



Epicentre Research Department

RESEARCH FAIRNESS INITIATIVE REPORT



ERD, Research Fairness Initiative Report

This RFI Report was produced according to the RFI guidelines that are current on the date of this publication. The RFI Guides and the criteria for validation of RFI Reports can be found on the RFI website (rfi.cohred.org). The publication of this report reflects the reporting organization's commitment to provide a fair and equitable research environment. The report has been validated by the RFI Team as compliant with current reporting criteria. The content of the report is the sole responsibility of the reporting organization. The Council on Health Research for Development does not endorse, nor take responsibility for, the specific content of the report.

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Glossary

AOU Assessment of Understanding
ARSO African Organization for Standardization
CAC Community Advisory Committee
CFAO Corporation for Africa & Overseas
CIOMS Council for International Guidelines of Medical Sciences
COHRED Council on Health Research for Development
DSA Data Sharing Agreement
ERB Ethics Review Board
ERD Epicentre Research Department
GCP Good Clinical Practices
GDPR General Data Protection Regulation
GFGP Good Financial Grant Practices
GPP Good Participatory Practices
ICH International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
IRB Institutional Review Boards
MSF Médecins Sans Frontières
MTA Material Transfer Agreement
NGO Non-Governmental Organization
PCR Polymerase Chain Reaction
PCV Pneumococcal Conjugate Vaccine
RFI Research Fairness Initiative
SOP Standard Operating Procedure
SDGs Sustainable Development Goals
WHO World Health Organization



Foreword

The development of an institution-wide research fairness improvement system – and the associated communication activities – is an integral part of the Epicentre 2020-2023 strategic plan, which aims – among others – to strengthen Epicentre's leadership in terms of promoting the highest standards in research, epidemiology, and training. As health determinants, key stakeholders, the global health agenda, and their consequences for populations change over time, Epicentre Research Department has a responsibility to promote the RFI as a continuously improved international standard for research, to promote the sustainability of research and the equitable distribution of the benefits of research. We aim to ensure that the outcomes of our research activities better inform public health decisions in humanitarian situations and improve access to quality healthcare.

Research fairness at Epicentre's Research Department is framed by policies and guidelines which aim – among other things – to promote fairness and justice in our research activities. More generally, the Research Department's values and work culture are in line with those of the Research Fairness Initiative, and promote transparency, equity, and fair partnerships in research.

Joining the Research Fairness Initiative is a unique opportunity for assessing our policies and practices, identifying areas for improvement, informing a plan for implementation of corrective actions, evaluating those activities, and elaborating strategic plans building on those achievements. It is also a chance to support an ambitious initiative promoting research equity and sustainability, creating a community of stakeholders with shared visions and values, and pushing for large-scale adoption of RFI as a research standard, in line with Epicentre Research Department's values.

Developing ERD's first RFI report provided valuable insights on specific areas with room for improvement. This allowed us to plan specific actions to address them. An implementation process of those actions is now in the planning phase. Specific goals non-exhaustively detailed in the "Summary of Short-Term Action" will be achieved within the next two years following the publication of ERD's first RFI report. These include documentation (SOPs, policies) and their implementation, reports, press & media actions, and more.

Activities will be monitored, evaluated, and reported in the follow-up RFI report submitted two years after certification. In the meantime, ERD will communicate on the Research Fairness Initiative, and encourage its partners to produce their first RFI report and start their certification process.

Executive Summary

Epicentre is a non-profit organization created in 1986 by and affiliated with Médecins Sans Frontières, which groups health professionals specializing in public health and epidemiology. Epicentre teams carry out research studies and offer their expertise to organizations requesting short-term field epidemiology studies in low- and middle-income countries. Responding to the direct and indirect effects of chronic and acute crises as well as to a general lack of access to basic health care in vulnerable populations through effective programs is a complex task that requires multiple competencies—all of which happen in an unpredictable environment-. There is frequently a lack of reliable data on disease burden and population demographics. Even where relevant data are present, the breakdown of health systems often means there is little access to these data for relevant analyses. Drugs, vaccines, diagnostics, and their programmatic delivery strategies are often woefully inadequate for vulnerable populations when transposed from rich country settings.

Epicentre Research Department's mission is to describe the health status of populations – to help prioritize activities – and to evaluate existing & new tools, strategies, and pharmaceutical products. We aim to perform research to help speed up the development of, and access to new and adapted healthcare innovations and improve care strategies. As commercial “pull” that may drive innovations is often absent in resource-poor settings, our focus is on projects which aim to fill this gap, allowing for the efficient testing, development, and scale-up of approaches that can improve medical practice. Our research and development activities are focused on late-stage developmental (phases II/III) and post-registration studies. Innovation activities may take the form of field trials or other approaches, to contribute to the improvement of national and international prevention and treatment protocols.

The Research Department aims to: contribute to the development and implementation of new vaccines, diagnostics, drugs, formulations, and programmatic strategies to improve MSF, and national and international guidelines while acquiring more knowledge; develop innovative approaches in data science to provide accurate and critical information for knowledge generation and decision-making; leverage partnerships with medical care providers, academic research institutes and policymakers, along with communities and authorities to ensure the relevance of our work and scalability; promote our innovative research model to improve access to new tools and information. Unlike other research models, Epicentre Research Department aims to have the capacity to conduct all aspects of study initiation, operations oversight, and dissemination.



Overview of the Research Fairness Initiative (RFI) and how ERD applied the RFI

Purpose of the RFI

The Research Fairness Initiative (RFI) is a continuous improvement system developed by the Council on Health Research for Development (COHRED) to improve the fairness, efficiency and impact of research collaborations globally. The RFI was created with the aim of improving global health, equity and development. However, the initiative may be, in principle, appropriate to any field of scientific collaboration, and it may be used by anyone who engages as actor or funder of research and research partnerships. A higher level of fairness in research has shown to result in greater efficiency and impact, longer-lasting partnerships, less conflict and reduced reputational risks. Hence, RFI is of relevance to stakeholders in any research collaboration where resources in research, administration and know-how may be distributed unequally. The RFI seeks to enable more capable research and innovation systems in every country to deal with the local, regional and global health and development challenges with a long-term view. The RFI is in direct support of the Sustainable Development Goals (SDGs) – particularly SDG 17 that is to ‘Strengthen the means of implementation and revitalize the global partnership for sustainable development’.

RFI domains, topics and indicators

The RFI is built on three domains which are each divided into five subtopics. Each topic is further subdivided into three indicators resulting in a total of 45 indicators. For each indicator, organizations are required to describe their current organizational practices, reference relevant standard operating procedures, policy directives or other written guidelines through an attachment or link, and to report on any future steps to improve that particular indicator over a two-year period.

Domain 1 - **Fairness of opportunity** – aims to improve the participation of all concerned in research at relevant stages of research development, often well before research even begins.

Domain 2 - **Fair process** – aims to improve fairness in how research is conducted and how research partnerships and programmes are implemented.

Domain 3 - **Fair sharing of benefits, costs and outcomes** – deals with improving fairness in sharing the costs, benefits and outcomes of research.

How ERD applied the RFI

ERD’s application to the RFI started with the production of the first RFI report in collaboration with the RFI team. A workgroup composed of ERD’s Director, Grant manager, and communication and reporting officer assessed how the Research Department carries out its research partnerships according to the model provided

by the Research Fairness Initiative. The Research Fairness Initiative report template was used to guide the whole process. For each topic, relevant policies and procedures were gathered and reviewed, and practices were assessed and documented in the draft report. Information meetings and collaborative brainstorming sessions were organized within Epicentre Research Department. The final drafts were then circulated to key members of the department such as senior staff, and section heads (laboratory, data management, and analysis, statistics, pharmacovigilance, etc.). After incorporating modifications based on feedback from key members of the Research Department, a final version was produced by the team in charge of the RFI at ERD. Before being submitted on the RFI platform, this version was validated by the director and key members of the department.



Domain 1

Fairness of Opportunity

Domain 1 aims to improve the participation of all concerned in research at relevant stages of research development often well before research even begins.

Increasing fairness of the opportunity that stakeholders have to influence studies or research programmes at the stage or stages where it most impacts on their own ability to learn, contribute or participate, provides a sound foundation for respect in the current and future research partnerships. Fairness of opportunity sets the scene for the fair and efficient research conduct and the fair and efficient sharing of costs and benefits later on. Partnerships with increasing respect for the interests and limitations of other partners last longer, work more efficiently, and create more resilience to overcome inevitable partnership stress productively.

Topic 1: Relevance to Communities in which Research is done

Why is 'relevance to communities' a Reporting Topic?

Focusing on the explicit national or institutional research priorities of partner/host institutions or countries maximises the potential for equality in research partnerships, from research preparation to conduct, to sharing benefits. Addressing the extent to which the research or innovation being undertaken is relevant to local communities can increase chances of translating important issues into sustainable solutions. Collaborative research that does not align with local interests risks fragmenting scarce expertise and resources of host countries or institutions.

Definitions:

Relevance to the population in which research is conducted: the justification for investing in research is that it may lead to 'new knowledge' that is generic and can be of global benefit. Where it involves human and animal participation, there is a well-developed body of research ethics guidelines that outline what are acceptable risks and benefits to these participants. Research ethics guidelines deal only very marginally with risks and benefits to communities in which research is conducted, and do deal hardly or not at all with risks and benefits of research on national research system capacities. This topic intends to make explicit what collaborative research does or should do to optimize the capacity that countries or populations have to use research collaborations to further their own research system, competitiveness and contributions to national development plans.

Existing Solution(s):

Adhering to stated international principles such as the principles of Alignment and Harmonisation outlined in the Paris Declaration.

Support host countries and institutions to set and regularly update their priorities in health, health research and innovation, and communicate these clearly.

Developing mutually acceptable agreements that can also deal with future priorities to ensure that this challenge does not result in stifling growth, innovation or expansion into other areas.

Visit the RFI website to see an increasing body of existing solutions, practices, and guidelines that you may want to incorporate in your organisation's research partnerships: <http://rfi.cohred.org>



1.1 Research priorities in communities where research is being conducted.

Attachments

Professional Development Policy
 Equality Policy
 Scientific Integrity Statement
 Charter of the Community Advisory Committee
 Guidance Document on Epidemiology

1.1.A

Please provide a narrative of how your organisation ensures that research is relevant to the communities in which it is conducted.

Answer:

The Obligations to Communities is a key ethical principle for Epicentre Research Department. It represents a range of possibilities, such as participatory action research, collaborative partnerships, work in consultation with the local population (see 2.2.B.i for details on the implementation of Community Advisory Committees), benefit-sharing and ensuring post-trial access.

Benefits are often societal in nature, such as obtaining new information about the causes of diseases, identifying health disparities across social groups, help speed up development & access of new and adapted healthcare innovations, improve care strategies, or the improvement of medical infrastructures as part of research projects, which in turn improves general access to these infrastructures (e.g., laboratories, health centers, digital surveillance, and alert management tools).

This relationship with the community, as well as strong links with NGOs, ministries and other local institutions, allows ERD to understand local and national priorities. Therefore, ERD only requests funding for projects that are consistent with these priorities.

Staff is local, for most on site hierarchical positions and in most countries where our research takes place. Health research priorities are determined in consultation among the staff of various locations and specializations (epidemiology, data science, statistics, laboratory sciences). In addition, Epicentre Research Department works in close collaboration with local NGOs, Ministries of Health, and Universities.

This approach allows to elaborate relevant long-term strategies through strong partnerships. For example, Epicentre Research Department in Uganda formed partnerships with the Ministry of Health, the Mbarara University of Science & Technology, and the Mbarara Regional Referral Hospital, and invested in the infrastructure through creation of a high-level laboratory. Studies conducted by Epicentre Uganda have led to improvements in treatment and prevention protocols benefiting the Ugandan population.

Close relationships with local authorities allow for rapid deployment of responses to crisis. In March 2020, Epicentre Research Department launched a national COVID-19 surveillance and alert program in Niger, coordinated by the Ministry of Health (MOH). Since the beginning of the COVID-19 crisis, Epicentre Research Department and the Ministry of Health teams have carried out more than 10,000 investigations in the country. As the system used to monitor COVID-19 cases has proved its worth in an emergency context, the consortium has now extended the use of this tool to the main diseases with epidemic potential in the country, such as cholera, malaria, meningitis, and measles. Raising awareness on community-based surveillance and training of local community health workers and health facility managers ensure the sustainability of this tool.

The Rotavirus Vaccine Safety and Efficacy study (or ROSE) is also great example of meaningful collaboration between Epicentre Research Department, local institutions, and communities in Niger. Rotavirus is the leading cause of severe diarrhea in the world. In Sub-Saharan Africa, 85% of children have been infected by the age of 18 months, with an estimated burden ranging from 200'000 to 500'000 deaths per year.

