

Ethics Review Board <i>Instituted by Médecins Sans Frontières</i>	Revision Number:	1
<u>EXEMPTION CRITERIA DOCUMENT No 2</u>	Date:	February 2017
SURVEYS BASED ON THE STANDARDIZED INTERSECTIONAL SURVEY PROTOCOLS APPROVED BY THE MSF ERB	Issued by: MSF ERB	Page 1 of 3

I. HISTORY AND MOTIVATION

At the MSF Ethics Review Board (ERB) meeting in 2012, the handling of ethics clearance for routine surveys was discussed. The ERB decided that surveys for vaccination, nutrition and mortality that make use of the ERB-approved standardized survey protocols do not require ERB review if the Medical Directors take responsibility for addressing the ethics issues.

II. PROCESS FOR THE ERB

The ERB decided on the following steps to provide ethics guidance for surveys:

- A. All MSF Operational Centres will develop and agree upon standardized protocols for vaccination, nutrition, and mortality surveys;
- B. The ERB will review and approve these standardized protocols and they can then be used across all sections;
- C. The ERB will establish criteria for review exemption for the field use of the ERB-approved standardized survey protocols, similar to those for the retrospective analysis of routinely collected data;
- D. The ERB will compose an ethics statement for use in publications of surveys that have complied with the exemption criteria; and
- E. The ERB will monitor and evaluate the process of exemption and the exempted protocols (as detailed in the MSF ERB Terms of Reference).

This process aims to empower investigators to take responsibility on the ground for all the ethical issues pertaining to their survey. Collectively, our focus and main interest is for surveys to be conducted ethically; survey communities and participants to be protected; survey data to be valid and beneficial; and investigators to be accountable.

III. CRITERIA

To qualify for exemption, the survey must adhere to the ERB-approved standardized protocol and the Medical Director must be satisfied that the following criteria are met:

1. The survey protocol must describe the particular context in which it is to be carried out;
2. Approval for the survey must be obtained from relevant local authorities (as appropriate);

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3. Procedures to protect privacy and confidentiality of participants and communities as well as data security must be clearly outlined;
4. Anticipated harms and plans to mitigate them must be described; and
5. Benefits to the population surveyed and plans for wider dissemination, including publication, must be described.

IV. PROCESS FOR SURVEYORS AND MEDICAL DIRECTORS

- A. To apply for an exemption, those conducting the survey on the ground must submit to their Medical Director:
 1. A completed protocol for the proposed survey; and
 2. A point-by-point outline as to how the protocol meets the five criteria listed above.
- B. Exemption status is to be determined by the Medical Director as they are ultimately responsible for meeting ethical standards. If the decision for exemption from review is taken by the Medical Director, the responsibility to ensure that ethical requirements are met lies with MSF.
- C. To qualify for exemption, surveys must follow the ERB-approved standardized and intersectionally-approved format; where there is deviation from the standardized format (except for deletion of questions), it can no longer be considered a standardized survey, it cannot receive exemption, and it must be submitted to the MSF ERB in the usual manner.
- D. During the implementation of the survey, if the survey content requires modification, or if there are new concerns about potential risks the survey may impose, then the ERB should be consulted.
- E. The results of these surveys can be published if they meet the five criteria and can be accompanied by the ethics statement provided by the MSF ERB (provided below).
- F. If a survey has already been conducted/completed and did not meet the exemption criteria or did not undergo ERB review, then the investigators cannot claim compliance with the exemption criteria nor ERB approval, and the results cannot be published using the MSF ERB ethics statement nor any other statement concerning the MSF ERB.

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- G. The Medical Directors are responsible for submitting the list of exempted protocols, the certificates of exemption, and the exempted protocols to the ERB on an annual basis.

V. ETHICS STATEMENT

If the survey exemption process set out above is followed, the investigators may include the following ethics statement in publications of survey results, as approved by the MSF ERB:

“The Médecins Sans Frontières (MSF) Ethics Review Board approved the standardized survey protocol used in this study. The MSF (Operational Centre) Medical Director determined that this particular survey met the MSF Ethics Review Board’s criteria exempting it from further review by the MSF ERB.”

If challenged by a journal, the investigators are responsible for demonstrating that their study met the relevant criteria.

VI. REVISION HISTORY

ERB EXEMPTION CRITERIA DOCUMENT NUMBER	TITLE	REVISION VERSION	DATE
1	Exemption criteria for surveys based on the standardized intersectional survey protocols approved by the MSF ERB	1	February 2017

*****Please make sure you have the most current version*****

You may direct your inquiries regarding versions of this MSF ERB document to the MSF ERB Secretariat at msferb-secretariat@msf.org