Between 2002 and May 2007, the MSF Ethics Review Board (ERB) reviewed 65 research proposals. The most common issues that arose were an insufficient informed consent procedure; lack of explicit community involvement; uncertain assurance that benefits would be made available to research participants and communities in the medium term; and the handling of tissue samples. The focus of this presentation is on retrospective analysis of data sets, an issue that has arisen several times in the past year. Approval for articles based on such analyses have been triggered by journals asking for ethics approval before publication, which has raised questions about the ethics issues in analysing routinely collected data for more than project management purposes.

In MSF many data are routinely collected to guide operations. Routine data collection and analysis generally does not need ERB approval. However, in some instances, ethics review should be sought before doing an analysis (and definitely before publication). Case studies will be presented to illustrate relevant issues: protection of patient confidentiality; whether individual informed consent is necessary; collaboration and partnership with local/national researchers; public health benefits versus potential harms to individuals and communities; whether a study community will receive the benefits of research; and avoiding premeditated research disguised as retrospective analysis of routine data to circumvent ethics review.

Analysis of routinely collected data to improve patient management directly does not need ethics review. However, ethics review should be sought as soon as a generalisable research hypothesis is to be tested. An external view will give some guarantee that major issues are not overlooked by the investigators. Since there is a “grey area” between testing a generalisable research hypothesis and routine monitoring of programmes, a short “decision framework” could be helpful to (a) raise awareness about ethics issues for authors of papers based on analysis of routinely collected data; (b) clarify when it is appropriate to submit a proposal to the ERB; and (c) present a simplified version of the full ERB framework.

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MSF is in the final stages of creating an Open Repository to archive its scientific publications. This is in order to showcase the considerable amount of research and publishing that MSF has produced and to make it more accessible to people who can use it – health care workers in the field, NGOs, and Ministries of Health in developing countries.

This presentation will demonstrate the pilot version of the site and invite comments from the conference participants.