BRV-PV is a relatively inexpensive, heat-stable oral vaccine given to infants in three doses at the same time as routine immunizations. Its introduction into national immunization programs could help reduce the burden on already overstretched national programs throughout sub-Saharan Africa. The primary objective of this study was to estimate the efficacy of three doses of the BRV-PV vaccine versus placebo against severe rotavirus gastroenteritis in healthy infants in Niger.

WHO Prequalification is the primary route by which resource-limited countries can access safe and affordable vaccines. Evidence of the efficacy, safety, and immunogenicity of the BRV-PV vaccine in an African setting would support prequalification of this formulation and increase global access. If proven effective and prequalified, the government of Niger would benefit from a low-cost vaccine tailored to the logistical and supply requirements of the national immunization program.

The positive results of the ROSE study, conducted in collaboration with the Niger Ministry of Public Health, established the efficacy and safety of BRV-PV, named RotaSiIL, and led Serum Institute of India to apply to market RotaSiIL in Niger. The marketing authorization was granted by the Niger Ministry of Public Health, making Niger the first African country to register RotaSiIL. A direct benefit of this study to the local community was the donation of 150,000 doses of RotaSiIL by Serum Institute of India private limited to the Niger Ministry of Public Health. In addition, RotaSiIL has been prequalified by WHO and is now available for use in sub-Saharan African countries.

Notes:

None.



1.1.B

Does your organisation have institutional policies or practices in place regarding conducting research in line with the priorities of countries and populations in which you conduct research?

Answer:

Yes we have a formal (written) policy in place

Notes:

- Professional Development Policy
 - Equality Policy
 - Scientific Integrity Statement
 - Epidemiology Guidance Document
 - Charter of the Community Advisory Committee
-

1.1.C

Does your organization plan to formalize these practices or make them explicit? * mandatory if above answer is chosen. Same should be for all answers with this structure across the questionnaire.

Answer:

Not applicable

Notes:

None.

1.1.D

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

None.

Notes:

None.

1.1.E

What steps does your organisation intend to take in the next one or two years to improve its policy and practice of addressing the research priorities of communities and countries where collaborative research is being conducted?

Answer:

Epicentre Research Department aims to perform research to help speed up development & access of new and adapted healthcare innovations and improve care strategies. As commercial “pull” that may drive innovations is often absent in resource-poor settings, our focus is and will remain on projects which aim to fill this gap, allowing for the efficient testing, development and scale-up of approaches that can improve medical practice.

Ensuring responsiveness to the needs of patients and populations requires consistent interaction. Partnerships may range from informal consultations and networking to the Research Department leading a multi-country and multi-partner consortium. Understanding of the research and innovations landscape in the areas where we work is also essential to ensuring successful projects.

Finally, contributing to the career progression of ERD staff members regardless of location allows them to acquire the necessary skills for supervisory and/or management positions. Communication and visibility are a core component to ensuring the longevity of the center and ensuring policy uptake. Greater visibility also helps to ensure that research needs are stimulated from the South.

These goals are part of Epicentre’s strategic plan for the Research Department (2020-2022).

Notes:

None.

1.1.F

Please indicate what priority level your institution assigns indicator 1.1. for improvement

Answer:

High – to be dealt with in the next 2 years

Notes:

None.



1.2 Actions if there are no research priorities.

Attachments

None

1.2.A

Does your organization have institutional policies or practices in place regarding how to proceed when – with reasonable efforts – it cannot find “credibly set and regularly updated” research priorities for the population concerned?

Answer:

We don't have any policies or practices in place

Notes:

None.

1.2.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

1.2.C

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

This is not applicable. Our approach relies on partnerships with medical care providers, academic research institutes and policymakers, along with communities and authorities to ensure the relevance of our work and scalability. Research priorities are set with, or, according to the suggestions of, local populations and local authorities. There are always research priorities and new research priorities emerging.

Notes:

None.

1.2.D

What steps does your organization intend to take in the next one or two years to improve regarding conducting research in situations where there is no clearly formulated research agenda? If you provide efforts to support countries or regions to develop their research agenda as part of your engagement, please state that here and provide examples.

Answer:

Not applicable

Notes:

None.

1.2.E

Please indicate what priority level your institution assigns indicator 1.2. for improvement

Answer:

High – to be dealt with in the next 2 years

Notes:

None.



1.3 Justification to research low priority topics.

Attachments

Epidemiology Guidance Document

1.3.A

Does your organisation have policies or practices in place regarding how it justifies the choice of research topic if the proposed research does not directly address the priorities of the population in which it will be conducted?

Answer:

Yes we have a formal (written) policy in place

Notes:

Subsection 2.5 Ethical Considerations – Guidance Document on Epidemiology

1.3.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

1.3.C

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

As mentioned below in point 1.2.A.i., our approach relies on partnerships with medical care providers, academic research institutes and policymakers, along with communities and authorities to ensure the relevance of our work and scalability. Therefore, research priorities are set with, or, according to the suggestions of, local populations and local authorities. In addition, all Epicentre Research Department Research is subject to ethics review and approval by local regulatory authorities in the study countries, whether mandatory or not. This is done to ensure that studies

or activities are relevant for the country, designed to conform with international ethical standards, and to protect the rights and welfare of participants.

Notes:

None.

1.3.D

What steps does your organisation intend to take in the next one or two years to improve its policy and practice of conducting research in situations where the research your conduct does not clearly address the research agenda?

Answer:

Not applicable

Notes:

None.

1.3.E

Please indicate what priority level your institution assigns indicator 1.3. for improvement

Answer:

Low – to be dealt with in the next 6 years

Notes:

Not applicable



Topic 2: Early Engagement of Partners

Why is 'Early Engagement of Partners' a Reporting Topic?

Deciding on each partner's aims, methods and implementation goals and plans for participating in specific research collaborations at an early stage of the partnership is crucial to achieving mutual understanding on roles, responsibilities and contributions of individuals and institutions involved. It increases a sense of ownership and commitment resulting in increased performance and less disruptions.

Definitions

Partner engagement: An agreement made between all partners of roles, responsibilities and contributions made by individuals and/or institutions involved in the collaboration. It is negotiated rather than simply specified by a lead partner, research sponsor or business. It is done in writing and all partners have copies.

Existing Solution(s)

Research Partnerships Agreements come in many forms and formats, in almost all fields of scientific endeavour. Find them on the web, on the RFI website, or from your partners. They can take the form of formal contracts, Memoranda of Understanding (MOU) or Memoranda of Agreement (MOA), individual documents. There are no internationally acceptable standards at this stage but many countries, institutions, research funders and businesses use proprietary agreements.

2.1 Relationship between the ‘main/lead/sponsoring’ and ‘other’ partners

Attachments

Scientific Integrity Statement
Research Collaboration Agreement Template

2.1.A

Please describe how your organisation works towards engaging partners at an early stage, to ensure fair involvement of all

Answer:

Although Epicentre Research Department occasionally works with partners and subcontractors, our projects are mainly conducted at Epicentre in Niger (Niamey, Maradi) and Uganda (Mbarara). Epicentre Research Department includes Epicentre Niger with headquarters in the capital (Niamey), a research center in Maradi and study sites in the region of Maradi; Epicentre Uganda with headquarters and a research center in Mbarara, and the Research Department in Epicentre Paris.

When projects are carried out in other countries, our interventions and interaction with the communities are strongly linked to those of MSF, with whom we have a close relationship. All research activities undertaken by Epicentre Research Department are joint and democratic efforts between all Epicentre entities involved, but also with funders, countries where projects take place and potential consortium partners.

All projects involving partners are framed by a standardized Research Collaboration Agreement which formalizes the involvement of each partner, among others. All partners contributing to research are involved as early as possible in the preparation of a project. Responsibilities are defined collaboratively in the study protocol and the study's organizational chart.

To limit the potential influence of funding-bodies in decision-making processes, funders are removed as much as possible from the study decision-making processes. All efforts are made to ensure scientific integrity, meaning that information will be shared with funders and manufacturers of medical products, but will not be subject to their approval.

Most exchanges on study conduct are documented by minutes that are circulated among all research partners for approval and accountability. If any members of a funding body or manufacturer of medical product are an integral part of discussions and interpretation of results, this will be stated in internal and external communications.

Notes:



None.

2.1.B

Does your organisation have a policy or practice in place regarding early engagement of partners, enabling them to influence focus, study design / protocol development, financing and implementation?

Answer:

Yes we have a formal (written) policy in place

Notes:

None.

2.1.C

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

2.1.D

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

None.

Notes:

None.

2.1.E

What steps does your organisation intend to take in the next one or two years to improve its policy and practice of dealing fairly and productively with the relationships in unequal partnerships?

Answer:

Epicentre Research Department's legal team will update the standardized Research collaboration agreement on a regular basis and ensure that legal advice be provided to partners, if necessary.

Notes:

None.

2.1.F

Please indicate what priority level your institution assigns indicator 2.1. for improvement

Answer:

Medium – to be dealt with in the next 4 years

Notes:

None.



2.2 SOPs for supportive actions to partners

Attachments

CAC Charter

2.2.A

Does your organisation have an institutional policy or practice in place for identify areas for focusing capacity building in partners included in research programmes?

Answer:

Yes we currently have informal practices in place but they aren't explicitly written down

Notes:

None.

2.2.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

Yes

Notes:

None.

2.2.C

In instances where you are the partner with less capacity – does your organisation have policies or practices in place requiring capacity building efforts for your own institution as part of the partnership agreement?

Answer:

Yes we currently have informal practices in place but they aren't explicitly written down

Notes:

None.

2.2.D

Does your organization plan to formalize these practices or make them explicit?

Answer:

Yes

Notes:

None.

2.2.E

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

The Research Department's team actively seeks collaborative professional development grants. These include projects that promote sustainable local health research capacity in Africa, based on the vision that building sustainable capacity requires the development of research leadership. This vision is informed by, and aligned with, key continental health strategies and development plans. The African Union's Agenda 2063, in line with Sustainable Development Goal 3, recognizes health as a critical factor in the continent's economic progress and has highlighted healthy and well-nourished citizens as a strategic goal.

Epicentre Research Department is an advocate for African-led research solving Africa's health problems. To achieve this, we seek for grants that will allow us to combine the building of local research capacity with the conduct of research that is locally relevant and responsive to common and emerging health issues in Africa. Our focus is on collaborative projects with organizations and authorities to mutually provide operational support, training, mentorship, competence development and sharing for researchers, medical staff, technical staff, and supervisors.

Although Epicentre Research Department occasionally works with partners and subcontractors, our projects are mainly conducted at Epicentre in Niger (Niamey, Maradi) and Uganda (Mbarara). The sustainability and improvement of Epicentre Research Centers' capacities is a major stake and imply continuous professional development to ensure a clear pathway to sustainability. This is done through providing opportunities for medical and scientific staff in various locations and/or institutions to receive additional training and further their careers, encouraging medical and scientific staff to be mentored and mentor others to sustain a vibrant research culture, providing opportunities for staff to promote visibility and



encourage discussion on the issues most pressing to them in terms of medical research.

Epicentre Research Department also takes part in infrastructure development and professional development projects. They range from setting up a PCR laboratory in Niger during the COVID-19 pandemic or the improvement of infrastructures and practices to ensure that our sites in Niger are ready to begin Phase 3 vaccine trials; to providing staff with access to higher degrees and experience in various locations and strengthening Epicentre Research Department's relations with local authorities to enable a rapid response in case of crisis and quality collaborations.

Finally, overhead allocation is divided between structural costs, Epicentre Niger operating costs, Epicentre Uganda operating costs, and improvement projects within the research department. Separate grants are sought after for infrastructure development and professional development.

Notes:

None.

2.2.F

What steps does your organisation intend to take in the next one or two years to improve its policy and practice of early engagement and inclusion of partners in decision making?

Answer:

Epicentre Research Department has formalized the implementation of local Community Advisory Committees that will actively participate in the studies conducted by the Research Department.

Successful biomedical and behavioral research requires the active participation of all stakeholders, including the communities in which studies are conducted. Community involvement builds trust and mutual understanding of the research questions and ensures respect for community values and cultural sensitivities. Community participation also generates important contextual information about the setting and acceptance of the study.

The overall goal of Community Advisory Committees (CAC) is to ensure that the research team and the community work in partnership to achieve the objectives of the various studies. CACs are established to foster a partnership between Epicentre study teams and members of the communities in which studies are conducted. The CAC is composed solely of volunteers representing the community.

