OCB Operational Research Framework

2019
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Important Note: This document is meant to describe the functioning of the OCB Operational Research Framework. It is an ongoing exercise and a document subject to changes.

Edited by Tony Reid, Jo Robays, Petros Isaakidis, Annick Antierens, Christina Psarra, Tom Ellman, Veerle Hermans, Samuel Sieber and LuxOR and SAMU Teams.

Last Version: December 2019
Glossary

CIOMS The Council for International Organizations of Medical Sciences (https://cioms.ch/)

Community Group of people that recognizes itself or is recognized by outsiders as sharing cultural, religious or other social features, backgrounds and interests. A community forms a collective identity with shared goals. However, what externally is perceived as a community might in fact contain many sub-groups. It might be divided into clans or castes or by social class, language, or religion.

Concept note A short outline of a research proposal (see Annex 1)

GCP Good Clinical Practice

Grey literature The materials and research produced by institutions and organizations outside traditional commercial or academic publishing channels. Common grey literature includes reports, government documents, evaluations, policy statements and issues papers, conference proceedings, newsletters, bulletins, and fact sheets.

Framework A broad system of rules that governs and regulates decision making and implementation of activities

Informed consent The voluntary agreement to participate in research. It is a process where a participant is informed about all aspects of the research including risks and benefits and after understanding them, voluntarily confirms his or her willingness to participate. It is an ethical and legal requirement for research involving human participants.

Literature review A critical analysis of published sources or literature on a topic. It can also refer to a descriptive, analytic summary of the existing material relating to a topic.

Medical department circle A working group consisting of different profiles and roles within the medical department that is following a specific theme, e.g. outbreaks, critical care, migration, primary health care, etc.

OR Advisor The OCB researchers following specific research domains

OR criteria The criteria used to assess and monitor a research proposal

Peer review The evaluation of research by one or more people with competences similar to those of the authors of the work (peers)

Project cycle The sequence of phases that a project goes through from its initiation to its closure

Public health The interdisciplinary field defined as "the science and art of preventing disease, prolonging life and promoting human health through organized efforts and informed choices of society, organizations, public and private, communities and individuals".

SORT-IT The Structured Operational Research and Training Initiative (SORT IT) is a global partnership coordinated by TDR, the Special Program for Research and Training in Tropical Diseases - of the World Health Organization which supports countries and institutions to conduct operational research based on their own priorities; builds sustainable operational research capacity; and
makes evidence-informed decisions for improving program performance.

**Study/Research Protocol**
The document that describes every step of a study including questions to be addressed, objectives, methodology, ethical and legal considerations, dissemination of the findings.

**Acronyms**

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAU</td>
<td>Advocacy and Analysis Unit</td>
</tr>
<tr>
<td>BRAMU</td>
<td>Brazil Medical Unit</td>
</tr>
<tr>
<td>CN</td>
<td>Concept Note</td>
</tr>
<tr>
<td>HQ</td>
<td>Headquarters</td>
</tr>
<tr>
<td>LuxOR</td>
<td>Luxembourg Operational Research</td>
</tr>
<tr>
<td>MedCo</td>
<td>Medical Coordinator</td>
</tr>
<tr>
<td>MENA</td>
<td>Middle East North Africa</td>
</tr>
<tr>
<td>OCB</td>
<td>Operational Center Brussels</td>
</tr>
<tr>
<td>ORAB</td>
<td>Operational Research Advisory Board</td>
</tr>
<tr>
<td>OR</td>
<td>Operational Research</td>
</tr>
<tr>
<td>PI</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>REMIT</td>
<td>Research Management and Impact Tool</td>
</tr>
<tr>
<td>SAMU</td>
<td>South Africa Medical Unit</td>
</tr>
<tr>
<td>SORT IT</td>
<td>Structured Operational Research Training Initiative</td>
</tr>
<tr>
<td>SRH</td>
<td>Sexual and Reproductive Health</td>
</tr>
<tr>
<td>VBD</td>
<td>Vector Borne Diseases</td>
</tr>
<tr>
<td>VPD</td>
<td>Vaccine Preventable Diseases</td>
</tr>
</tbody>
</table>
1. OPERATIONAL RESEARCH FOR HUMANITARIAN ACTION

1.1. WHY THIS FRAMEWORK

This document is not meant to be a guideline on how to conduct research, although it sometimes refers to useful resources. Rather, it is to provide a framework to better structure OCB’s operational research efforts to assure that they are responding to the needs and priorities of MSF, are feasible and adequately resourced. Before engaging in a research project, questions need to be answered: will the research be conducted in an ethical and scientifically sound way; is there sufficient operational space; are the human resources available and adequately trained; are the financial resources allocated? OCB addresses these issues by introducing this framework, a five-step process to assure that the key stakeholders within MSF, both in the field and at headquarters, are involved. They must agree that the results of the research are important for MSF operations and/or have broader operational/policy implications. This is to avoid poorly-planned, or under-resourced studies of limited value to MSF; such studies would be unethical and a waste of precious resources, possibly putting patients and populations at risk.

1.2. INTRODUCTION

From a humanitarian organization’s perspective, operational research (OR) is defined as “the search for knowledge on interventions, strategies or tools that can enhance the quality, effectiveness or coverage of programs in which the research is being conducted”\(^1\),\(^2\).

WHO defines OR as “the use of systematic research techniques for program decision making to achieve a specific outcome. OR provides policy-makers and managers with evidence that they can use to improve program orientations”\(^3\). OR is thus concerned with the generation and utilization of evidence to be used for humanitarian action and it should not be considered through the narrow lens of “research for publication”.

Medical humanitarian needs remain immense: from the classic gaps in access to primary and secondary levels of health care, to heavy burdens of infectious and chronic diseases affecting populations all over the world.

In an ever-challenging humanitarian aid landscape, systematic reviews have revealed the persistence of evidence gaps and the need for high quality and relevant data to inform and guide health

interventions in humanitarian crises. “The failure to generate and use evidence in policy and response makes humanitarian action less effective, less ethical and less accountable”⁴.

Despite the positive developments for generating of evidence on health interventions in humanitarian crises during recent years - 79% of high-quality literature was produced since 2000 – the quantity of evidence varies substantially by health topic from communicable diseases and outbreaks to hygiene and environmental health⁵.

OR generates knowledge on health care provision and patient management and helps to identify solutions to problems that limit program quality, efficiency and effectiveness, or to determine which alternative service delivery strategy would yield the best outcomes. In simple terms it has been described as “the science of doing better”⁶.

