

International Medical Corps Research Review Committee (RRC) Guidelines

Background

For more than three decades, International Medical Corps has provided lifesaving support to communities around the world through its relief, development and training activities. While it has previously engaged with external partners in operational research activities, it has not had a formal mechanism for defining its global research agenda and related priorities or evaluating specific research proposals.

The recent outbreak of Ebola Virus Disease (EVD) in West Africa both highlighted the dearth of published research to guide management for patients with EVD while also offering a wealth of opportunities to conduct clinical and operational research in order to improve the humanitarian response to future outbreaks. Concurrently, International Medical Corps evolved its technical expertise and agency capacity in the field of infectious diseases control through responding to the EVD outbreak in Liberia, Sierra Leone and Guinea as well as Emergency preparedness efforts in support to MOH in Mali. This response catalyzed our opportunity to engage in both clinical and social science research.

The goal of the Research Review Committee (RRC) is to provide a uniform format for evaluating internal and external proposals for research studies that will be funded by International Medical Corps; conducted at International Medical Corps facilities; or directly involve International Medical Corps programs or field staff.

Procedures

Submission

Prospective researchers should simply submit the following documents to the [RRC](#):

- 1) A formal research protocol (Appendix 1). This can be adapted from a protocol previously submitted for grant funding or ethical review.
- 2) A detailed explanation of the resources, activities and deliverables necessary to carry out the research with a delineation of which components will be provided by the research team and which will be provided by International Medical Corps (Appendix 2).
- 3) Proof of international ethical IRB approval and appropriate local approval for the research (required before project can begin but not before RRC submission).

Screening

The RRC will screen all submissions and summarize the primary logistical, scientific, and ethical considerations utilizing a standardized checklist to ensure that all requirements are met (Appendix 3). If needed, the RRC may schedule a brief meeting with the external researchers to clarify their research plan or answer any additional

questions as needed. The RRC may also provide guidance to external researchers, based on availability, to aid them in crafting their submission.

Primary Review

After initial submission of the necessary documents outlined above, the RRC members will have 10 days to review the proposal and respond to the investigators with their initial feedback and comments. Based on their review, the RRC may accept the proposal, invite the researchers to submit a revised proposal, or reject the proposal.

Secondary Review

Proposals that receive support for advancement from a majority of RRC members will be forwarded on for secondary review, which will involve consultation with relevant members of the country teams, field teams, and desk officers where the research will be implemented. In general, deference will be given to the field teams regarding the decision to implement a research study.

Depending on the research project, secondary review may also involve legal or financial review within International Medical Corps or review by external experts. The secondary review process will likely take 1-2 weeks.

The input from the field teams and others involved in the secondary review will be transmitted back to the RRC, which will attempt to make a final decision on the research proposal within one month of its original submission. If the RRC recommends that the proposal be advanced only if specific modifications are made, the proposal will be sent back to the sponsors for modification, after which the proposal may be returned to the RRC for reconsideration.

Implementation

After receiving final approval from the RRC, the research team will begin coordinating with the International Medical Corps country teams/field teams around implementation of the research study. In general, for external research proposals, it is expected that the research team will have full time staff in the country/area where the research will be conducted so that the burden of implementation does not fall on International Medical Corps field staff.

Appendix 1: Research Protocol

The research protocol should be no more than 4 pages, excluding references and attachments, and should include the following:

1. **Cover Page:** This should include a listing of the principal investigator, co-investigators, and institutional sponsors, as well as a brief summary of the research.
2. **Funding Source:** Existing or potential funding sources
3. **Background and Significance:** Presentation of the issue that is proposed to be the focus of the technology or area of research. A brief review of the significance, literature review, and justification of need for the activity to be carried out (e.g., gaps in services)
4. **Principal Aims and Hypothesis:** Clear statement of the principal aims and research hypothesis/learning question
5. **Study design:** type of study to be conducted (e.g. cross sectional study, clinical trial). Description of the population from which data will be collected and how they will be selected (e.g. multi-stage, cluster, randomized, LQAS, qualitative approaches, etc.) and inclusion/exclusion criteria
6. **Methods:** Outline of proposed analytic methods, including:
 - a. **Data sources:** defend adequacy in terms of the availability and quality of data
 - b. **Variables:** principal independent and dependent variables (potential confounding variables), or in the case of qualitative research: themes/topics to be explored – if applicable
 - c. **Analysis methods:** statistical analysis methods or qualitative data analysis methods
7. **Human subject/Beneficiary protection** (e.g. patient confidentiality, etc.)
8. **Ethical Review:** Plan for external ethical review, including both local and international ethical approval
9. **Deliverables:** dissemination plan including report of assessment, presentations, potential peer review journals for submission
10. **Timeline:** Including the period of preparation for the study, conduct of the study, and dissemination of results
11. **References**
12. **Annexes:** Supportive documents as needed (letters of support, prior studies, budgets, data collection tools, etc.)