The objectives of the CAC are to:

- Strengthen communication with study participants
- Help highlight areas of public health concern for the community

- Contribute to the development and implementation of research studies to ensure that they are appropriate for the community
- Contribute to an ongoing dialogue with study teams by providing meaningful information about the communities involved
- Communicate all community concerns (both negative and positive) to study teams for consistent analysis

Notes:

None.

2.2.G

Please indicate what priority level your institution assigns indicator 2.2. for improvement

Answer:

Medium – to be dealt with in the next 4 years

Notes:

None.



Topic 3: Making Contributions of Partners Explicit

Why is 'Making Contributions of Partners Explicit' a Reporting Topic?

The essence of high quality partnerships is good contracting . Many of the conditions conducive to good research and innovation partnerships can be arranged through expert contract negotiation. In most research partnerships, the expertise needed for negotiations and contracting is highly skewed.

Definitions

Adequate contracting competence: The capacity to be able to negotiate and conclude high quality and precise contracts between two or more partners while ensuring fair contribution and fair value of the partnerships for one's own organisation. Making contributions explicit does involve written agreements, MOUs or contracts or any combination. Negotiating contracts is different from the technical and legal aspects of contracts. Both 'contract negotiation skills' and 'contracting expertise' are essential competencies for all partners in a collaboration.

Timely contracting

Enabling all prospective partners to participate in all aspects of contract formulation at a time when changes to contracts can still be made.

Existing Solution(s)

Refer to existing guidelines like the KFPE principles. Establish a competent research contracting office at national and/or institutional level. It is probably no longer a 'fair' solution to contract with individuals in institutions instead, all contracting should be done through research contracting / management offices that are properly constituted. These offices are far better placed to ensure fairness to all including countries, communities and organisations and to maximize transparency (see later). Ensure that there is access to such competence for all stakeholders.

3.1 Role clarification in research partnerships

Attachments

Epidemiology Guidance Document
Sample Organizational Chart for studies

3.1.A

Please provide a narrative describing how your organisation takes steps to ensure that all partners roles and responsibilities are made explicit prior to research taking place.

Answer:

First, research protocol writing at Epicentre Research Department is designed as a collaborative effort between the relevant research partners. This document includes a clear statement of roles and associated responsibilities and is signed – at least – by the Study Director / Sponsor / Sponsor Representative; the Sponsor / Coordinating Institution; and the Principal Investigator / Sponsor's Investigator.

An organizational chart and a corresponding flow chart are then discussed among all research partners. Those describe the roles and responsibilities of each partner, as well as the flow of information between them. Please find attached a simplified sample organizational chart for studies which do not involve an investigational product. Each study has a unique organizational chart, and the terminology is adapted to each specific study.

Epicentre Research Department personnel – who are all permanent employees – change in these roles over time depending on their unique professional development needs. The position of the different partners in this organizational chart depends on their key roles and responsibilities in the project (Study Director / Sponsor / Sponsor's Representative; Sponsor / Coordinating Institution; Principal Investigator / Sponsor's Investigator / Coordinating Principal Investigator; Site Principal Investigator (PI) / Site Investigator; Co-Investigator; Other significant contributors).

Finally, all research collaborations are framed by a standardized Research Collaboration Agreement that addresses study conduct, protocol, roles & responsibilities, confidentiality, archiving, monitoring, publications, authorship, intellectual property rights, finance, and other aspects of the collaboration. This document is negotiated with each partner, tailored to each study, and ensures equitable partnerships and explicit roles and responsibilities prior to the start of research.

Developing study communications with a team of people can be a challenging task, especially when contribution to the final product can be unequal. Authorship represents an explicit way of assigning responsibility and giving credit for intellectual work, based on the honest contributions reflected in the final product.



Section 7.2 of the Epicentre Research Department's Guidance Document on Epidemiology addresses the following questions: Who merits authorship? Who is designated as the first and senior author of the resulting journal article? How should the rest of the authorship order be determined? Epicentre Research Department still has room for improvement in ensuring (first) authorship for national francophone staff, therefore promoting their contribution to published work (see Sub-section 7.2 Authorship – Guidance Document on Epidemiology).

Epicentre Research Department is committed to improve program outcomes in relation to medical care and prevention, to assess the feasibility of new strategies or interventions, and to advocate for policy change. For these outcomes to occur, the knowledge gained from the conduct of research must be effectively communicated to the appropriate people. This requires translation into a form applicable to a target population, and communication to populations in a relevant and meaningful way. Sharing research findings aims to improve health through long-term behavior change, program adoption, organizational change, or policy adoption.

Participants and communities should be made aware of the results of the study or activity for which their data was used, regardless of the size or nature of the activity or study. This is done with the help of the Community Advisory Committee through community meetings, presentations, leaflets, and other forms of communication appropriate to each context.

The Research Department follows WHO's Good Participatory Practices (GPP) guidelines. It provides systematic guidance on how to cooperate with stakeholders in the design and conduct of clinical trials and is applicable to other studies as well. Epicentre Research Department's GPP Workbook helps research teams plan, document, and organize their stakeholder engagement activities. The instructions facilitate the development of a comprehensive stakeholder engagement package at a particular research site.

The tools used for disseminating findings will depend on the type of study performed and the quality of the analysis. This can take the form of a research report, a descriptive paper, a targeted an evaluation, a press release, a policy brief, or a publication in a peer-reviewed journal. Epicentre Research Department makes every effort to ensure that articles appearing in peer-reviewed publications are available to individuals for free (see Section 7. Communication and Dissemination of Findings – Guidance Document on Epidemiology).

Notes:

None.

3.1.B

Does your organisation have policies or explicit statements on roles, responsibilities, fair contributions and fair benefits for all partners during research,

with regard to the key areas outlined in the list below? Authorship on any publication resulting from this study?

Answer:

Yes we have a formal (written) policy in place

Notes:

None.

3.1.C

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

3.1.D

Feedback to study population?

Answer:

Yes we have a formal (written) policy in place

Notes:

None.

3.1.E

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:



None.

3.1.F

Follow-up Actions. [Data ownership and Intellectual Property Rights related to research projects are dealt with separately later]?

Answer:

Yes we currently have informal practices in place but they aren't explicitly written down

Notes:

None.

3.1.G

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

3.1.H

SOPs for conflict resolution?

Answer:

Yes we have a formal (written) policy in place

Notes:

None.

3.1.I

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

3.1.J

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

None.

Notes:

None.

3.1.K

What steps does your organisation intend to take in the next one or two years to improve its policy and practice of dealing with these three issues in particular: sharing of authorship, feedback requirements to communities / populations where research was conducted, and requirements for follow up actions after research findings have been announced?

Answer:

Epicentre Research Department guidelines, policies, and practices are continually updated and improved, according to new guidelines and standards.

Notes:

None.

3.1.L

Please indicate what priority level your institution assigns indicator 3.1. for improvement

Answer:

Low – to be dealt with in the next 6 years



Notes:

None.

3.2 Making potential beneficial impact explicit before starting research.

Attachments

Informed Consent SOP
Epidemiology Guidance Document

3.2.A

Does your organisation have institutional policies or practices in place regarding making the potential benefits to participant populations explicit – at time of study and partnership development?

Answer:

Yes we have a formal (written) policy in place

Notes:

SOP PP02 – Informed Consent

Subsection 2.5 Ethical Considerations – Guidance Document on Epidemiology

3.2.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

3.2.C

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

Prior to implementing a project, ERD consults with local authorities, the community, and conducts mass awareness campaigns (e.g., for vaccination campaigns) when relevant. The development of protocol and consent documentation (e.g., ICF/IAF,



Informed consent SOPs) is an integral part of Epicentre's processes to make the potential benefits and risks of studies explicit to all potential participants.

Whether performing field epidemiology, observational studies, or interventional studies, Epicentre Research Department's activities are conducted with care for scientific rigor, minimizing harm and maximizing the benefits for participants.

This implies a free and informed consent process – tailored to each study – by which a participant voluntarily confirms his or her willingness to participate in a study/trial, after having been informed of all aspects of the trial that are relevant to the participant's decision to participate, including potential risks and potential individual or societal benefits. If new information that may be relevant to the participant's participation in the study, the participant is verbally informed in a timely manner. Consent can only be sought after ascertaining that the prospective participant has adequate understanding of the research. Therefore, study nurses, counselors or physicians administer an approved "Assessment of Understanding" (AOU) tool to verify that the participants understand the key concepts, risks, and benefits of the study. A participant may not be enrolled in the study if the AOU test is not passed.

Current guidelines for the conduct of clinical trials (ICH-GCP) do not provide explicit or standardized guidance on best practices for providing care for health problems that arise in clinical trials participants during their follow-up. In addition, Epicentre Research Department frequently conducts studies in contexts where participants do not have health insurance. Therefore, the Research Department is committed to ensure that study participants receive appropriate free medical care.

Epicentre Research Department covers all expenses related to Adverse Events, Serious Adverse Events or Suspected Unexpected Serious Adverse Reactions, as defined in the study protocol. The Research Department may also cover medical events other than Adverse or Serious Adverse Events for certain studies. If this is the case, it should be documented in the study protocol, consent forms, and information sheets. During community engagement exercises, this information will also have to be relayed to the target population.

Notes:

None.

3.2.D

What steps does your organisation intend to take in the next one or two years to improve on this, i.e. to make sure that a priori total benefit statements become part of contracts and partnership agreements?

Answer:

Epicentre Research Department's legal team continuously reviews and improves contracts and partnership agreements, to add elements and/or comply with new requirements and standards, which includes incorporating total benefit statements in contracts and partnership agreements.

Notes:

None.

3.2.E

Please indicate what priority level your institution assigns indicator 3.2. for improvement

Answer:

Low - to be dealt with in the next 6 years

Notes:

None.



Topic 4: Ensuring That Matching and Other Co-Financing Mechanisms Do Not Undermine Opportunities for Fair Participation of All Partners

Why is 'Ensuring That Matching and Other Co-Financing Mechanisms Do Not Undermine Partner Opportunities for Fair Participation of All Partners' a Reporting Topic?

'Co-payments' are increasingly expected as part of partnerships. This may imply equal financial contributions even though standard of living in one partner institution or country is substantially higher/lower than in another¹⁸. As a result, equality in payments are not usually possible, which is often a major reason why partnership equality suffers also in other areas, such as decision-making in study design or focus.

Definitions

Matching contributions: Usually, but not always, this is used in the sense of 'making equal financial contributions', though other ratios than 50/50 can also be specified.

Fair matching contributions

Specification of expected financial contributions that includes an accepted measure of weighing the financial contribution in terms of the partner's or partner country's overall income, standard of living, or purchasing power, or other measure of wealth.

Existing Solution(s)

Negotiate financial contributions in terms of i) roles and responsibilities in the collaboration, ii) using a weighed measure of ability to contribute financially. For countries, World Bank listings such as GDP, GNP or status as low, lower-middle, higher-middle- and high-income ranking can be used. Alternatively, organisational research budgets, hamburger equivalents, and others are available to create a weighing. There is no generally accepted standard to measure research specific weights at this time.

4.1 Equal co-financing.

Attachments

None

4.1.A

Please describe how your organization works towards promoting fairness in relation to co-financing and equitable contribution of partners to research.

Answer:

Not Applicable

Notes:

None.

4.1.B

Does your organisation have institutional policies or practices in place to deal with differences in spending ability between partners?

Answer:

We don't have any policies or practices in place

Notes:

None.

4.1.D

In particular, does your organisation consider the following issues: 'fair' co-financing in terms of financial contribution to total research expenditures

Answer:

Not applicable

Notes:

None.



4.1.C

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

4.1.D

In particular, does your organisation consider the following issues: 'fair' co-financing in terms of financial contribution to total research expenditures

Answer:

Not applicable

Notes:

None.

4.1.E

In particular, does your organisation consider the following issues: substantial differentials in currency strength and organisational budgets of partners in a partnership

Answer:

Not applicable

Notes:

None.

4.1.F

In particular, does your organisation consider the following issues: 'fair' or 'equitable' contributions if there are great differentials in purchasing power

Answer:

Not applicable

Notes:

None.

4.1.G

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

None.

Notes:

None.

4.1.H

What steps does your organisation intend to take in the next one or two years to improve its policy and practice of dealing with the relations between research partners that contribute or that can only contribute in unequal measure?

Answer:

None.

Notes:

None.

4.1.I

Please indicate what priority level your institution assigns indicator 4.1. for improvement

Answer:

None.

Notes:

None.



4.2 Alternatives to equal co-financing.

Attachments

None

4.2.A

Does your organisation have policies or practices in place regarding the measurement of non-financial contributions of partners?

Answer:

We don't have any policies or practices in place

Notes:

None.