The boundaries between research, and monitoring and evaluation are not explicit or exclusive. OR teams deploy various research methods to analyze data generated from different sources in MSF projects. Monitoring and evaluation is performed on activities or interventions already implemented or ongoing and the analysis usually happens systematically, while operational research is more targeted analysis to answer specific questions; it may use routinely-collected monitoring data to do so.⁷ See Annex 2 for more definitions.

1.3. THE PURPOSE OF OPERATIONAL RESEARCH FOR MSF

MSF’s aims and actions are first and foremost medical. The notion of quality care for individual patients is central to our humanitarian objective and improving our medical practice and operational choices are part of our ongoing activity.

OR provides MSF with evidence to make informed choices on the most effective interventions and addresses the gaps observed in disease and patient evidence. Programmatically, it helps MSF to decide what we should do, or not do, or stop doing; which medical needs and populations we should target and how; and whether or not we are having the expected impact. Evidence generated by OR can also be used to evaluate new models of care and to advocate for improved policies and practices at national and international levels.

The purpose of this OR Framework is to be a practical guide for anyone in OCB (medical coordinators, project medical referents, epidemiologists, medical referents, etc.) who wants to develop a research proposal. The framework will help to develop research projects that aim to:

1. Improve the quality of program outcomes, the associated medical care and operational strategies.

⁶ https://www.who.int/hiv/pub/operational/or_guide_gf.pdf?ua=1
OR can be used in many ways: to understand the context, disease burden, and target population/communities; to assess barriers to access health care; to identify constraints in intervention strategies; to assess, validate and improve models of care; to evaluate the quality of our patient management; and to evaluate the impact of our interventions. OR can provide better understanding of new or insufficiently known diseases, their transmission, pathogenicity, clinical manifestations and complications. OR studies can provide information on disease prevalence, incidence, infectivity of pathogens and transmission. It can strengthen epidemiological capacity and offer important data on the prognosis, outcomes and confounding factors of a disease. In these ways OR can directly contribute to improving program design and performance, and the "quality of MSF assistance" by providing evidence-based medicine.

2. Promote innovation and assess the feasibility of new interventions
OR can be used to test new tools, strategies and approaches, such as diagnostics and therapeutics, in different patient groups and communities. It can evaluate new technologies or treatments proven in academic centers for feasibility in humanitarian field settings where conditions are closer to on-the-ground reality. MSF has, and will continue, to conduct research in settings where academic research is impractical or neglected, such as in conflict and disaster settings.

3. Advocate for policy and practice change
OR can provide evidence to support advocacy for policy change internally at MSF, or in the field, and at national or international levels. OR is a credible tool to demonstrate lack of access to health care, or gaps in health care provision, or supply shortages of essential medical items, or other human rights issues. Since OR evidence is generated through scientifically sound methods, it strengthens credibility for MSF’s ‘medical témoignage’. By making OR knowledge widely available through open-access publication and feeding evidence to advocacy and communication campaigns, OR can potentially influence public discourse and policy making.

4. Document MSF health activities
OR can document or capitalize on the experiences of the health care interventions carried out by MSF teams. Research projects can be developed at different stages of the project cycle, to see whether goals were met and what lessons can be learned to “do better next time”.

5. Improve MSF’s understanding of the humanitarian context and global public health issues
By continuously assessing MSF programs, OR fosters a better understanding of the health issues of global importance and the evolution of medical humanitarian needs and trends. This enhances MSF’s choice of where to target new areas for medical aid.

2. OPERATIONAL RESEARCH CRITERIA
Operational Research needs to be relevant, scientifically sound, and beneficial for MSF patients and the communities involved. OR teams should ensure that the methods used are rigorous and ethical and that participants’ rights are respected and protected.

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OR projects shall be designed and implemented to meet the following criteria and no activity should be launched without their being addressed:

1. **Relevant**
   OR should be conducted to support MSF operational needs in the field; it shall be timely and designed in line with the objectives of the OCB medical, operational and advocacy strategies and correspond to populations’ needs.

2. **Actionable, and having measurable OR outcomes**
   OR should be designed with measurable objectives and estimable timeframes to deliver actionable results that are beneficial to populations in need.

3. **Ethical**
   OR must always be conducted according to international standards for ethics. It must follow the MSF Ethics Research Framework\(^9\) and meet national ethics requirements in countries where OR is conducted.

4. **Transparent**
   OR teams shall demonstrate clarity in the design, implementation and decision-making processes of projects, informing the participants and communities involved as well as sharing their findings and conclusions with them.

5. **Accountable**
   Researchers bear ownership and responsibility for their actions to the participating community and should respect applicable frameworks and operational regulations of OCB. OR accountability extends to the use of research findings and appropriate dissemination of the conclusions.

6. **Scientifically Rigorous**
   OR study design and implementation must be scientifically valid, meeting high standards of methodology and analysis to answer the research question(s). Study designs must be clear and reproducible.

7. **Legal**
   OR shall respect the applicable legal requirements for research, both in Europe and in participating countries, including issues related to privacy and data protection.

8. **Resourced**
   OR shall only be conducted when human and material resources are available to ensure quality, efficiency and effectiveness during the research process and implementation of findings. Resources

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shall be sufficient to include engagement of local communities\textsuperscript{10}, including collaboration with the local scientific community.

3. PRIORITIZATION OF OPERATIONAL RESEARCH PROJECTS

Prioritization is a constant challenge for OR. While many research projects meet the OR criteria, they need to be prioritized given limited research resources and the multitude of information gaps.

The guiding principle for prioritizing MSF research studies is their potential impact at individual, local, national, regional and/or international level, as well as internally on the MSF movement.

MSF-OCB should invest its research resources in initiatives that:

1) fit the OR criteria as mentioned above;
2) cannot be conducted by other actors (for example, research in humanitarian emergencies, or on specific diseases where MSF has a unique experience, or in populations that remain neglected);
3) will achieve an impact on its own operations within a clearly defined timeframe.

Each new study proposal should have a clear description of the type of impact (individual, local, national, international, organizational), the anticipated magnitude of the impact, and the strategy and available resources towards achieving it.

Factors that may increase the priorities of a proposal include:

1. Emergency context

The OR project is designed to run in an emergency context where it is expected to provide findings to support critical decision making by MSF in the emergency.

