Guide to Research - Getting Started

DEVELOPMENT OF OPERATIONAL RESEARCH IN MSF
A ROUGH GUIDE FOR FIELD STAFF
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The following is a "Quick Start" for field staff interested in developing an operational research project. It is an outline only and you will need to consult the relevant people in your OC, as processes for developing operational research may vary between sections.

1: Do you have a **great idea**? Formulate it into a clear research question of 1-2 sentences. Do a quick literature search or ask around to find out what is already known and/or published, or currently being researched on the issue. Check that someone else in MSF (or elsewhere) isn't already researching the question by checking the Operational Research Agendas or the website www.clinicaltrials.gov site.

2: **Discuss** your idea with colleagues/local experts/ your medical coordinator: is this question relevant and important for our patients and for MSF? Does it produce new, useful information? Is the research feasible? Consider your capability, project resources, time, and patient numbers. What methodology is suitable: review of data, survey, observational case description, quantitative/qualitative, or randomized trial? What are the potential ethical issues e.g. risk-benefits for patients?

3: Formulate a 1-2 page **concept paper** (see a suggested format annexed) to discuss with your medco/medical director. You are strongly encouraged to get assistance refining your question/topic from specialists and epidemiologists at headquarters.

4: If all agree, a **formal research protocol** can be developed. This should follow best research standards (ask for examples from HQ) and include background, hypothesis, objectives, methods, sampling frame, intervention or procedures, outcome measures, analytical approach, time-frame, ethics, research partnerships/collaborations, and how the research findings will be used to improve patient care or programme delivery. The formal research protocol must be approved by the medical director and will be used for ethics approval as necessary. It is wise to involve research specialists and medical experts at headquarters early in the process to minimize your hassles and produce an acceptable protocol. It is also very desirable to have local researchers and/or Ministry of Health staff involved from the start.

5. **Ethics issues** are always very important. Remember: our patients are usually extremely vulnerable and we have an obligation to ensure our research maximizes benefit versus harm. We may be acting out of the best of intentions but this in itself is not sufficient to ensure ethical research. In addition, the research must be of good quality or the results will be worthless, and the whole exercise a waste of time and resources.

Ethics review should take place in the country of origin of the study as well as with MSF Ethics Review Board (ERB). This is especially true if the research is:

- a clinical trial, or
- involving blood/tissue samples
- involving children, patients in mental health or psychosocial programmes or other very vulnerable groups eg women surviving SGBV, or
- if there are any other concerns about ethics

Some studies that involve only review of routinely-collected program data may not require ethics review but remember all peer-reviewed journals require ethics review before they accept an article for publication. So, consider this at the outset. For this kind of study, MSF ERB will do an expedited review that is quite quick.

In practice, all research protocols should be reviewed by the Medical Director who will also decide whether ERB review is necessary[1].

6. **Operational considerations** must come first. Thus, the impact of the research on the MSF project has to be taken into account and the research should be planned with the knowledge and support of the other field staff. It should be built into the project's Annual Action Plan (budget, personnel, etc) and be added to the section's Operational Research Agenda.

7. **Research quality** depends on asking the right question and planning an appropriate design to answer that question. It does not mean doing huge studies that are costly. The objective of operational research is to answer questions that are relevant to MSF projects and improve care, with the bonus of being useful in other contexts. Since MSF carries out its programmes in unique settings with vulnerable populations, careful documenting of MSF's experience is invaluable and worthwhile getting published. With this in mind, it is wise to check the quality of routinely-collected data you intend to use.

8. Finally, be prepared to **commit** significant time and personal resources to any research project. It always takes more of both than you expect and the typical time from inspiration to publication can take a year or more. However, if you are committed, MSF has people and resources to help. Remember that, although it is demanding, it is also very satisfying to create new knowledge that can be used by others to improve care. Courage and good luck!

[1] See annexed the MSF ERB's framework for review. Normally, review by a local/national ERB in the country is also expetced.

Ethical Framework used by the MSF ERB for Medical Research in MSF

Principles	Benchmarks
Collaborative Partnership	1) Engage in partnership with national and/or international research institutions as relevant and appropriate. 2) Collaborate with local and national researchers, health policymakers, and the community to share responsibilities for determining the importance of health problem, assessing the value of the research, planning, conducting, and overseeing the research, and integrating the research into the health system. 3) Respect the community's values, culture, traditions, and social practices. 4) Contribute to developing the capacity for researchers, health policymakers, and the community to become full and equal partners in the research enterprise. 5) Ensure recruited participants and communities receive benefits from the conduct and results of research 6) Share fairly the financial and other rewards of the research.
Social Value	1) Specify the beneficiaries of the research. 2) Assess the importance of the health problems being investigated and the prospect of value of the research for each of the beneficiaries. 3) Devise and implement mechanisms to enhance the social value of the research by: • Disseminating knowledge gained locally, nationally, regionally and internationally; • Making drugs or interventions tested and found to be effective available to the local community through advocacy, by involving policy makers from the start, by staying long enough after research ends to ensure its application. 4) Prevent supplanting the extant health system infrastructure and services.
Scientific Validity	1) Ensure the scientific design of the research realizes social value for the primary beneficiaries of the research. 2) Ensure the scientific design realizes the scientific objectives while guaranteeing research participants the health care interventions they are entitled to (this includes a sample size sufficient to reach objectives). 3) Ensure the research study is feasible given the social, political, and cultural environment and with sustainable improvements in the local health care and physical infrastructure.
Fair Selection of Study Population	1) Select the study population to ensure scientific validity of the research. 2) Select the study population to minimize the risks of the research. 3) Formulate clear inclusion and exclusion criteria. 4) Identify and protect vulnerable populations.
Favorable Harm-Benefit Ratio	1) Assess the potential harms and benefits of the research to the study population in the context of the individual participants to be enrolled. 2) Assess the harm-benefit ratio for the community (and involve the community in doing so where appropriate[2])
Independent Review	1) Ensure public accountability through scientific and ethical review according to international standards. 2) Ensure public accountability through transparency and reviews by a local ERB or other relevant body.

[2] How is the community defined? Is it the potential beneficiaries? The community leaders? Persons who may be in the community but derive no direct benefit from the research? Power relationships must be considered when deciding who should be involved in assessing harms and benefits of the research.

Principles	Benchmarks
	3) Ensure independence and competence of the MSF ethical review.
Informed Consent	1) Involve the community in establishing appropriate recruitment procedures and incentives for the participants. 2) Disclose information in culturally and linguistically appropriate formats. 3) Ensure that consent procedures are acceptable within the local community (may include supplementary community and familial consent procedures). 4) Ensure that participants fully comprehend the research objectives and procedures[3]. 5) Obtain consent in culturally and linguistically appropriate formats. 6) Ensure that potential participants are free to refuse or withdraw from the research at any stage without penalty.
Respect for Recruited Participants and Study Communities	1) Develop and implement procedures to protect the confidentiality of recruited and enrolled participants (including samples of body fluids/tissues). 2) Provide enrolled participants with relevant new information that arises in the course of the research. 3) Monitor medical conditions, including research related injuries, of enrolled participants and provide care at least as good as existing local norms. 4) Inform participants and the study community of the results of the research.

[3] In some instances, this may require an educational process for the community and potential participants.