4.2.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

4.2.C

If so, is equality in partnership defined beyond 'equal co-financing' or 'co-financing in proportion to benefits?

Answer:

Not applicable

Notes:

None.



4.2.D

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

None.

Notes:

None.

4.2.E

What steps does your organisation intend to take in the next one or two years to improve its policy and practice of dealing with measuring non-financial contributions to research collaborations and how this will be used to off-set financial contributions?

Answer:

None.

Notes:

None.

4.2.F

Please indicate what priority level your institution assigns indicator 4.2. for improvement

Answer:

None.

Notes:

None.

4.3 Research outside national priorities and co-financing.

Attachments

None

4.3.A

Does your organisation have institutional policies or practices in place regarding discounting the absence of matching in defining equity in the partnership in such cases – i.e. consider partners equal in spite of low or no financial or other contributions?

Answer:

We don't have any policies or practices in place

Notes:

None.

4.3.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

4.3.C

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

None.

Notes:

None.



4.3.D

What steps does your organisation intend to take in the next one or two years to improve its policy and practice of dealing with requirements for partner contributions when not dealing with institutional or national priorities?

Answer:

None.

Notes:

None.

4.3.E

Please indicate what priority level your institution assigns indicator 4.3. for improvement

Answer:

None.

Notes:

None.

Topic 5: Recognition of Unequal Research Management Capacities Between Partners and Providing for Appropriate Corrective Measures

Why is 'Recognition of Unequal Research Management Capacities Between Partners and Providing Appropriate Corrective Measures' a Reporting Topic?

Collaborations are key to research development^{19 20}. Successful collaborations do not just depend on field-specific research expertise. Successful collaborations are also crucially dependent on the institutional / organisational ability to manage all the processes surrounding actual research including project management, financial management, contracting and contract negotiations. A reduced capacity in any of these areas may mean reduced ability for some partners to obtain fair terms for collaboration, to guarantee financial transparency, or to deliver projects on time. For the entire partnership, important gaps in management capacity puts delivery and quality of research results, as well as reputations at risk. There is, therefore, a special responsibility for institutions in the role of 'lead partner' to assess key management competencies of partners and to provide appropriate supporting actions where needed, as part of beginning of research collaborations.

Definitions

Research management capacity: the ability to manage research projects and programmes in terms of financing, human resources, communication, contracting and contract negotiation, and logistics. It is a collective term for using the resources needed to successfully complete research projects or programmes with most efficient use of resources, while maximising impact. Research management is a complex field and few, if any organisation, government or business, has all competencies needed at least not in the same level of expertise.

NB. 'Research Management' is also used in a narrower sense: that of project management of individual research projects. For purposes of this RFI Reporting Guide, it is used in the broader sense outlined above.

Existing Solution(s)

COHRED provides specific expertise in contract negotiation and contracting through its Fair Research Contracting group. See: www.cohred.org/frc

The ESSENCE group of research funders provides a guide on research budgeting. See: http://www.who.int/tdr/publications/five_keys/en/.

In accounting, there are several international standards for financial reporting. Choose one of these.



5.1 Research Management Capacity

Attachments

Third Party Guide

5.1.A

Please provide a narrative describing how your organisation determines research and financial management capacities of partners, or if you are the partner with less capacity, how your organisation ensures that its own capacity in these areas can be increased in the partnership context.

Answer:

As mentioned in topic 2, our projects are conducted at Epicentre Research Centers in Niger (Niamey, Maradi) and Uganda (Mbarara) or MSF research centers. The sustainability and improvement of Epicentre Research Centers' capacities is a major stake and imply continuous professional development to ensure a clear pathway to sustainability. This is done through providing opportunities for medical and scientific staff in various locations and/or institutions to receive additional training to further their careers, encouraging medical and scientific staff to be mentored and mentor others to sustain a vibrant research culture, providing opportunities for staff to promote visibility and encourage discussion on the issues most pressing to them in terms of medical research. Staff from all locations work together daily and consistent mentoring is provided to the different staff members. For example, Epicentre Research Department's Grant Manager supervises and provides support to all financial managers.

Epicentre Research Department also takes part in infrastructure development and professional development projects. They range from setting up a PCR laboratory in Niger during the COVID-19 pandemic or the improvement of infrastructures and practices to ensure that our sites in Niger are ready to begin Phase 3 vaccine trials; to providing staff with access to higher degrees and strengthening Epicentre Research Department's relations with local authorities, to enable a rapid response in case of crisis and quality collaborations.

The approach to Epicentre Niger aims to provide a platform for the advancement of individuals as well as research in the country by proposing a model which does not rely upon diploma-driven or academic-centered professional development. Staff aim to contribute to positive change and advance their careers, but as the constraints linked to an academic career are not present, staff members aim for contributing to change rather than to scientific publication. Aspects of scientific publication are addressed on an individual basis, but do not form the basis for professional advancement.

The research center in Mbarara provides a platform to conduct high-quality studies necessitating significant financial, technical, and human resources over a long-time

period. Epicentre built upon the existing scientific infrastructure in Mbarara, formed partnerships with the University and invested in the infrastructure through creation of a high-level laboratory. Research Centre staff contribute to teaching in research methods, supervision, and mentorship in research to students from the Faculty of Medicine of the Mbarara University of Science and Technology. In addition, Epicentre laboratory staff contribute to modules for bachelor's and master's courses in microbiology, molecular biology, and medical laboratory sciences. Laboratory Science students can gain valuable experience in the Research Center's laboratory.

Notes:

None.

5.1.B

Does your organisation have institutional policies or practices in place for determining research management capacity of partners prior to entering into agreements – specifically when your organisation is the 'lead' partner in a research programme?

Answer:

Yes we have a formal (written) policy in place

Notes:

None.

5.1.C

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

Note: This is an extremely rare occurrence for Epicentre Research Department. The Research Department's Third-party guide is an overview of the minimum requirements to enter into a contractual relationship or partnership with the Research Department.



5.1.D

Do these policies or practices include mechanisms to increase research management capacity of partners when gaps are identified?

Answer:

Not applicable

Notes:

This is not included in the Third-party guide, but it is part of our informal practices. For more information, please refer to Topic 2, subsections 2. and 2.2, and subsection 5.1.A.v. below.

5.1.E

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

Prior to entering into an agreement with a partner, Epicentre Research Department discusses and evaluates the partner's ability to perform the tasks that will be included in the agreement. If weaknesses or difficulties are identified, Epicentre Research Department can provide support of various kinds: knowledge and skill sharing, supervision, mentoring, operational support, laboratory support, or data management support. This support is individualized to each partner, each subject, and tailored for each project.

Notes:

None.

5.1.F

What steps does your organisation intend to take in the next one or two years to improve its policy and practice dealing with research management assessment and taking of supportive actions as part of research collaborations?

Answer:

Epicentre Research Department will capitalize on the informal and punctual nature of the support we provide (for example support on COVID surveillance for the Ministry of Public Health in Niger, support on budget management for the INRB (Democratic Republic of Congo)) into a more formal approach.

Notes:

None.

5.1.G

Please indicate what priority level your institution assigns indicator 5.1. for improvement

Answer:

Medium – to be dealt with in the next 4 years

Notes:

None.



5.2 Financial Management Capacity

Attachments

Third Party Guide

5.2.A

Does your organisation have institutional policies or practices in place for determining financial management capacity of partners – specifically when your organisation is the ‘lead’ partner in a research programme?

Answer:

Yes we have a formal (written) policy in place

Notes:

None.

5.2.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

5.2.C

Do these policies or practices include mechanisms to increase financial management capacity of partners when gaps are identified?

Answer:

Yes

Notes:

None.

5.2.D

Does your organisation use internationally accepted accounting practices, and require your partners to also use these?

Answer:

Yes

Notes:

None.

5.2.E

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

None.

Notes:

None.

5.2.F

What steps does your organisation intend to take in the next one or two years to improve its policy and practice dealing with financial management assessment and taking of supportive actions as part of research collaborations?

Answer:

Epicentre Research Department is being certified for working in compliance with Good Financial Grant Practice (GFGP). GFGP is an international quality standard used in 43 countries, developed in collaboration with the African Organization for Standardization (ARSO) and a global community of grantors and grantees.

Certification to GFGP as a symbol of accountability and trust allows the Research Department to assure funders that we provide governance of their funds to the highest standards, enhances our ability to attract further funding and strengthens our grant management capabilities. Being listed as a GFGP certified organization includes the Research Department in a community which both private and corporate donors are searching to find trusted partners to fund.



Notes:

None.

5.2.G

Please indicate what priority level your institution assigns indicator 5.2. for improvement

Answer:

Medium – to be dealt with in the next 4 years

Notes:

None.

5.3 Contracting and Contract Negotiation capacity

Attachments

None

5.3.A

Does your organisation have institutional policies or practices in place for determining contracting and contract negotiation capacity of partners – specifically when your organisation is the 'lead' partner in a research programme?

Answer:

Yes we currently have informal practices in place but they aren't explicitly written down

Notes:

None.

5.3.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

No

Notes:

None.

5.3.C

Do these policies or practices include mechanisms to increase contracting and contract negotiation capacity of partners when gaps are identified?

Answer:

Yes

Notes:

None.



5.3.D

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

Our current practice is to ensure that any agreement for research is reviewed by our dedicated legal representative. This means that any deficiencies in dealing with partners are supported by legal support and review.

Notes:

None.

5.3.E

What steps does your organisation intend to take in the next one or two years to improve its policy and practice dealing with deficiencies in contracting capacities between partners in a research collaboration?

Answer:

ERD plans to work on further template agreements which can be shared with partners first, instead of them being sent to us for review and signature. Finally, After having received its GFGP certification, the Research Department is committed to encouraging all partners to achieve GFGP certification.

Notes:

None.

5.3.F

Please indicate what priority level your institution assigns indicator 5.3. for improvement

Answer:

Medium – to be dealt with in the next 4 years

Notes:

None.

Domain 2

Fair Process

Domain 2 aims to improve fairness in how research is conducted and research partnerships and programmes are implemented. Domain 2 encourages all who engage in research collaboration to make explicit their actions in five key aspects of research programme implementation. Expectations of different partners are usually different, sometimes very different. By creating clarity in how organisations deal with these challenges in principle and in practice, research stakeholders can reduce negative consequences of miscommunications or misunderstandings and can increase the capacity of all partners to live up to the expectations that others may have of them.



Topic 6: Minimising Negative Impact of Research Programmes on Systems

Why is 'Minimising Negative Impact of Research Programmes on Systems' a Reporting Topic?

Even when collaborative research focuses on research priorities of the population in which research is conducted, there may still be harmful effects for the community. Requesting that research collaborations and partners reflect not only on the potential benefits in terms of the research topic, but also on potential negative impact on other parts of communities and countries can help avoid harmful consequences.

Examples include:

Recruiting nurses out of the health service as trial monitors in a large clinical trial in resource- poor settings may deprive the health system of essential staff needed to deliver care.

External researchers may cause health, cultural or social harms through the manner in which research is being conducted, results are being reported or health interventions based on the research are being implemented if they do not have sufficient access to local expertise.

Externally funded research may take up the time and resources of nationally funded institutions and experts so that locally needed research may suffer.

Existing Solution(s)

Include an explicit review of 'side-effects' or 'non-intended consequences' and of 'opportunity costs' of research collaborations, especially where it concerns research in resource-poor populations or countries.

Engage local scientists and, where appropriate, community representatives in study design and implementation.

Ensure that communication between partners remains consistently high and examines potential negative impact throughout the collaboration.

Use existing guidelines for fair research partnerships and practice while preparing and conducting research are adopted during the research programme.

Find, modify and simplify existing (environmental, biodiversity, policy, etc.) impact assessment protocols, as there is no 'research impact assessment' tool available at this time.

6.1 Assessing potential or actual harm of research.

Attachments

Epidemiology Guidance Document

6.1.A

Please describe how your organisation takes measures to reduce the impact on research on national systems.

Answer:

Epicentre Research Department aims to be a driving force for positive change in national systems through advances in epidemiology and research to improve medical care for populations. Our activities are not alternatives to existing health structures, but rather support these systems through financial support for medical events, collaborations with national and local authorities, as well as donations and resource sharing with local health structures.

Epicentre Research Department maintains close links with Ministries of Health and other national institutions, and works with them whenever possible. The vast majority of staff working at Epicentre Research Department are local or from surrounding countries. This is true for all Epicentre locations, except for the Paris office, which has an international staff. We follow a strict salary scale to not disrupt the labor market in countries where we conduct research.