2. Importance of OR identified by operations

- There is a strong operational buy-in/demand by MSF field teams and/or operations and/or national collaborating partners (MOH, etc) for the evidence from the study.
- The research evidence would provide a tool for advocacy striving to achieve policy and practice change.
- The evidence is important to an internal change of practice within MSF.

3. **Timeliness**

- Coinciding with the opening or closing of a project, either to support the design of new activities or the capitalization of project interventions.
- Alignment with project objectives and timeframes and effectively advocate for evidence-based change within a project’s lifespan.
- Releasing the study findings within a specific time-frame to meet advocacy goals.

4. **Innovative models of delivery**

The research is based on a “model of delivery” for an intervention that has the potential of preventing disease or saving lives in the near future. Examples: an innovative strategy for vaccination; screening for disease in specific groups; or administering treatment to vulnerable groups.

While these factors are all considered in the prioritization process, other influences may be the OCB Research Agenda\(^\text{11}\) or ad-hoc operational requests. The Research Agenda is a result of various consultations at different levels including medical department circles, cells, AAU, medical referents, ORAB, intersectional working groups and others.

4. **OPERATIONAL RESEARCH: STAGES AND THE DECISION-MAKING PROCESS**

Good OR design and a clear implementation process strengthens scientific validity and increases the chances that the evidence obtained will answer the original OR question as unambiguously as possible. The OCB OR design process includes the following stages:

- **Stage 1 – Research Idea:** Identifying a relevant operational research question
- **Stage 2 – Concept Note:** Assessing OR criteria and operational impact, identifying key OR objective(Figure 1)
- **Stage 3 – Protocol Development**
- **Stage 4 – OR Implementation** (Figure 2)
- **Stage 5 – Dissemination of OR findings, Policy and Practice Change** (Figure 3)

**STAGE 1 – RESEARCH IDEA: IDENTIFYING A RELEVANT OPERATIONAL RESEARCH QUESTION**

Research questions may be generated at field level or HQ but ultimately must be relevant to MSF operations and patients. **Open consultations** and discussions should take place to identify interest among field actors and HQ referents.

As a research idea is taking shape, consider asking for support from the OR team through the OR Inbox: operationalresearch@brussels.msf.org. Write a short description of the idea, send it to the OR

\(^{11}\) OR Research Agenda is in process and will include input from the OCB medical strategy, various working groups, operations and medical referents.
inbox and ask for support to fulfill the next steps, including better formulation of the research question, literature review and development of the concept note (CN). See Annex 1 for the CN Template.

A crucial aspect of any research idea is a good understanding of the literature around the proposed research topic to establish the rationale for your study. Check first in MSF resources such as MSF Field Research and ReMIT to make sure the research question has not been answered before by MSF.

A more thorough literature review can then be performed during the development of the protocol to confirm that the question truly answers a gap in the scientific literature.

If the research idea is generated from HQ, discussions should be held at field level in a mission or project that could potentially host the study.

If the research idea is generated from the field, the process shall include the MedCo or PMR, FieldCo and HoM as well as any other team members who would be affected by the study. Field representatives shall then contact the Research Advisor assigned to that field of study directly or through their cell representatives to discuss and receive feedback on their idea.

Before moving to the next stage, it is very important to ensure that there is interest from both sides (field & HQ) and willingness to explore the research idea further; for this it is advisable to have the engagement of at least three different actors/profiles.

**Stage 2 – Concept Note: Assessing OR criteria and operational impact, identifying key OR objectives**

Once the research idea has been discussed with the appropriate people, a Concept Note (CN – See Annex 1) is developed. It is a standardized tool to succinctly define the research idea with the main stakeholders and includes the following:

- The main research question(s)
- Objectives and expected outcomes of the study (performance improvement, innovation, policy change and advocacy, investigation, and knowledge acquisition),
- Setting
- Methodologies and study population(s)
- Resources - human and others, timeframe
- Potential risks and concerns
- Expected impact and dissemination of results

The CN needs to be primarily validated by the MedCos. They bear responsibility at field level for the CN, while other members of the country mission coordination or medical referents may also be involved. CNs from the field can be drafted with the support of OR Advisor and occasionally by them exclusively. CNs shall not exceed two pages. CNs usually originate from the field but also may come from medical referents, research units, the medical department, operations, or the analysis unit. For topics with no Identifiable OR Advisor or medical referent - the Medical Strategic Advisor should be contacted.
At this point, CNs should be sent to the OR Inbox before proceeding to the next steps: operationalresearch@brussels.msf.org.

From there, the responsibility to assess the study against the OR Criteria, prioritization and scientific validity is with the OR Advisor.

Once the CN is received by the OR Advisor, a round of discussions with representatives of the different departments, the Policy and Practice Advisor and others, should be organized to apply the OR criteria and to determine whether the study is feasible and a priority.

The OR Advisor shall provide initial feedback within two to three weeks after the receiving the CN. If the CN is greenlighted, the OR Advisor will consult with the LuxOR Program Officer, OR coordinator and/or the SAMU OR Coordinator to define the extent of involvement of OR team members to develop the study protocol.

![Diagram](image)

*Figure 1: From the research idea to the Concept Note*

If the research question is not judged as a priority, then it should be put on hold or discontinued. The CN shall be stored on the LuxOR Sharepoint and online in ReMIT.

**STAGE 3 – PROTOCOL DEVELOPMENT**

If the research question presented in the CN is greenlighted, then the next stage is the development of a full study protocol.

Developing a protocol is the responsibility of the Primary Investigator (PI) or Co-Investigators (Co-PI)\(^{12}\). The PI is not necessarily the person who drafted the CN but can be someone else depending on the skills required and the human resources available, but at this stage the assignment of a PI needs to be finalized. The PI expands the approved CN to a full protocol after conducting a thorough

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\(^{12}\) Roles are further explained at the Operational Research Project Team chapter, p.23
literature search and having consulted experts in the field and relevant field workers. The PI is responsible for inviting and incorporating input from all co-investigators and contributors, liaising with partners and following the research process through to completion. The OR Advisor may be involved in protocol development, working with the PI, or in some cases may actually be the PI.

Study Protocols can be developed from standardized templates for different study types and designs or developed from scratch. Examples of ERB approved protocols can be found on ReMIT.

The generation of a study protocol is not a linear or one-step process but requires ongoing consultations at different levels and with different actors. The involvement of study participants, community members, and local MSF staff enriches the process and increases the chances of identifying and answering the research question properly. It requires considerable skills and the time required should not be under-estimated.

