarding such matters are made with

[1] Available from http://fieldresearch.msf.org/msf/handle/10144/618703

the Chair and/or the Vice-Chair. The same ERB members who reviewed the original protocol (if available) may be asked to conduct the review.

VIII. Decisions of the ERB

The evaluation of the declaration of end of study of an ERB-approved protocol will result in one of the following actions:

A. ***Accepted***: The declaration, final report and other documents are accepted by the ERB, and the research is closed-out.

B. ***Conditionally accepted***: The declaration, final report and other documents are not yet accepted by the ERB; it requires the completion of one or more requirements (for example, justification for early discontinuation, provisos such as justifications in changing the definitions of outcomes or exposures of interest, explanations regarding additional analysis conducted, etc).

C. ***Not accepted:*** The declaration, final report and other documents are not accepted by the ERB. Non-acceptance may be due to the following: the final report and/or the manuscript/published article and/or oral or poster presentation is not consistent with the ERB-approved protocol; or noncompliance or misconduct were identified by the ERB. Appropriate action will be carried out as described in the MSF ERB Terms of Reference.

In addition, MSF will be asked to report on the assessment of impact of closed research.

IX. Interfaces

A. MSF ERB End of Study Notification Template, version 1 October 2016 and further updates

X. Revision history

SOP NUMBER	TITLE	REVISION VERSION	DATE
4	Review process for continuing review of approved protocols: declaration of end of study	1	November 2016

XI. Approved:

Doris Schopper, Chair Person

Date: November 2016