System impact assessment is included in the mandatory risk/benefit analysis prior to each study. As mentioned below in Topic 8, the purpose of ethical review is to ensure 1. that studies or activities are designed to comply with relevant standards and 2. that the rights and welfare of participants are protected and 3. that the risk-benefit ratio is favorable. This framework is meant to encourage our researchers to think critically about their protocols, justify their methods, think about possible harms and benefits, and consider what the implications of their research might be.

Risks posed by experimental trials are often greater than other types of risks. However, any type of research may result in burden. These risks are of particular concern in vulnerable populations. First, there are ethical considerations in the practice of programs and routine medical care, where participants must demonstrate the voluntary nature of their participation. Second, surveillance and program monitoring activities involve the regular, ongoing collection of data. The benefits of collecting the data must be balanced with the possible risks and harms to participants, such as the risk of confidentiality breach. Data should be anonymized and should not be collected if they will not be used, as per ICH GCP Guidelines.

Risks must be minimized, while anticipated harms must be minimized or mitigated, in order to achieve a positive risk/benefit ratio. Epicentre Research Department also



follows the guidance of the Médecins Sans Frontières Ethics Review Board (MSF ERB) as well as those of the national authorities. If the system impact assessment demonstrates unreasonable risks or an unfavorable risk/benefit ratio, we will not conduct the research. If unexpected adverse events occur during a study, Epicentre Research Department will pause the study and may terminate it.

Epicentre Research Department covers all expenses related to Adverse Events, Serious Adverse Events or Suspected Unexpected Serious Adverse Reactions (SUSARs) as defined in the study protocol. In some settings, medical events other than those mentioned above may be covered. If this is the case, it should be documented in the study protocol. For example, if the study takes place among children and/or other vulnerable people and/or in a rural area where access to care is limited, it is prudent to remove as many barriers to access to health care as possible.

Finally, if participation in research involves a significant commitment from participants in terms of time or effort, investigators may wish to provide compensation to reimburse them for these inconveniences (Lost wage, transportation costs, etc.). In these cases, during the informed consent process, the study team must explain to potential research participants: 1) the nature of the compensation for their participation in the research, and 2) expectations for receiving said compensation, especially if research participants withdraw prior to the study's completion.

Compensations should not be presented as a benefit of research. The level and kind of compensation must take into consideration the vulnerabilities of the research population to minimize the possibility of undue influence. Undue influence may impact the ability of prospective subjects to fairly evaluate potential research risks and make appropriate judgments about participation. It may also prompt subjects to conceal information that would exclude them from enrolling or continuing in a research study. Compensation and other inducements should be carefully considered and validated by ERBs.

Notes:

None.

6.1.B

Does your organisation have policies or practices in place regarding conducting 'system impact assessments' of partners – specifically when your organization is the 'lead' partner in a research programme – and particularly when conducting research in low-resource environments?

Answer:

Yes we have a formal (written) policy in place

Notes:

Subsection 2.5 Ethical Considerations – Guidance Document on Epidemiology

6.1.C

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

6.1.D

Do these policies include assessment of both potential and actual negative impact, and dissemination of results to partners?

Answer:

Yes

Notes:

None.

6.1.E

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

None.

Notes:

None.



6.1.F

What steps does your organisation intend to take in the next one or two years to improve its policy and practice related to impact assessment of research collaborations?

Answer:

The Research Department aims to actively seek for grants to improve it's team's capacity to conduct impact assessments, as this is a topic where we lack funding to do so.

Notes:

None.

6.1.G

Please indicate what priority level your institution assigns indicator 6.1. for improvement

Answer:

Medium – to be dealt with in the next 4 years

Notes:

None.

6.2 Reducing negative impact of research

Attachments

None

6.2.A

Should the 'system impact assessment' demonstrate potential for unintended harm to people or services, does your organisation have institutional policies or practices in place that enable research leaders to put in place preventive actions rapidly?

Answer:

Yes we have a formal (written) policy in place

Notes:

None.

6.2.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

Subsection 2.5 Ethical Considerations – Guidance Document on Epidemiology

6.2.C

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

As mentioned above, if the system impact assessment demonstrates unreasonable risks or an unfavorable risk/benefit ratio, we will not conduct the research. If unexpected adverse events occur during a study, Epicentre Research Department will pause the study and may terminate it.

Notes:



None.

6.2.D

What steps does your organisation intend to take in the next one or two years to improve its policy and practice related to preventing negative impact, if any, of research collaborations – especially in low-income countries and populations?

Answer:

Epicentre's Research Department updates its policies and procedures - including guidance documents and quality manuals which are reviewed every two years - to improve its practices and meet high international standards.

Notes:

None.

6.2.E

Please indicate what priority level your institution assigns indicator 6.2. for improvement

Answer:

High – to be dealt with in the next 2 years

Notes:

None.

6.3 Compensation for unintended (negative) consequences of research

Attachments

Medical Coverage for Participants in Studies

6.3.A

If, in spite of taking adequate preventive action, there are substantial negative consequences of research programmes for individuals, populations or countries, does your organisation have institutional policies or practices in place to deal with this effectively and adequately?

Answer:

Yes we have a formal (written) policy in place

Notes:

None.

6.3.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

6.3.C

Does your organisation involve all partners in this?

Answer:

Yes

Notes:

None.



6.3.D

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

6.3.E

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

Epicentre Research Department purchases insurance for each study for which it is responsible and ensures that it also covers partners, if applicable. Insurance costs are anticipated and included in project budgets.

The Research Department has also purchased insurance coverage for partners who are not covered for malpractice issues, as study insurance does not cover those. However, as an international medical humanitarian NGO, the Research Department does not hold its own liability coverage.

Notes:

None.

6.3.F

What steps does your organisation intend to take in the next one or two years to improve its policy and practice related to preventing negative impact, if any, of research collaborations – especially in low-income countries and populations?

Answer:

The Research Department will conduct an internal analysis to ensure that its insurance coverage is comprehensive. This is a necessary process to ensure the insurance extension granted to our potential partners is also comprehensive.

Notes:

None.

6.3.G

Please indicate what priority level your institution assigns indicator 6.3. for improvement

Answer:

Low - to be dealt with in the next 6 years

Notes:

None.



Topic 7: Fair Local Hiring, Training and Sourcing

Why is 'Fair Local Hiring, Training and Sourcing' a Reporting Topic?

The 'business of research' is a key benefit of engaging in research beyond the primary knowledge generation or product/service development. Salaries for consultants, purchase of consumables and hiring of external support services can multiply the health and economic impact of research and innovation to partners well beyond direct research equipment, facilities and salaries contributed to the partnership.

Failure to come to fair agreements is likely to deprive host institutions and countries of such benefits and to favour the lead institutions or sponsoring countries.

Definitions

Local sourcing and content: Refers to staff, facilities, consumables, or services used in research that are sourced from countries or institutions in which research partners are located.

Existing Solution(s)

An explicit assessment can be done of what can be (reasonably) sourced locally or regionally, including expertise, networks and business. A plan to maximize use of local resources should become part of a best practice contract.

There is a wealth of literature on 'research capacity building'. Use one of the many guides and guidelines available from the RFI Website resource pages: <http://rfi.cohred.org/relevant-source-documents-papers-books-and-websites/>

7.1 Local staffing and sourcing of consumables and services.

Attachments

Procurement Policy
Operations Manual
Professional Development Policy
Diversity and Equality policy

7.1.A

Please provide a paragraph describing how your organisation works towards promoting fair hiring, training of staff and sourcing of consumables locally

Answer:

The Research Department at Epicentre is an equal opportunity employer. The Department does not discriminate based on religion, color, national origin, medical situation (including pregnancy, childbirth, or other medical conditions), sexual orientation, gender identity, gender expression, age, status as an individual with a disability, or other applicable characteristics whether protected legally or not. All employees and applicants have the right to full and equal consideration based on merit and other relevant meaningful criteria. Practically, this implies that when faced with two equal CVs, and as far as possible, the Research Department will select the individual representing and belonging to an under-represented social group. Our commitment to the principles of equality, universality, equal pay, representation, participation, and non-discrimination is formalized in Epicentre Research Department's Diversity and Equality Policy. Epicentre Research Department uses a salary scale, identical to that used by MSF, which was approved by Epicentre's Board of Directors, and is accessible to all.

The majority of staff posts within Epicentre, such as field investigators, data managers, data sciences staff, laboratory technicians, investigators, monitors, epidemiologists, and statisticians require advanced training in technical areas. Development of research capacity involves, above all else, an investment in the creation of an enabling environment for future research and development of technical competencies through individual and departmental level trainings. The Research Department also focuses on the idea that staff broaden their professional development by spending time in various locations and institutions, providing them with exposure and development of skill sets.

Our training program spans three different areas. First, ongoing seminars and individual mentoring aim to provide a common knowledge base, understanding of the international research environment and interpersonal skills that enable all our personnel to take part in a shared culture, thereby ensuring cohesion within the group. Second, we provide ongoing development of professional skills, focusing on technical aspects for researchers. Third, we aim to address the need for professional advancement within everyone's career path. Continuing education allows Epicentre Research Department personnel to acquire the skills and knowledge required to



perform in their positions. This facilitates both internal advancement within the organization as well as providing opportunities for employment in other organizations.

An effective supply process is essential for Epicentre's Research Department to carry out its projects. As many other humanitarian actors, Epicentre Research Department is aware that the quality of drugs is not always properly guaranteed on the global market (WHO Medicines Strategy 2004-2007). Therefore, Epicentre Research Department selects products that have been pre-qualified by the WHO, or are registered in a highly regulated country, or have successfully passed the MSF evaluation & meet the WHO norms and standards. The general policy of the organization is to select its sources of pharmaceuticals and supply them to its teams wherever they operate and wherever it is authorized to do so. In some countries indeed, National Drug Authorities do not allow humanitarian organizations to import drugs. In such contexts, drugs are purchased on the domestic market and the responsibility to assure the quality of pharmaceuticals is incumbent on local authorities.

The supply chains to our projects involve mainly medical supplies, including drugs, medical devices, and specialized food, and therefore pose specific challenges. Non-medical products are important but represent a smaller proportion of our total turnover. For the latter, we always favor local sourcing. At Epicentre Research Department in Niger, for example, vehicles and electrical equipment, including generators, are purchased locally. Supplies and consumables for the offices and staff houses are purchased locally, and what cannot be purchased is ordered internationally. The same is true for mechanical parts: at the local level, we refer most often to the Corporation for Africa & Overseas (CFAO), as well as to spare parts sales establishments selected by the MSF mechanical reference for West Africa. If a part cannot be obtained, then it is ordered internationally.

Notes:

None.

7.1.E

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

7.1.F

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

None.

Notes:

None.

7.1.G

What steps does your organisation intend to take in the next one or two years to improve its policy and practice related to hiring local staff?

Answer:

The Research Department seeks to expand its efforts to guarantee equality of opportunity. Our objective is to achieve a staff composition representative of diversity, or at least in proportion to the median composition of currently available pools of candidates. To this end, the Department aims to broaden the pool of qualified candidates for job categories in which socio-cultural groups are underrepresented compared to current staff, especially when employment opportunities exist within supervisory posts. The Department also encourages staff representing underrepresented socio-cultural groups to participate in professional development activities, and to take advantage of mentoring and opportunities. The Research Department also commits to a gender integration process, i.e., “the process of assessing the implications for women and men of any planned action, including policies, in all areas and at all levels. It is a strategy for making women’s as well as men’s concerns and experiences an integral dimension of the design, implementation, monitoring and evaluation of policies and guidelines in all spheres so that women and men benefit equally, and inequality is not perpetuated. The goal is to achieve gender equality” (ECOSOC, 1997). Gender integration encompasses not only our staff composition, but also the conduct of our activities and research in terms of their design and implementation. We would finally like to further encourage dialogue between practitioners and researchers from different fields, and provide more networking opportunities for staff, especially for female scientists.

Notes:

None.



7.1.H

Please indicate what priority level your institution assigns indicator 7.1. for improvement

Answer:

High – to be dealt with in the next 2 years

Notes:

None.

7.2 Support for local capacity development.

Attachments

Professional Development Policy
Diversity and Equality policy
Procurement Policy

7.2.A

Does your organisation have institutional policies or practices in place to increase local staff and/or increase ability to produce quality products and services locally, when there is lack of availability of local expert staff, or inability to produce consumables or services of sufficient quality to satisfy research standards requirements?

Answer:

Yes we have a formal (written) policy in place

Notes:

None.

7.2.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

7.2.C

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

None.



Notes:

None.

7.2.D

What steps does your organisation intend to take in the next one or two years to improve its policy and practice related to local sourcing of consumables and services?