Once the study protocol is drafted, it is reviewed by the OR Advisor (LuxOR, SAMU or other OR support). The OR Advisor is responsible for organizing a milestone meeting face-to-face or via video conference with Ops representatives from the cell, medical referents as well as other relevant HQ actors and the field teams to ensure understanding of the study’s primary and secondary objectives and alignment with Policy and Practice goals. All study protocols are to be edited by the Medical Editor and reviewed by the OR Coordinator before submission to the ERB. More details on the Policy and Practice assessment can be found in Annex 3.

Financial and human resources planning

At this stage a more detailed budgeting and planning of resources is required; the availability of resources, both human and financial should be re-assessed. Studies could still be stopped or put on hold at this stage if there are not sufficient resources for the study to be executed properly. To enable budgetary, human resources and time management planning, OR projects should be included in mission annual action plans and presented at the AROs.

Legal requirements

Legal requirements derive from three different sets of rules:

1. Laws of the country of the MSF sponsor
2. International rules (CIOMS, GCP etc.)
3. Laws of the country where the study is performed

This analysis is done on case by case basis. Some areas of law require a common approach and thus MSF has created an intersectional/international project unit entitled: “Shared Specialist Project - Medical Research, Innovation and Data” which hosts shared specialist legal advisors offering advice and support to research teams.
Ethics

All MSF protocols must be reviewed by the MSF Ethics Review board (ERB). In addition, approval must be obtained from national ethics committees where the research is being carried out, and from any academic partner (where applicable). OR Advisors, the OR coordinators or Strategic Medical Advisor need to be involved to ensure this process is complete. Submission to the MSF ERB requires the following:

1. finalized protocol
2. completed ERB research template
3. CVs of the PIs.

They must be submitted via the medical director’s designates (currently the SAMU OR Coordinator (petros.isaakidis@joburg.msf.org), the LuxOR Medical Editor (tony.reid@brussels.msf.org) or the Strategic Medical Advisor (annick.antierens@brussels.msf.org)). Studies of retrospective, routinely-collected program data may be exempted from formal MSF ERB review by applying to the medical directors designates. Exemption from MSF ERB review does not exempt MSF from complying with any relevant ethics and regulatory requirements in the country where the study is planned.

All necessary documents to complete the ERB submission can be found in the OR Framework Library on the website (https://msfintl.sharepoint.com/sites/grp-lux-opsresearch/SitePages/Operational-Resear.aspx) and on MSF Field Research in the Research Resources section.

STAGE 4 – OR IMPLEMENTATION

Once a protocol is approved by operations and the medical department, the MSF ERB and national authorities, the research team can proceed to implementing the study. The steps typically include:

- **Appointment and/or recruitment of the appropriate research staff.**

  It is useful to designate a study coordinator who will follow the study to completion on the ground. It may include a focal person among existing staff, recruitment of additional human resources, or allocation of HQ support staff (such as a Mobile Implementation Officer). Depending on the study design, other specialized study staff may be needed. Research activities may be heavy and time-consuming and should not be added to the tasks of regular staff. Thus, consider recruiting extra staff with particular skills, such as interviewers, data managers, laboratory techs, or environmental health experts.
• **Training of research staff**
  Depending on the complexity of the study, training of research staff may be necessary. Common topics include interview/survey techniques, data protection, confidentiality and ethical conduct. The study protocol should document this training. Questionnaires, other survey tools, or innovative technologies, should be pre-tested/piloted before the study begins.

• **Preparation of research materials**
  All materials to be used in the study, including interview guides, survey questionnaires, data collection tools (databases, apps for tablets/smartphones), and any other equipment should be available at the start of the study and tested for functionality.

• **Primary data collection and analysis.**
  When all staff and study materials have been prepared, primary data collection can be initiated. **Note that this can only begin after receiving all ethics approvals.**

• **Writing up the study’s findings**
  Once the analysis is complete, the next step is usually writing an article for publication in a peer-reviewed journal. It is a good strategy to choose your journal before writing the draft, and to follow the journal’s author guidelines to do it right the first time. Writing support is available through the OR team. Be sure all authors meet the ICMJE’s authorship guidelines and all must sign off on the submission to the journal. Authors of LuxOR-based articles are encouraged to have the final draft reviewed by the Medical Editor before submission.

• **Preparations for policy & practice change, advocacy and communication measures**
  Based on the initial policy & practice assessment, a communication/engagement strategy should be prepared using the plan outlined in the protocol. The process can be supported by the OR Advisor or by the LuxOR Policy & Practice Advisor.
• **Closure**

After completion of the analysis, study materials need to be appropriately secured. Study data must be stored in a secure location for five to seven years, depending on the jurisdiction of the study. The data cannot be reanalyzed for a new study unless the participants have agreed to this analysis. Any biological material must be disposed. Details of what is stored where should be entered into ReMIT, where the history of the study is recorded.

**STAGE 5 — DISSEMINATION OF OR FINDINGS, POLICY AND PRACTICE CHANGE**

The plans for disseminating the results outlined in the protocol should be followed. These may include an article for a peer-reviewed journal, or presentation at a national or international conference. It also must include feedback to the local community where the study took place as well as national partners. The OR Advisor is responsible for ensuring that the plans for dissemination and policy and practice change are implemented but ultimately, medical referents, field staff and other staff involved must contribute their parts.

*Figure 3. Dissemination and Policy and Practice*
Annex 1: Concept Note Template

Please note that all green-lighted concept notes will be uploaded on ReMIT, the Research Management and Impact Tool: [https://remit.oca.msf.org/](https://remit.oca.msf.org/)