Annex 2: Resource Listing

This should not be a formal budget, but rather a clear delineation of all the resources and activities necessary to carry out the research. The areas where International Medical Corps support will be needed should be clearly specified. Researchers can utilize the template below:

1. **Human Resources:** In general, dedicated research staff should carry out all research activities in order to minimize the burden on International Medical Corps staff. Clearly delineate the number of external staff that will be provided, their specific roles and training, how they will be recruited, and who will pay their salaries. When it is absolutely necessary for research activities to be carried out by International Medical Corps staff members, the number and types of staff who will be involved, the training they will be provided (if needed), and the specific types of activities they will need to carry out should be specified, including an assessment of the time it will take to carry out those activities.
2. **Logistics**
 - a. Housing: Specify where external research staff will be housed and who will pay the cost of their housing.
 - b. Food: Specify how food and water will be obtained for external research staff and who will pay the cost.
 - c. Transport: Specify the number of cars and drivers necessary for external staff or other study activities and who will pay the costs.
 - d. Communication: Specify who will provide external research staff with internet and mobile phones and pay the cost of airtime.
 - e. Medical evacuation: Specify who will be responsible for medical evacuation of research staff or medical evacuation insurance.
 - f. Office space: Specify the space that will be needed for the research staff to conduct their activities and what kinds of storage areas for study supplies, equipment, data forms, etc.?
3. **Equipment and Supplies:** This will vary significantly by study. In general, it is expected that all supplies and equipment related to the research study will be provided by the external sponsors, except for those supplies and equipment that would be utilized in normal operation by International Medical Corps staff at the facility. This should also include the printing or photocopying of data collection forms or other the utilization of other data collection instruments.
4. **Community Engagement:** Independent of local ethical approval, specify whether this research will also require engagement with local officials and community members and the role that International Medical Corps will be expected to play in facilitating that engagement. Include activities such as arranging meetings with local government officials or community members, supporting local radio announcements, etc.
5. **Dissemination:** Detail who will be involved in the analysis and write-up of research results and how those results will be disseminated both locally and internationally.

Appendix 3: Standard Research Review Checklist

Engagement	Met	Unmet	N/A	Comment
There is a technical focal point involved in this proposal				
There is a Principle Investigator, either external or internal, clearly identified				
There is collaboration between national and/or international partnering institutions				
Existing or Potential Funding Sources	Met	Unmet	N/A	Comment
There is a donor or potential donor identified for this research				
<i>[If budget is provided]</i> There are no potential funding gaps identified based on the proposed research and its respective budget				
There is no potential conflict of interest between the donor and the proposed research partner(s), including IMC				
Background and Assessment	Met	Unmet	N/A	Comment
There is sufficient evidence that defines the need for this intervention or study among the selected beneficiary population				
Review of existing knowledge shows a need for research on this intervention or issue				
Principle Aims and Hypothesis	Met	Unmet	N/A	Comment
The specific aims and hypothesis clearly address the needs of the beneficiary population stated in the background and assessment				
Answering the proposed research question has strong and practical potential to benefit the target population				
Study Design	Met	Unmet	N/A	Comment
The study design focuses on sustainable improvements in programming, local health care, physical infrastructure, and/or food systems				
<i>[for integrated operations research]</i> The study design is feasible for the existing IMC intervention(s)				
IMC and partner has the technical capacity to manage the proposed research				
Methods and Protection Issues	Met	Unmet	N/A	Comment
Research methodologies are in line with the study design				
<i>[for quantitative analyses]</i> Dependent, independent variables, potential confounders and effect modifiers, and data analysis are clearly stated				

Methods clearly define fair beneficiary selection criteria (inclusion and exclusion)				
There is a favorable risk-benefit ratio at the beneficiary or research participant and population level				
Methods include selected beneficiaries privacy, opportunity to withdraw, and well-being monitored, where applicable				
Ethics Review Requirements	Met	Unmet	N/A	Comment
The proposed research underwent or will undergo ethics review by an institution review board or similar committee				
Deliverables	Met	Unmet	N/A	Comment
Deliverables are feasible for the proposed research				
Deliverables include the communication of results to the beneficiary population, local communities, and government				
Timeline	Met	Unmet	N/A	Comment
Activities proposed are in line with the research and deliverables				
References	Met	Unmet	N/A	Comment
Literature, assessments, and other sources of information are valid and properly referenced in the proposed research				