Answer:

As mentioned above and in our Procurement Policy, Epicentre Research Department always favors local sourcing over international sourcing for non-medical products and services such as maintenance of vehicles and electrical equipment. The continued improvement of laboratory capacity in Niger and Uganda contributes to local sourcing of consumables and services by reducing the need to send samples abroad for analysis and increasing our need for laboratory consumables. Epicentre Research Department's professional development policy supports local staff's ability to produce quality research and services locally. First, departmental level trainings, consistent mentorship, and inclusive & equal opportunity recruitment increases diversity among staff members, improves staff members qualifications and increases our understanding of staff qualifications and capacities. Second, leadership skills training and tailored training plans for medical and scientific staff improve staff technical competencies and staff qualifications, which allows trained staff to take-on supervisory positions, mentor, and train others. This strategy will result in an enlarged pool of competent supervisors and mentors, and an increased visibility and prominence of research centers. This contributes to an internationally and locally relevant research agenda by ensuring that the issues and concerns of populations where we work are included. The overall goal is to ensure that high-quality and ethical epidemiology and research is conducted with consistency and continuity.

Notes:

None.

7.2.E

Please indicate what priority level your institution assigns indicator 7.2. for improvement

Answer:

High – to be dealt with in the next 2 years

Notes:

None.



Topic 8: Respect for Authority of Local Ethics Review Systems

Why is having 'Respect for Authority of Local Ethics Review Systems' a Reporting Topic?

Research Ethics Review Committees (RECs) or Institutional Review Boards (IRBs) are essential components of good research systems. Besides aiming to maximise protection for people participating in research, RECs/IRBs have influence on study design, protocol execution, population selection, benefit sharing at individual, community and, sometimes, institutional and national levels. Lack of expertise results in one-sided reviews that may often not optimize protection and benefits of host countries, institutions or populations.

Existing Solution(s)

There are many REC/IRB training courses available around the world. Assessment of host expertise in this field may show deficiencies, in which case remedial steps can be taken, for example, specific additional training related to research topics or provision of a budget for a host to appoint a third party as a reviewer.

Install an expert support system, such as the RHInno Ethics platform (www.rhinno.net) or some of the many other ethics review capacity services available. Some are listed on the RFI website resource pages: <http://rfi.cohred.org/relevant-source-documents-papers-books-and-websites/>.

Most international ethics guidelines are widely read and accepted as best practice. Make an explicit statement in the RFI Report on which (one or more) are the foundation for your organisation's policies and practices in ethics review of research collaborations.

8.1 Research Ethics Approval

Attachments

Epidemiology Guidance Document
Quality Management Plan

8.1.A

Please provide a narrative describing how your organisation takes steps to make sure local ethics review systems are respected and supported.

Answer:

Research conducted by Epicentre Research Department is consistent with ethical standards and practices in the field of research. They have been defined as follows:

- In 2016 by CIOMS (Council for International Guidelines of Medical Sciences) and the World Health Organization in the International Guidelines for Ethics
- By the ethical principles for medical research involving human subjects defined in the Declaration of Helsinki by the World Medical Association

Scientific and methodological validity is a fundamental ethical prerequisite. Research must be scientifically valid, accurate and appropriate. Epicentre Research Department ensures that all its research activities are submitted to the appropriate local authorities and committees. All Epicentre Research Department research is subject to ethical review in the countries concerned and when appropriate, by the Ethics Committee of MSF. Ethical concerns relate primarily (but not exclusively) too:

- Harm Reduction
- Obligations towards communities
- Free and informed consent
- Privacy and confidentiality

Epicentre Research Department has guidelines to facilitate submissions of study protocols to national ethics review systems in countries where we work frequently (Ivory Coast, Ethiopia, Ghana, Guinea, Niger, Uganda). This is to ensure that the requirements of the countries in which we work are understood and respected.

Notes:

Subsection 2.5 Ethical Considerations – Guidance document on Epidemiology

Subsection 3.1 Ethical Review – Quality Management Plan

8.1.B

Does your organisation have institutional policies and practices for dealing with the ethics review of research in which you participate?



Answer:

Yes we have a formal (written) policy in place

Notes:

None.

8.1.C

Does your organization plan to formalize these practices or make them explicit?

Answer:

Yes

Notes:

None.

8.1.D

Do these specify the need for and process of finding local REC/IRB, and indicate where final responsibility for approval lies?

Answer:

Yes

Notes:

None.

8.1.E

Do these specify which international ethics guidelines are the basis for your organisation's policies and practices related to ethics review?

Answer:

Yes

Notes:

None.

8.1.F

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

None.

Notes:

None.

8.1.G

What steps does your organisation intend to take in the next one or two years to improve its policy and practice related to increasing respect for local ethics review of research in which your organisation is a partner?

Answer:

Epicentre Research Department will focus on updating the ethics documentation of the Guidance Document on Epidemiology that frame our work. In addition, we will update and extend the repository of guidelines for national ethics committees in all countries where we work.

Notes:

None.

8.1.H

Please indicate what priority level your institution assigns indicator 8.1. for improvement is a partner?

Answer:

Medium – to be dealt with in the next 4 years

Notes:

None.



8.2 Supporting local Research Ethics Review capacity

Attachments

None

8.2.A

Does your organisation institutional policies or practices in place to support REC/IRB capacity to conduct high quality ethics review efficiently, such as the use of digital platforms, or access REC/IRB administrative support on-line?

Answer:

Yes we currently have informal practices in place but they aren't explicitly written down

Notes:

None.

8.2.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

Yes

Notes:

None.

8.2.C

Do these include enabling access to global expertise independent of the main sponsors, given the increasingly complex global research problems that exist?

Answer:

Yes

Notes:

None.

8.2.D

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

The Research Department actively seeks for capacity building grants to support National ERBs in countries where we conduct research. We are currently collaborating with the Ethics Committee in Niger to provide them with more international exposure and help them improve and accelerate their processes.

Notes:

None.

8.2.E

What steps does your organisation intend to take in the next one or two years to improve its policy and practice related to increasing respect for local ethics review of research in which your organisation is a partner?

Answer:

The Research Department has begun to set up scientific committees composed of technical and operational representatives from several institutions. We actively and closely collaborate with most local ethics committees in the countries where we conduct research. The Research Department also brings support to the SEA-RAFES project through IP Dakar. This project aims to build a functional collaborative platform between French-speaking African National Ethics Committees (NECs), other French speaking or non-French speaking ethics committees, research community, populations, national authorities, and international organizations. This network will play a key role in exchanges with other CNEs to extend this approach to non-French speaking countries.

Notes:

None.

8.2.F

Please indicate what priority level your institution assigns indicator 8.2. for improvement

Answer:

High – to be dealt with in the next 2 years

Notes:

None.

Topic 9: Data Ownership, Storage, Access and Use

Why is having 'Respect for Authority of Local Ethics Review Systems' a Reporting Topic?

Research Ethics Review Committees (RECs) or Institutional Review Boards (IRBs) are essential components of good research systems. Besides aiming to maximise protection for people participating in research, RECs/IRBs have influence on study design, protocol execution, population selection, benefit sharing at individual, community and, sometimes, institutional and national levels. Lack of expertise results in one-sided reviews that may often not optimize protection and benefits of host countries, institutions or populations.

Existing Solution(s)

There are many REC/IRB training courses available around the world. Assessment of host expertise in this field may show deficiencies, in which case remedial steps can be taken, for example, specific additional training related to research topics or provision of a budget for a host to appoint a third party as a reviewer.

Install an expert support system, such as the RHInnO Ethics platform (www.rhinno.net) or some of the many other ethics review capacity services available. Some are listed on the RFI website resource pages: <http://rfi.cohred.org/relevant-source-documents-papers-books-and-websites/>.

Most international ethics guidelines are widely read and accepted as best practice. Make an explicit statement in the RFI Report on which (one or more) are the foundation for your organisation's policies and practices in ethics review of research collaborations.



9.1 Data Ownership and Accessibility Agreements.

Attachments

Data Sharing Flowchart
Intellectual Property Policy
Material Transfer Agreement
Service and Consulting Agreement
Data Sharing Policy

9.1.A

Please provide a description of how your organization deals with data ownership and use within its collaborations?

Answer:

A fundamental responsibility of Epicentre Research Department is to protect and as far as possible not compromise the rights and interests of the participants. Sharing research data is a necessary component of research. The benefits of greater data sharing have been increasingly recognized as a means of enhancing the utility of research, adhering to transparency recommendations, and providing opportunities for additional research. At the same time, there is a clear requirement to ensure that the rights and interests of participants, investigators, and other stakeholders are not compromised through data-sharing practices.

Epicentre Research Department is fully committed to conforming to international guiding principles on data sharing, including providing qualified research institutions access to anonymized or pseudonymized participant-level or aggregated data from our studies (including clinical trials, morbidity/mortality surveys, epidemiological interventions, etc.) to conduct legitimate scientific research.

Epicentre Research Department is committed to strictly respecting, in all cases, the medical confidentiality, privacy, and dignity of participants and their communities, and complying with the General Data Protection Regulation 2016/679 dated 27 April 2016 and any other EU or Member State legislation, regulation, recommendation, or opinion replacing, adding to, or amending, extending, reconstituting, or consolidating the EU General Data Protection Regulation (GDPR).

In addition, Epicentre Research Department signed the WHO joint statement on public disclosure of results from clinical trials in 2017. As stated by the WHO: “The signatories of this joint statement affirm that the prospective registration and timely public disclosure of results from all clinical trials is of critical scientific and ethical importance. Furthermore, timely results disclosure reduces waste in research, increases value and efficiency in use of funds and reduces reporting bias, which should lead to better decision-making in health”.

This joint statement also provides guidelines - among others - for sharing participant’s data that:

- Sets a basis for the facilitation of research through greater access and sharing of datasets

- Supports the development of explicit ethical and & frameworks that govern data collection & use and enables the development of international norms and standards for sharing of Individual Participant's Data from clinical trials.
- Encourages open access policies and considers that publications describing clinical trial results should be open access from the date of publication, wherever possible.

Notes:

None.

9.1.B

Does your organisation have institutional policies or practices in place for deciding on data ownership agreements – including rights of use of data for publication – with all partners if your organisation is the 'lead' partner?

Answer:

Yes we have a formal (written) policy in place

Notes:

None.

9.1.C

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

9.1.D

Does your organisation have requirements in place for your own organisation to share in ownership even if your organisation is not the 'lead' partner? If yes, please attach examples below or provide a description if no attachments are available.

Answer:

Yes



Notes:

None.

9.1.E

Does financial contribution matter when deciding on data-ownership and use? If yes, please attach examples below or provide a description if no attachments are available.

Answer:

Yes

Notes:

Ideally, financial contribution should not influence decision-making regarding data-ownership and use. However, in practice, financial contribution skew negotiations and decision-making regarding data-ownership and use.

9.1.F

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

None.

Notes:

None.

9.1.G

What steps does your organisation intend to take in the next one or two years to improve its policy and practice related to sharing data ownership?

Answer:

The Research Department wants to work towards an improved process to hold the lead institution accountable for making results available, in cases when the Research Department is not the lead institution. This can either be open access or controlled access for individual patient-level data depending on the sensitivity of the data.

Notes:

None.

9.1.H

Please indicate what priority level your institution assigns indicator 9.1. for improvement

Answer:

Low - to be dealt with in the next 6 years

Notes:

None.



9.2 Material Transfer Agreements

Attachments

Material Transfer Agreement

9.2.A

Does your organisation have institutional policies or practices in place for deciding on material transfer agreements, including storage and future use, between partners?

Answer:

Yes we have a formal (written) policy in place

Notes:

None.

9.2.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

9.2.C

Do you use internationally accepted MTAs or do you use other? If yes, please attach examples below or provide a description if no attachments are available.

Answer:

Yes

Notes:

None.

9.2.D

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

None.

Notes:

None.

9.2.E

What steps does your organisation intend to take in the next one or two years to improve its policy and practice related to material transfer agreements?

Answer:

Experience in using these model agreements has taught us that it would be beneficial to simplify them to ensure that they are well understood by all partners. Therefore, the Research Department will be working on a simplified and updated version of the current Material Transfer Agreement template.

Notes:

None.

9.2.F

Please indicate what priority level your institution assigns indicator 9.2. for improvement

Answer:

Low – to be dealt with in the next 6 years

Notes:

None.



Topic 10: Encouraging Full Cost Recovery Budgeting and Compensation

Why is 'Encouraging Full Cost Recovery Budgeting and Compensation' a Reporting Topic?