<table>
<thead>
<tr>
<th>Date</th>
<th>Date of concept note send to OR Inbox: <a href="mailto:operationalresearch@brussels.msf.org">operationalresearch@brussels.msf.org</a></th>
</tr>
</thead>
<tbody>
<tr>
<td>Responsible/Contact person [Name + email]</td>
<td></td>
</tr>
<tr>
<td>1. Research Question</td>
<td>Describe the main study question in 1 sentence.</td>
</tr>
<tr>
<td>2. Key Objective</td>
<td>What do you want to achieve?</td>
</tr>
<tr>
<td>3. Secondary Objectives</td>
<td>State any secondary objectives you may see at this stage (if applicable)</td>
</tr>
<tr>
<td>4. Study Significance</td>
<td>- Why is this study relevant and a priority for MSF? &lt;br&gt; - What is the expected impact of this study at national or international level, internally and externally to MSF? &lt;br&gt; - Does the study contribute to an OCB research agenda /strategy document?</td>
</tr>
<tr>
<td>5. Study Site</td>
<td>- Study location/setting: describe where you propose doing the study and outline benefits/risks of proposed study sites &lt;br&gt; - Conflict: Are any study sites located in a conflict setting?</td>
</tr>
<tr>
<td>6. Methods Design</td>
<td>☐ Observational study &lt;br&gt; ☐ Randomized trial &lt;br&gt; ☐ Systematic review &lt;br&gt; ☐ Case report &lt;br&gt; ☐ Diagnostic study &lt;br&gt; ☐ Mixed methods study &lt;br&gt; ☐ Qualitative research &lt;br&gt; ☐ Quality improvement study &lt;br&gt; ☐ Prediction model &lt;br&gt; ☐ Other, please state ________</td>
</tr>
<tr>
<td>7. Literature Review &amp; Contacts</td>
<td>Briefly describe your desk research findings, also describe here any consultation you may have had with MSF actors and identified interest for the study</td>
</tr>
<tr>
<td>8. Methods: participants, procedures, analysis</td>
<td>Please provide as much information as possible but it not available yet, your research advisor will guide you through this &lt;br&gt; - Study participants: &lt;br&gt; - Data sources and collection: &lt;br&gt; - Data analysis:</td>
</tr>
<tr>
<td>9. Estimated Timeframe</td>
<td>Please indicate any potential conflicts with other project developments, as it is very important for the OR design &lt;br&gt; Please make an estimate on how long the study might take. Also provide suggested start date and/or reasons for time restrictions</td>
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<tr>
<td>10. Research Team</td>
<td>Describe the research team and human resources needed (e.g. statistician, input from other specialists, field time)</td>
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| 11. Proposed Partners, Local Resources and Collaborations | - Who else have you, or might you, involve?  
- Are national staff foreseen to be involved as co-investigators?  
- Are national authorities and/or other local actors involved? |
| 12. Risks and Ethical Concerns | Describe potential risks to patients. Also consider risks to not be able to complete the study (e.g. operational constraints, cooperation of authorities, financial resources...) |
| 13. Legal Risks | Have you identified any potential legal risks? |
| 14. Resources/Costs | Include cost estimate if known and if someone (Operational Cell, Medical Department, others) who have agreed on the budget needed. |

### Implementation/ impact and dissemination

| 15. Implementation/Impact | How do you expect to use findings within MSF and/or externally?  
Go back to the purpose statement – how will each expected impact be achieved? |
|---------------------------|------------------------------------------------------------------|
| 16. Dissemination of Findings | Describe how findings will be disseminated: including translation of research into booklets or other advocacy materials as appropriate.  
- MSF (project, mission, headquarters)  
- Towards participants  
- Community  
- In country partners (including MoH)  
- International dissemination (including WHO and other agencies, scientific publication) |

#### Agreements

**Authorship:** list possible authors (at least 1st and last)

### Acknowledged by (Yes, No, NA)

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Annex 2: Monitoring and Evaluation, Surveillance and Assessments

**Monitoring** activities in humanitarian action provide information on an ongoing basis for different users during a project’s life cycle. It differs from evaluation in that it tracks progress against objectives, providing opportunity to adjust a project’s operations. The subject of analysis is the project, and it provides MSF with data for evaluation at various times during a project’s life.

**Evaluation** is “the systematic and objective assessment of an on-going or completed humanitarian intervention, its design, implementation and results.” Evaluations usually use monitoring data to assess the design or strategy, implementation, and results of interventions of established MSF programs. They can also be designed specifically to assess a focused aspect of a project. Evaluation can be external or internal and provides capitalization and accountability, and sometimes project reorientation (i.e. changing objectives).

**OR** focuses on specific questions that are deemed important for MSF to answer in order to improve their programs, provide evidence for changing policy and practice or explore how new approaches fare in marginalized communities. The research questions usually arise from a more distant perspective than that of a single project, but may use a project’s data to answer them. OR often uses routinely-collected project data, but not always, as other research methods can be employed such as qualitative methods, mixed methods or even systematic reviews. Thus, OR can be intimately involved with monitoring and evaluation, but has a different perspective.

**Surveillance** in public health is “the continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice.” Surveillance systems are essential to offer warnings of public health emergencies and support the epidemiology of health issues. A surveillance system consists of on-going collection of data, its analysis, the dissemination/feedback of the conclusions, and the implementation of a response based on those conclusions. Surveillance systems may collect information on mortality (crude, age, sex and cause specific), nutritional status, morbidity of significant public health concerns, diseases of epidemic potential and other additional indicators (e.g. food security, access to health). Surveillance also takes place at health structure level where data should be systematically collected, analyzed and interpreted to identify changes in presenting pathologies, increased incidence of complications and nosocomial infections.

**Assessment** aims to identify problems, their etiologies, and consequences, and to determine the best response. The priorities in any assessment are the current and potential future needs of a population within its context (political, economic, social and other) by considering the population

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14 OECD/DAC 2012

16 WHO definition of Surveillance in Public Health, [https://www.who.int/topics/public_health_surveillance/en/](https://www.who.int/topics/public_health_surveillance/en/)


18 Assessment Toolkit, PART I: PRACTICAL STEPS FOR THE ASSESSMENT OF HEALTH AND HUMANITARIAN CRISES (2012), Vienna Evaluation Unit, written by Alena Koscalova and edited by Sandra Bauer

19 Ibid
characteristics, knowledge, attitudes and practices towards a disease, and current coping mechanisms.
Annex 3: Policy and Practice Assessment

During the policy and practice assessment the following key questions need to be addressed. The Policy & Practice Referent in OCB should be involved in developing this strategy.

- What internal MSF practices or external policies and practices are the study findings likely to affect or change?
- Who are the key stakeholders concerned with a potential policy or practice change? What measures and products may be required to reach and convince them (e.g. published research, updated guidelines or protocols, toolkits, advocacy pieces, communication campaigns, health promotion, partner meetings)?
- How will uptake/impact of the research project be identified? What are the indicators for change and how are they expected to be measured and reported?
- Who is responsible for implementing recommendations within MSF as well as encouraging local partners or external partners (governments, donors, WHO) to do so?
- What financial and human resources are required to implement policy and practice changes and which MSF stakeholders need to be consulted to provide support?
- What is the timeframe for the dissemination strategy?
Annex 4: Generic Study Protocols

- Mortality Survey

- Nutrition Survey

- Qualitative research protocol outline
Annex 5: The Operational Research Team

The Principal Investigator (PI)

The PI, who could be from MSF or an external agency/institution, is the primary individual responsible for the entire research process from development of the study protocol, conduct and administration of the research, writing up the results, and ensuring dissemination. It is important that the PI remain consistent throughout the length of the study, including dissemination.

