



**Exemption Criteria - retrospective analysis
of routinely-collected clinical data from
pre-existing, established programs**

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<p style="text-align: center;">Ethics Review Board Instituted by <i>Médecins Sans Frontières</i></p>	Revision Number:	2
EXEMPTION CRITERIA DOCUMENT No 1	Date:	November 2016
<p style="text-align: center;">RETROSPECTIVE ANALYSIS OF ROUTINELY COLLECTED CLINICAL DATA FROM PRE-EXISTING, ESTABLISHED PROGRAMS</p>	Issued by: MSF ERB	
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I. BACKGROUND

At the MSF Ethics Review Board (ERB) meeting in June 2010, the handling of ethics clearance for *a posteriori* operational research studies based on routinely-collected clinical data was discussed.

The ERB decided that *a posteriori* analyses of routinely collected clinical data do not require ERB review, if the medical directors take responsibility for addressing the ethics issues.

II. CRITERIA

The following criteria must be fulfilled to qualify for exemption from ERB review:

1. Studies/articles are based on routinely-collected clinical data from pre-existing, established programs.
2. They are either descriptive/evaluative or targeted evaluations.
3. Confidentiality is respected; no individual patient identifiers are revealed or used.
4. Harm is minimal but acknowledged where relevant.
5. Potential benefits to both the program and the community are described. Since the goal is publication, the relevance to a wider audience is described.
6. Collaborative involvement and, if applicable, authorship from a local authority or partner (Ministry of Health, DHO, other NGO) is encouraged. If relevant and applicable, consultation with a body representing the community is desirable.
7. If the decision for exemption from review is taken by the respective medical director, the responsibility to ensure that ethical requirements are met lies with MSF. This, however, does not exempt MSF from complying with any relevant regulatory requirements in the country from where the data originate. In some countries, local ethical review may still be required.

III. RESPONSIBILITIES

The investigators / authors are responsible for submitting the research protocol, which should include how the criteria above are met, to their respective medical director and for securing the medical director's approval for exemption.

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The medical directors are responsible for documenting exemptions from ERB review and sending copies of the exemption certificates and exempted protocols to the ERB.

IV. ETHICS STATEMENT

If the above criteria and conditions are met, then the authors can insert into their article the following statement that has been approved by the MSF ERB:

“This research fulfilled the exemption criteria set by the Médecins Sans Frontières Ethics Review Board for a posteriori analyses of routinely collected clinical data and thus did not require MSF ERB review. It was conducted with permission from (Medical Director, Operational Centre) Médecins Sans Frontières.”

If challenged by a journal, the authors are responsible for demonstrating that their study meets these criteria.

V. UNCERTAINTIES AND OTHER CONCERNS

In cases where the medical director and/or investigators/authors are not certain whether the criteria were met, or if they have any other ethics concerns, they should submit their study protocol to the MSF ERB for advice. In that case, they should indicate how their study attempted to address these criteria.

VI. REVISION HISTORY

ERB EXEMPTION CRITERIA DOCUMENT NUMBER	TITLE	REVISION VERSION	DATE
None	Retrospective analysis of routinely collected clinical data	1	June 2010
1	Retrospective analysis of routinely collected clinical data from pre-existing, established programs	2	November 2016

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