Inadequate provision for overhead costs results in chronically under-funded research institutions that have no budgets for staff development, establishment of communication offices, subscriptions to professional literature, hiring contracting and negotiating expertise, purchase of IT research or ethics management systems, financial management systems, high level reporting, and so much more that makes a research institution a great research institution. It can also keep low-middle income countries and institutions in a state of perpetual dependence on decisions by expatriate partners and research funders.

Definitions

Full cost recovery budgeting: Ensuring that all costs to deliver research outputs are covered in financial agreements of research partnership and not just 'direct' costs or other selective costs like consumables, equipment or facilities. All costs, including administration, research management, communication, infrastructure upkeep, transport, and more in short all costs necessary to ensure that research can be done excellent and on time, are included in 'full cost recovery' budgets.

Existing Solution(s)

Build agreements on the systems that need to be in place using the Research Fairness Initiative as a guide.

Agreements from any lead partner or external research sponsor to engage in joint budgeting for all reasonable overhead costs not simply allowing a maximum percentage of grant.

Providing realistic and equitable allocations to overhead costs for all partners taking into consideration that different partners may have very different base-funding.

10.1 Full Cost Recovery Budgeting

Attachments

Financial Statement

10.1.A

Please provide a narrative describing what measures your organisation takes to deal with budgeting and compensation in research partnerships?

Answer:

Although Epicentre Research Department sometimes works with partners and subcontractors, our projects are mainly conducted in Epicentre Research Centers in Niger (Niamey, Maradi) and Uganda (Mbarara). The sustainability and development of Epicentre Research Centers is a major stake and involves full recovery of direct and indirect costs incurred during a project.

It is critical that all identifiable costs related to the implementation of projects be fully budgeted in the proposals for funding and subsequent workplans. This includes staff, infrastructure, and any other direct inputs to the project, including administrative costs, support costs and development costs.

Support costs should also be identified and specified in the proposal budget. Those may include a portion of rent, utilities (e.g., electricity, fuel), training, administrative services, management, and supplementary staff costs not directly linked to the main purpose of the project's activities.

Estimated indirect costs must be fully recovered. For 2021, the overheads earned on Research Department projects are allocated as follows:

- 50% will be allocated to Epicentre Niger
- 25% will be allocated to the Research Department in Paris
- 25% will be allocated to Epicentre Uganda

The differences between Epicentre Niger and Uganda stem from the fact that Epicentre Uganda receives guaranteed funding from MSF for operating costs, up to 1 million euros per year.

Separate grants for infrastructure development and professional development are also obtained to ensure the sustainability and development of Epicentre research centers. These may include projects to improve laboratory capacities and infrastructures, improve IT infrastructures and staff capacities, provide staff with access to trainings, higher degrees, and experience in various locations and institutions.

Notes:

None.



10.1.B

Does your organisation institutional policies or practices in place which require itself and its partners do 'full cost recovery' budgeting as opposed to 'marginal' or other incomplete recovery budgeting?

Answer:

Yes we have a formal (written) policy in place

Notes:

Financial Statement, "Overhead allocation" subsection

10.1.C

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

10.1.D

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

None.

Notes:

None.

10.1.E

What steps does your organisation intend to take in the next one or two years to improve its policy and practice to achieve full cost recovery budgeting of partners in research collaborations?

Answer:

Not applicable.

Notes:

None.

10.1.F

Please indicate what priority level your institution assigns indicator 10.1. for improvement

Answer:

Medium – to be dealt with in the next 4 years

Notes:

None.



10.2 Improving/Standardising Budgeting

Attachments

None

10.2.A

Does your organisation have institutional policies or practices in place requiring partners to provide standardized budgets?

Answer:

Yes we currently have informal practices in place but they aren't explicitly written down

Notes:

None.

10.2.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

Yes

Notes:

None.

10.2.C

Does your organisation prescribe or recommend international research budgeting guidelines?

Answer:

Yes

Notes:

Good Financial Grant Practice (GFGP)

10.2.D

Does your organisation provide financial expertise to partners needing support to prepare and manage research budgets?

Answer:

Yes

Notes:

None.

10.2.E

Does your organisation have policies or practices in place requiring itself and its partners to adhere to internationally accepted accounting practices, including the conduct of external financial audit on research programmes?

Answer:

Yes we currently have informal practices in place but they aren't explicitly written down

Notes:

None.

10.2.F

Does your organization plan to formalize these practices or make them explicit?

Answer:

No

Notes:

None.

10.2.G

If you do not have any attachments to share, please describe your practice in the text box below.



Answer:

Epicentre Research Department is being certified for working in compliance to Good Financial Grant Practice (GFGP). GFGP is an international quality standard used in 43 countries, developed in collaboration with the African Organization for Standardization (ARSO) and a global community of grantors and grantees.

Notes:

None.

10.2.H

What steps does your organisation intend to take in the next one or two years to improve its policy and practice to ensure competency and standardization of research budgeting in all partners in research collaborations?

Answer:

After having received its GFGP certification, the Research Department is committed to encourage all partners to achieve GFGP certification.

Notes:

None.

10.2.I

Please indicate what priority level your institution assigns indicator 10.2. for improvement

Answer:

Medium – to be dealt with in the next 4 years

Notes:

None.

Domain 3

Fair Sharing of Benefits, Costs & Outcomes

Domain 3 deals with improving fairness in sharing the costs, benefits and outcomes of research. In specific, this component of the RFI focuses both on short-term costs, benefits and outcomes of individual studies, but also on the medium- and long-term impact that research collaboration can have on the ability of partners to grow their own research capacity, increase their ability to compete in attracting research and research funding, on social impact, and on future economic benefits of research in terms of economic activity, technology sector growth, and both technical and social innovations benefits accruing to all in the partnership.



Topic 11: Research System Capacities

Why is 'Research System Capacities' a Reporting Topic?

Any knowledge-based society needs a strong research (and innovation) system. Similarly, to be successful in business requires access to cutting-edge science. To develop this, partnering with others for expertise, funding, access to critical technologies or to populations is essential. Therefore, besides the new knowledge gained by research collaborations, a key outcome for all stakeholders is increased research capacity and ability to compete in the market for researchers, research funds and research partnerships. In any consideration of research, the impact of research collaborations on institutional or national research capacity is an essential aspect.

Definitions

Research (and innovation) system: the total of institutions, individuals, governance, legislation and economic activity that contributes to research (and translating research into scalable products).

Research system capacity

The ability of the research system to deal effectively with research needs to address local / national priorities and to be competitive in the international environment to attract the best personnel, external investments and research partnerships.

Existing Solution(s)

There is a wealth of literature on research capacity building, and some on evaluation⁴⁴. Much of this focuses on training of individuals rather than on increasing research system performance. Some publications are available through the RFI Website resource page: <http://rfi.cohred.org/relevant-source-documents-papers-books-and-websites/>

An institution can obtain research system capacities by adopting fairness guidelines like the Research Fairness Initiative.

11.1 Training

Attachments

Professional Development Policy

11.1.A

Please provide a paragraph describing what your organisation does to promote the improvement of research system capacities for partners who have fewer resources, or if you are the partner with less capacity, how your organisation ensures that the collaborations it enters into are geared towards also improving your own capacity

Answer:

Epicentre Research Department supports the improvement of systems through financial support for medical events and medical networking opportunities, collaborations with national and local authorities, as well as donations and resource sharing with local health and medical structures and NGOs. This is done on a grant by grant and project by project basis. Some projects also support local institutions, such as capacity-building projects for patient follow-up, data management, or epidemiological surveillance of diseases with epidemic potential.

Notes:

None.

11.1.B

Does your organisation have institutional policies or practices in place requiring and/or providing resources for training and higher education of research staff?

Answer:

Yes we have a formal (written) policy in place

Notes:

None.

11.1.C

Does your organization plan to formalize these practices or make them explicit?



Answer:

Not applicable

Notes:

None.

11.1.D

Does your organisation have criteria to determine these priorities?

Answer:

Yes

Notes:

None.

11.1.E

Does your organisation specify requirements or budget allocations for training?

Answer:

Yes

Notes:

None.

11.1.F

Does your organisation specifically provide training in research management, including staff in the following categories: financial, project management, communication, contract managers, community or business liaison?

Answer:

Yes

Notes:

None.

11.1.G

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

None.

Notes:

None.

11.1.H

What steps does your organisation intend to take in the next one or two years to improve its policy and practice of providing training to or require training from partners in research collaborations?

Answer:

The Research Department has a specific grant for the professional development of Epicentre Niger staff and has set up a dedicated budget for internal training. We have applied - along with several partners - for a funding from the African Academy of Sciences that includes a research capacity building component which consists of embedding gender, equity, and inclusion into local capacity building initiatives to foster a support research culture, enhance health emergency preparedness be enhanced in the context of research capacity building, and increasing collaboration between African countries.

We also aim to continue our efforts in terms of professional development by focusing on our gender integration process mentioned in Topic 7. and 14. We also recruited a quantitative epidemiologist, the first Nigerien PhD to work with Epicentre Niger, who will bring significant expertise for future projects and trials.

Finally, the Research Department is in the process of setting up formal agreements with universities to provide training, receive training, and foster research collaboration.

Notes:

None.



11.1.1

Please indicate what priority level your institution assigns indicator 11.1. for improvement

Answer:

Medium – to be dealt with in the next 4 years

Notes:

None.

11.2 Increase (Predictable) Funding.

Attachments

None

11.2.A

Does your organisation have institutional policies or practices in place for supporting partners to become better able to identify, write applications for and manage competitive grants, and to advocate national authorities to increase research system funding in a more predictable manner?

Answer:

Yes we currently have informal practices in place but they aren't explicitly written down

Notes:

None.

11.2.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

Yes

Notes:

None.

11.2.C

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

The Research Department provides both internal and external training courses opportunities to our staff. Those are specifically designed for Epicentre Research Centers and staff to be increasingly competitive when applying for grants.



Notes:

None.

11.2.D

What steps does your organisation intend to take in the next one or two years to improve its policy and practice of supporting the growth of predictable financing as part of collaborative research?

Answer:

We are currently developing a grant tracker, that will allow us to track all pending and obtained grant application. This system will allow for better time management in terms of financial and administrative deliverables for awarded grants, better planning in the development of grant proposals through the ability to visualize upcoming grants, and better follow-up of pending grant applications.

Notes:

None.

11.2.E

Please indicate what priority level your institution assigns indicator 11.2. for improvement

Answer:

High – to be dealt with in the next 2 years

Notes:

None.

Topic 12: Intellectual Property Rights and Tech Transfer

Why is 'Intellectual Property Rights and Tech Transfer' a Reporting Topic?

Unfair provisions of sharing intellectual property rights will affect the individuals, institutions and countries that have participated or invested in the research negatively, reducing the potential benefits they would have received if intellectual property rights were shared.

Existing Solution(s)

Use existing contracting guidelines such as 'WIPO Standards, Recommendations and Guidelines'. Use the services of national IP offices, or organisations like PIIPA (www.piipa.org). Engage with COHRED's Fair Research Contracting team.



12.1 Technology Transfer

Attachments

None

12.1.A

Please describe how your organization deals with technology transfer and intellectual property rights in research collaborations.

Answer:

The term intellectual property refers to intangibles that are protected by the principles of patents, copyrights, trademarks, and trade secrets. Our approach focuses on putting patients and beneficiaries first with decisions regarding the possible acquisition of patents, ownership, and licensing terms being made on a case-by-case basis. Decisions regarding IP aim to contribute to ensuring access and encouraging further innovations.

Epicentre Research Department recognizes its responsibility to manage its research and other materials and products, so as to maintain accessibility to research outputs. We ensure that scientific results are disseminated as widely as possible, through publications in scientific and non-scientific publications, and other appropriate channels including conferences and social media.

Epicentre Research Department does not put patents on research outputs, does not finance activities through IP revenue, and does not seek profit through IP revenue. Other non-patent types of IP such as confidential information and copyrights may be considered, particularly with respect to scientific publication. For example, it may be necessary to acquire IP, to facilitate access (or partner's access) to proprietary research materials, or to ensure equitable access and affordability of the product of research.

When IP acquisition is deemed necessary, Epicentre Research Department makes efforts to ensure that its partners will not use the acquired and/or help in IP in a manner that impedes follow-up research or access and affordability of the product of its research. We will not accept projects in which IP is an insurmountable barrier to follow-up research and access to research outputs.

Notes:

None.

12.1.B

Does your organisation have SOPs or standard guidelines on technology transfer, specifically to partners in low- and middle-income countries and populations?

Answer:

We don't have any policies or practices in place

Notes:

Not Applicable

12.1.C

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

12.1.D

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

Not Applicable

Notes:

None.

12.1.E

What steps does your organisation intend to take in the next one or two years to improve its policy and practice of technology transfer?

Answer:

Not Applicable



Notes:

None.