A Co-Principal Investigator (co-PI) may also be from MSF or an external institution. They should bring substantial technical knowledge to the project and be responsible for the overall conduct of the research along with the PI.

Co-Investigator

A Co-Investigator is considered a senior/key person who can devote a specified percentage of time to the project. Co-investigators should bring technical and/or substantive research experience and commit to reviewing all project-related documents and materials. Their role and responsibility during development, implementation, and dissemination of the research project should be clearly specified in the protocol.

Individuals who are eligible to be a co-investigator include the project or mission epidemiologist, medical coordinator, appropriate medical referent, head of mission and field coordinator, as well as medical and paramedical practitioners in the field. This is not an exhaustive list and the appointment of co-investigators will be study specific. Co-investigators may include national representatives, and partners from other organizations offering opportunities for local researchers to advance their research skills.
Annex 6: The MSF OCB Operational Research Units

OR has become increasingly integrated into MSF OCB program activities and during the last decade the organization has expanded human resources to facilitate OR with dedicated units in Luxembourg (LuxOR), South Africa (SAMU) and Brazil (BRAMU). OCB has helped develop the SORT IT OR training course (now with WHO) which builds OR capacity in low and middle-income countries; MSF has established an ethics review board (ERB), an innovation fund and an online publications repository (https://fieldresearch.msf.org/msf and ReMIT). MSF regularly contributes to major scientific conferences and hosts annual research events such as the OCB Operational Research Day, Epicentre Day, UK Scientific Day and Pediatric Days. MSF OCB authors publish a large number of studies in peer reviewed scientific journals enhancing MSF’s scientific credibility.

LuxOR

The Operational Research Unit, LuxOR, is part of the Medical Department of OCB under the umbrella of MSF-Luxembourg. It is responsible for overseeing the research inventory for OCB and coordinates and conducts research projects in close collaboration with field teams and international partners. The unit plays an active role in disseminating research findings within the international MSF-movement and partner organizations and advocating for evidence-based policy and practice changes.

The LuxOR team is currently composed of an OCB-OR Coordinator/LuxOR Director, a Program Officer, a qualitative researcher, four senior researchers, a Policy, Practice & Communications advisor, a medical editor, a medical data analyst and other ad hoc personnel all of whom have program, research and publications skills.

The research team provides:

➢ OR support in a wide range of research domains in cooperation with operations and medical referents
➢ Research capacity building through training and educational programs such as SORT-IT
➢ Support for quality data collection and analysis in MSF programs; training and supervision for data managers
➢ Technical support and advice to the epidemiologists’ pool
➢ Support to field teams and researchers to develop OR protocols and prepare publications for scientific journals
➢ Support and training on qualitative research methodology
➢ Maintains the online repository, MSF Field Research, that archives and makes available all MSF-authored articles published in peer reviewed journals free of charge.

Each research domain is followed by one of the members of the team who act as Research Focal Points (see Figure 4).
Figure 4. Key Operational Research domains assigned to OR focal persons

SAMU (Southern African Medical Unit)

SAMU is an OCB decentralized medical unit in South Africa and has a direct functional relationship with LuxOR regarding operational research activities; it autonomously manages the HIV/TB and Hepatitis research files. SAMU provides technical support to field epidemiologists in the region.

BRAMU

The Brazilian Medical Unit (BRAMU) provides technical support to activities related to migration, non-conventional situations of violence and emerging health issues. BRAMU incorporates interdisciplinary methods, including medical, epidemiological and social sciences. Currently, BRAMU is providing technical support to projects on migration and violence through the design, implementation of new/existing methodologies and tools as well as monitoring their impact on operations.

Other research capacity in the Medical Department

OR projects are also being carried out by other OCB partners such as the Middle Eastern North African (MENA) hub in Lebanon and medical units hosted in partner sections (Italy, Denmark). They often collaborate with the LuxOR team.
The Medical Director remains ultimately accountable for all medical activities undertaken by OCB, including medical research. The Medical Director has delegated overall responsibility for research to the OR Coordinator and has assigned several responsibilities, including ethics oversights, to other representatives of the Medical Department (Strategic Advisor), LuxOR (Medical Editor) and SAMU (OR Coordinator).

At LuxOR the implementation of research projects belongs to the research domains’ OR Advisors. They communicate with the medical and operational referents and support field teams in the allocation of OR human resources.

At SAMU the responsibility for implementation of OR projects is with the Country Focal Point (CFP), unless there is a specific delegation of responsibility. The CFP communicates with the cells’ medical referents on priorities and practicalities. At field level, responsibility lies with the Medical Coordinator. The CFP and the Medical Coordinator, with the advice of the OR Coordinator and technical advisors, assign a Principal Investigator (PI) to each study.

Relationship with the field

Currently, there is no line management between the field and OR members; field staff receives technical support and guidance but remain under the management of their respective mission or project referents.

Epicentre was founded as an association by MSF in 1986 to provide epidemiological expertise to underpin field operations. Currently, Epicentre conducts field epidemiology, observational and interventional studies, but also interventional trials, qualitative research and training. While the Epicentre HQ is in Paris, it collaborates with all MSF operational centers and international working groups. Epicentre has assigned several researchers to Brussels to collaborate with OCB projects and to work with the Emergency Unit on outbreaks.
Annex 7: Exemption Criteria - retrospective analysis of routinely-collected clinical data from pre-existing, established programs

See Field Research Website: https://fieldresearch.msf.org/handle/10144/618799

Template for exemptions of Routinely Collected Data

ExemptionTempl ative.doc
Annex 8: Ethics Considerations

All research conducted by MSF, with MSF investigators and/or including MSF patients, must have ethics review and approval. This approval must come from two sources:

- **MSF Ethics Review Board**
- **National Ethics Committee** of the country where the study will be implemented.

In some cases, approval must also be obtained from **Ethics Committees of research partners**, especially academic institutions.

**MSF Ethics Review Board (MSF ERB)**

MSF created its own stand-alone ERB in 2002 to serve all operational centers. Its members are not employees of MSF and the board is entirely independent of MSF. The ERB ensures that studies adhere to universal humanitarian imperatives of alleviating human suffering, preserving human dignity as well as protecting and respecting human rights regardless of race, creed, nationality or political belief. Given the unique context of most MSF projects, there are unique ethical challenges, which may not be captured by typical research ethics committees, and the MSF ERB takes them into account. In addition, the ERB also provides advice to MSF sections regarding other ethics issues beyond research considerations.

- **Study Protocol Submission**

Studies should be submitted to the MSF ERB when the protocol is finalized and validated by all investigators, contributors and supporters. ERB approval must be obtained before data collection can start; note that ethics approval cannot be given retrospectively. The submission dossier shall include:

- The full study protocol and its annexes such as informed consent forms, questionnaires, material transfer agreements,
- The completed MSF ERB submission template,
- CVs of the PI and Co-Pi. In cases when both PI and Co-PI are not very experienced, include the CV of the most experienced co-investigator who acts as a mentor for the research.

All documents must be provided in English and should be sent by the PI to the delegates of the medical director: for LuxOR - the Medical Editor; for SAMU – the OR Coordinator; and for all others, the Strategic Medical Advisor.

Depending on the protocol, its complexity and the potential risks for study participants, staff and MSF, the review usually takes between two to six weeks, but sometimes considerably longer.

Most reviews require the study authors to respond to methodological or ethics concerns raised by the ERB at least once. Responses to the reviews are prepared by the PI and include:

- a point by point response to the ERB’s comments,
- an amended protocol in track changes,
- a clean version of the amended protocol,
- any amended or new annexes in track changes.
All responses to reviews should be submitted to the ERB through the original delegate as above. Time to respond to ERB remarks should be as short as possible and not exceed six weeks.

- **Amendments after approval**

Any amendment to a protocol that occurs after MSF ERB approval will have to be resubmitted by the PI to the MSF ERB through the same process as above. Submission for approval of an amendment will need to include:

- a completed amendment form (see annex)
- a copy of the amended protocol with the amendments in track changes
- a clean version of the amended protocol
- any amended annexes with track changes or new annexes

- **Other notifications to MSF ERB**

In the following situations, the PI must notify the MSF ERB:

- delays in implementation (ie over one year); an extension form must be completed,
- the study has been cancelled or was stopped prematurely - see annex,
- any breach of study protocol,
- any severe adverse event occurring to any of the study participants.

- **Exemptions**

In order to reduce the workload of reviewing the large number of OR studies, the ERB put in place a procedure to exempt from full review some studies that were judged as low risk to participants and staff. There are two types of studies in this category:

1. Retrospective analyses of routinely-collected clinical data of pre-existing, established programs, provided:
   - they fulfill the seven criteria for exemption (see annex 8 or document on fieldresearch.msf.org\(^{20}\))
   - and the template for exemption is signed off by the medical director (or one of their delegates)

or

2. Three specific, pre-approved standardized surveys: retrospective mortality, vaccination coverage, and nutrition surveys, provided:
   - They follow the standard protocol validated by MSF ERB (see Annex 4 and on fieldresearch.msf.org\(^{21}\))
   - Validation must be obtained by the Medical Department Referent before the survey starts; no retrospective clearance will be accepted.

This exemption process does not exempt MSF from national ethics approval or from complying with any relevant regulatory requirements in the country from where the data originate.

\(^{20}\) [https://fieldresearch.msf.org/handle/10144/618667](https://fieldresearch.msf.org/handle/10144/618667)

\(^{21}\) [https://fieldresearch.msf.org/handle/10144/618942](https://fieldresearch.msf.org/handle/10144/618942)
National Ethics Committees

Every study must also be submitted to a National Ethics Committee to ensure transparency and accountability. Researchers (PI and Co-PI) should link with the Medical Coordinator to obtain information related to the country’s regulations including:

- contacts with the National Ethics Committee
- the submission procedure
- review timelines and costs
- possible exemption procedures.

Submission to a National Ethics Committee is the responsibility of the PI, but can be delegated to the Medical Coordinator if necessary and feasible. In countries with no established National Ethics Committee there may be alternatives such as an ethics committee of a national academic institution.

In exceptional cases, submission to a National Ethics Committee may not be possible. National authorities may be unwilling to have research conducted in the country or there may be legal issues that put the study participants, the project or research staff at risk. However, waiving the National Ethics Committee approval can only be possible by permission of the Medical Director. In these cases, the MSF ERB can only provide advice and cannot provide complete ethics approval since that would require local ethics approval.

• Other Ethics Committees

In cases where the research is planned in partnership with academic institutions, the partner is responsible for obtaining ethics approval from their own ethics committee.

Submission to the different ethics committees (MSF ERB, National Ethics Committee, partners) can be done in parallel, thus speeding up the process but, it is important to note that whenever amendments to a protocol are made in response to one committee’s review, the other committees must be notified. This strategy may cause some confusion and delay if there are multiple changes required by each committee, so that it may be wise to get MSF ERB approval before applying to a National Committee. Experience shows that MSF ERB is the most rigorous in reviewing protocols and therefore starting there might be a good option. Changes requested by the national ERB should be fed back to the MSF ERB.
Annex 9: Scientific Publications

Importance of scientific publications

Why publish OR? Publishing in peer-reviewed scientific journals is a form of "quality control". The credibility accorded to a study following publication is important when it comes to presenting evidence for discussing policy changes and can further enhance advocacy efforts.

Peer review is an integral part of this process and, although often laborious and time consuming, it is almost always a valuable process leading to improvements in a manuscript. Input from good peer reviewers results in better and stronger papers and enhances the message being delivered.

Publication of OR also facilitates wider dissemination and improved access to information that MSF has created. MSF policy is to use open access journals for publication, thereby offering readers in low and middle-income countries access to the information without cost.

The process of documenting experiences and lessons learned is a valuable process in itself revealing preconceptions and permitting critical reflection upon a program's impact and orientation.

Authorship

Deciding on who should or should not be included as a study author is sometimes difficult. This decision should be handled in a clear, transparent and fair manner right at the start of a project. While the actual contributions of individuals may change over time, and this might affect study authorship hierarchy, there should be general agreement on who will be the principal author and what the contributions and responsibilities of individual authors will be.

- **Study authors**

Peer reviewed journals quote international guidelines on study authorship as per the definition of the International Committee of Medical Journal Editors (ICJME): "Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; 3) give final approval of the version to be published; 4) Authors should meet all four conditions."

MSF-supported studies should have **MSF authors clearly identified**. The order of authors shall represent relative contributions of individuals in the study. There are no internationally published guidelines on this, but generally the first author does most of the work and gets most of the glory. The order of the rest of the authors generally reflects their relative contributions and while the final position is often given to the most senior "mentor” of the study, this is not a fixed rule.

All authors must send the final version of their manuscript before submission to a journal for approval to the LuxOR or SAMU Coordinator and the Medical Editor.

- **Acknowledgements**

Individuals who do not qualify as authors but who have contributed to an article should be listed in the Acknowledgements section. They should also be informed that they are being acknowledged and their signed consent may be required by the journal. Examples of those who might be acknowledged

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include technical advisors, data collectors, a department chair who provided general support, or individuals who were involved with routine care of patients under study. Financial and material support should also be acknowledged.

Open Access Publication

MSF has a policy regarding open access publishing which states that “MSF supports open access publishing and strongly encourages its authors to prioritize journals that offer full open access when deciding where to submit their papers. MSF also aims to make all its scientific research and commentary articles published in peer-reviewed journals available to the public free-of-charge on its website, MSF Field Research, within six months of publication, while respecting publishers’ copyright”.

Choosing a scientific Journal for the publication will depend on the journal’s subject interests, the readership, the type of study and the potential impact of the results. For OR, these factors are all more important than selecting a journal based on its impact factor. However, open access comes with a cost, and whenever possible MSF authors should ask for a reduction in fees or a waiver, based on MSF’s charitable status. At the same time, publication costs should be built into the planning stages of an article and they should be assigned to either the project in the field, or a financial line at HQ. Publication in journals that charge unusually high costs must be justifiable (eg very important study or high potential for large scale or very relevant policy changes) and validated by the Medical or Operational Director (who will bear the costs). Researchers should avoid searching for funding open access costs after their article is accepted for publication.

Abstract submission – Presentation at Conferences

OR results can also be presented in national or international conferences either orally or as posters. This aspect of dissemination should be part of the initial planning, to be discussed with the relevant referents, operations or the advocacy unit. Costs for presenting an abstract must also be considered in the planning stages.

Confirmation for submission for publication or of abstract/poster/presentations

Submission of a manuscript for publication in a peer reviewed journal or of an abstract for a conference should only be carried out when both the content and the possible budget issues have been approved: scientific validity should be confirmed by the relevant medical referents and OR focal persons; operational implications should be reviewed by the cell and mission coordination; the budget should be secured.
Annex 10: Health Data Protection Policy and Data Sharing Policy

As a medical humanitarian organization MSF collects and uses the data of patients and communities to respond to their health and welfare needs. MSF also uses the data it collects for different purposes such as program monitoring and evaluation, audits, advocacy and research. In handling all types of data, OR teams follow the MSF Health Data Protection Policy, available on MSF Field Research. Data protection must take into account:

1. How identifiable are the individual study participants, their families or community?
2. How many people are authorized to have access to the data, and how many possible points of breach of data protection exist?
3. In case of a breach, how many people can be affected by it and how serious would be the possible harm be if the data ended up in the wrong hands?

To comply with the above, the following provisions should be in place for every research project:

1. Only collect the data needed to answer the research questions – no fishing for results.
2. Whenever possible, data will be anonymized\(^{23}\) (no names, no other clear identifiers and no individual codes) or pseudonymized\(^{24}\) (names and direct identifiers are replaced by a code).
3. Data should only be shared among those people directly involved in the study (data minimization).
4. Study participants’ records, questionnaires, and files should be stored under lock and key during the study and retained in a secure environment after publication for five to seven years. The research database should be kept in a secure and password protected computer (ideally with no internet access).
5. Informed consent must be requested from participants (or their parent/guardian) for their participation in every study but different provisions will apply depending on the type of research:

   a. Prospective research
   
   Informed consent will always be required. It shall always include a clear explanation of the research and its objectives, how it will be implemented and what are the benefit/risks for the participants. In most cases the consent form will be signed by the participant (or their parent/guardian) but for studies that represent limited risks for the participants, or there is a reluctance to sign a document for security reasons, informed consent can be obtained verbally; this must be documented.

\(^{23}\)Anonymization - defines anonymous information, as ‘information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable’.

\(^{24}\)Pseudonymization is defined within the GDPR as “the processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information, as long as such additional information is kept separately and subject to technical and organizational measures to ensure non-attribution to an identified or identifiable individual” (Article 4(3b)).
The informed consent form may have an additional point regarding secondary use of the de-identified research data, as MSF may want to use it for further research or meta-analysis. Participants may refuse and if so this should be clearly documented in the patient database.

For biologic samples that will be sent to an external laboratory and/or will be stored for potential secondary research, participants must specifically give consent.

b. Retrospective research:
OR is often performed on data that has already been collected, either in routine programmatic or clinical activities or in surveys/assessments. In these cases, it is not possible to obtain informed consent. Possible strategies to address this include:

a. Requesting blanket consent from all patients in a project to use their de-identified data, via an opt-out policy when patients come for consultation.

b. In some cases, it may be possible to go back to the participants to ask for their consent, either because they are still under MSF’s care or because they are easily contacted.

c. In most cases, however, it is not possible to obtain the informed consent from the participants. In that case it might be possible to obtain a waiver of consent by the ethics committees. This will depend on the type of study, the study population and the related risks.

Sharing research data with third parties

Requests to share MSF research data can come from research partners, national authorities, the World Health Organization, scientific journals, and other researchers.

MSF recognizes the ethical responsibility to share de-identified research data openly, transparently and in a timely manner to support evidence for the greater public health good. However, appropriate safeguards need to be in place. Whenever the research includes a partner, a Data Sharing Agreement must be signed prior to implementation. The purpose of using the shared data and how it will be handled should be clearly identified. These requests should be discussed and validated by the Medical Director (or the Medical Strategic Advisor). It will be important to consider:

- What are the potential risks for the study participants and MSF
- Was the study protocol approved by the relevant ethics committees?
- Signing a Data Sharing Agreement (always in the case of secondary Research).
- Whether all provisions as set out in the Health Data Protection Policy and the Data Sharing Policy have been met.