12.1.F

Please indicate what priority level your institution assigns indicator 12.1. for improvement

Answer:

Low - to be dealt with in the next 6 years

Notes:

Not Applicable

12.2 Sharing Intellectual Property Rights

Attachments

Consulting Agreement
Intellectual Property Policy

12.2.A

Does your organisation have explicit pre- and post-research discussions and negotiations with all partners concerning the sharing of IPR – now and in the future?

Answer:

We don't have any policies or practices in place

Notes:

Not Applicable

12.2.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

N/A

12.2.C

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

Not Applicable

Notes:

None.



12.2.D

What steps does your organisation intend to take in the next one or two years to improve its policy and practice of sharing IPR with partners in research collaborations?

Answer:

Not Applicable

Notes:

None.

12.2.E

Please indicate what priority level your institution assigns indicator 12.2. for improvement

Answer:

Low – to be dealt with in the next 6 years

Notes:

None.

12.3 Contracting Support for IPR

Attachments

None

12.3.A

Does your organisation have a policy or practice in place which provides for (as 'lead' partner) or requires (as 'other partner') support for IPR contracting to ensure fairness?

Answer:

We don't have any policies or practices in place

Notes:

Not Applicable

12.3.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

12.3.C

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

Not Applicable

Notes:

N/A



12.3.D

What steps does your organisation intend to take in the next one or two years to improve its policy and practice of supporting partners or requiring support from partners to better negotiate IPRs in research collaborations?

Answer:

None.

Notes:

None.

12.3.E

Please indicate what priority level your institution assigns indicator 12.3. for improvement

Answer:

Low – to be dealt with in the next 6 years

Notes:

Not Applicable

Topic 13: Innovation System Capacities

Why is 'Innovation System Capacities' a Reporting Topic?

For purposes of this RFI Reporting Guide, we define 'innovation system capacity' as the ability of countries or institutions to transform research knowledge into useful and scalable products or services. Countries with high innovation system capacities benefit from spin-off economic activities where innovations can be produced, jobs can be created and new patents can be locally filed. Thus, many benefits result from innovation system capacities that are created beyond the primary knowledge generation or product/service development and beyond direct impact on health of a population.

Existing Solution(s)

Create specific commercialization plans, and support partners' ability to take new knowledge into production for scalable solutions.

Refer to increasing impact evaluations of 'innovation hubs'.

Involve Ministries of 'Trade and Industry' in research partnership design.



13.1 Ensuring Socio-Economic benefits for Local Communities

Attachments

None

13.1.A

Please describe in a narrative what measures your organization takes to ensure that research collaborations promote the develop of innovation capacity in countries and partners where this is lacking, or if your own country / organization requires this capacity, how you ensure this is taken into account in research collaborations.

Answer:

Throughout its history, Epicentre Research Department has been a driving force in bringing about positive change through epidemiology and research advances leading to improvements in the medical care of the populations where we work. We aim to perform research to help speed up the development and access of new and adapted healthcare innovations and improve care strategies. As mentioned in Topic 1, the commercial “pull” that may drive innovations is often absent in resource-poor settings. Therefore, our focus is on projects which aim to fill this gap, allowing for the efficient testing, development and scale-up of approaches that can improve medical practice.

Research and Development activities are focused on late-stage developmental (phase II/III) and post-registration studies. Field trials and other approaches have the objective to contribute to the modification of national and international prevention and treatment protocols. Those activities contribute to the development and implementation of new vaccines, diagnostics, drugs, formulations, and programmatic strategies to improve national guidelines.

Notes:

None.

13.1.B

Does your organisation include clear statements in research contract negotiations and in research partnership agreements on how future spin-off economic activities resulting from the research will be shared with all partners?

Answer:

We don't have any policies or practices in place

Notes:

Not Applicable: Epicentre Research Department does not seek profit from the outcome of its activities.

13.1.C

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

13.1.D

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

Not applicable

Notes:

None.

13.1.E

What steps does your organisation intend to take in the next one or two years to improve its policy and practice of localizing innovation system capacities?

Answer:

Not applicable

Notes:

None.



13.1.F

Please indicate what priority level your institution assigns indicator 13.1. for improvement

Answer:

Low - to be dealt with in the next 6 years

Notes:

Not applicable

13.2 Support Innovation Culture

Attachments

None

13.2.A

Financial support for innovation?

Answer:

Yes we currently have informal practices in place but they aren't explicitly written down

Notes:

None.

13.2.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

No

Notes:

None.

13.2.C

Non-financial support for innovation – e.g stimulating and facilitating discussion on innovation following research?

Answer:

Yes we currently have informal practices in place but they aren't explicitly written down

Notes:

None.



13.2.D

Does your organization plan to formalize these practices or make them explicit?

Answer:

No

Notes:

None.

13.2.E

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

Epicentre Research Department organizes medical events that bring together local and international experts, key stakeholders, and representatives from local authorities around key medical and public health policy challenged. We also participate and contribute to local events organized by associations and universities on various medical subjects such as public health, biology, pediatrics, mental health, or surgery.

Notes:

None.

13.2.F

What steps does your organisation intend to take in the next one or two years to improve its practice regarding advocacy and stimulation of an innovation culture?

Answer:

Epicentre Research Department has the knowledge necessary to anticipate potential need for technological and research innovations Therefore, we intend to seize opportunities of new partnerships to reinforce our international positioning and provide a wider bandwidth for innovation and take part in specific consortium to respond to needs of patients and communities. We also aim to promote our innovative research model to improve access to new tools and information. Unlike other research models, Epicentre aims to have the capacity to conduct all aspects of study initiation, operations oversight, and result dissemination.

Notes:

None.

13.2.G

Please indicate what priority level your institution assigns indicator 13.2. for improvement

Answer:

Medium – to be dealt with in the next 4 years

Notes:

None.



Topic 14: Due Diligence

Why is 'Due Diligence' a Reporting Topic?

Excellent research requires excellent research institutions, which in turn can be boosted by a system conducive to research and innovation. Inadequate provision for minimising the environmental, social and cultural impact of research and innovation activities may limit future research opportunities of institutions or countries. Similarly, positive actions should be reflected upon and adopted whilst conducting research, such as following and implementing the Sustainable Development Goals (SDGs) and encouraging women's participation in science.

Existing Solution(s)

Conduct a pre-research assessment to identify key areas on environmental impact in the context of the research that is being contemplated. Create a plan that addresses these environmental, social and cultural concerns without detracting from the primary research purpose and without (unreasonable) increase in project costs⁵². Refer to national and international guidelines stimulating the equal participation of women in science.

14.1 Achieving International Development Goals.

Attachments

Sustainability Policy
Diversity and Equality policy
Professional Development Policy
Epidemiology Guidance Document

14.1.A

Please provide a description for how your organization ensures that it works towards achieving national and global social and development goals when working in collaboration with others

Answer:

Our projects are framed by the UN SDG and contribute to the following specific goals:

Goal 1: Economic growth must be inclusive to provide sustainable jobs and promote equality

Epicentre Research Department regularly donates unused drugs, vaccines, or other medical products to local health institutions. In addition, and as mentioned in topic 1, most of our staff is local, for all hierarchical positions and in all countries where our research takes place. Since our recruitment procedure is backed up by a clear Diversity and Equality policy, and every staff is included in a professional development program, jobs created by Epicentre Research Department are sustainable and promote equality. Our salary scale ensure that our activities do not disturb the local labor markets.

Goal 3: Ensure healthy lives and promote well-being for all at all ages

Epicentre Research Department provides epidemiological expertise, conducts field epidemiology activities and research projects to contribute to MSF's goal of providing medical aid in areas where people are affected by conflict, epidemics, disasters, or otherwise have poor or non-existent access to health care. Our activities include, but are not limited to, responding to emergency situations, conducting monitoring and evaluation activities, investigating emerging medical and humanitarian issues, and conducting research and development.

We are strongly committed to ensuring universal access to health care for all, improve existing health structures, and promote immunization, as one of the most cost-effective health interventions.

Goal 4: Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all

As mentioned above, our Professional Development policy equally applies to all Epicentre Research Department staff irrespective of location and job title. We are committed to provide staff with continuing education opportunities, to acquire skills



and knowledge that will improve their performance in their position and facilitate internal advancement within the organization as well as providing opportunities for employment in other organizations.

Goal 5: Achieve gender equality and empower all women and girls

Epicentre Research Department is an equal opportunity employer. Epicentre Research Department does not discriminate based upon religion, color, national origin, medical situation (including pregnancy, childbirth, or medical conditions), sexual orientation, gender identity, gender expression, age, status as an individual with a disability, or other applicable characteristics whether protected legally or not. All employees and applicants have the right to full and equal consideration based on merit and other relevant meaningful criteria.

Epicentre Research Department adheres to the principle of equal pay, whereby every position reasonably considered as equal in skill, effort, responsibility and working conditions are compensated equally, independently from individual characteristics. All the Epicentre Research Department's staff have equal rights and opportunities to participate in decision-making processes affecting their life at work. Staff composition should be representative of diversity of underrepresented groups, particularly in supervisory positions.

The Research Department commits to a gender integration process, i.e., "the process of assessing the implications for women and men of any planned action, including policies, in all areas and at all levels. It is a strategy for making women's as well as men's concerns and experiences an integral dimension of the design, implementation, monitoring and evaluation of policies and guidelines in all spheres so that women and men benefit equally, and inequality is not perpetuated. The goal is to achieve gender equality" (ECOSOC, 1997). Gender integration encompasses not only our staff composition, but also the conduct of our activities and research in terms of their design and implementation.

Goal 9: Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation

Epicentre Research Department has the knowledge needed to anticipate the potential need for implementation research and technological innovations. As previously mentioned, we aim to perform research to help speed up development and access to new and adapted healthcare innovations.

Therefore, along with professional development for staff, Epicentre Research Department also focuses on maintaining and developing infrastructures, allowing for the efficient testing, development, and scale-up of approaches that can improve medical practice.

Goal 10: Reduce inequalities within and among countries

Epicentre Research Department focuses on helping speed up the development and access of new and adapted healthcare innovations and improve care strategies for populations living in unstable conditions or with inadequate access to care. Our approach – to have the capacity to conduct all aspects of study initiation, operations oversight, and dissemination – contributes to local, national, and international policy changes.

Recently, Epicentre Research Department Niger conducted a cluster-randomized trial during a meningococcal group C epidemic evaluating the effectiveness of single-dose ciprofloxacin prophylaxis. Current projects continue to focus on improving diagnosis and therapies for malaria, pneumococcal diseases, and cholera. Epicentre Research Department Uganda's research has contributed to policy changes including the seminal AQUAMAT trial that showed that artesunate significantly reduces mortality in African children with severe malaria. Current projects continue to focus on improving diagnosis and therapies for tuberculosis, HIV, central nervous system infections, as well as trials on Ebola, Yellow Fever, and PCV vaccines.

Notes:

None.

14.1.B

Does your organisation have explicit executive policies or strategies to maximize the contributions of its research collaborations towards achieving one or more international development goals?

Answer:

Yes we have a formal (written) policy in place

Notes:

None.

14.1.C

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

14.1.D

Are there any specific goals that act as a guideline for your institution? If yes, please provide a description in the box below



Answer:

- o Our projects are framed by the following UN SDG specific goals:
- o Goal 1: Economic growth must be inclusive to provide sustainable jobs and promote equality
- o Goal 3: Ensure healthy lives and promote well-being for all at all ages
- o Goal 4: Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all
- o Goal 5: Achieve gender equality and empower all women and girls
- o Goal 9: Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation
- o Goal 10: Reduce inequalities within and among countries

Notes:

None.

14.1.E

If you do not have any attachments to share, please describe your practice in the text box below

Answer:

None.

Notes:

None.

14.1.F

What steps does your organisation intend to take in the next one or two years to improve its policy and practice of aligning your research efforts with organisational support to achieve international development goals?

Answer:

ERD will develop a Sustainable Development Goals Tracking Tool to track and visualize progress toward the UN Sustainable Development Goals. This will allow for better planning in the development of grant proposals aimed at achieving these goals.

Notes:

None.

14.1.G

Please indicate what priority level your institution assigns indicator 14.1. for improvement

Answer:

Low - to be dealt with in the next 6 years

Notes:

None.



14.2 Negative environmental impact

Attachments

Travel Policy
Sustainability Policy

14.2.A

Does your organisation have explicit policies or practices to ensure that research programmes assess, report and minimize environmental impact?

Answer:

Yes we have a formal (written) policy in place

Notes:

None.

14.2.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

14.2.C

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

None.

Notes:

None.

14.2.D

What steps does your organisation intend to take in the next one or two years to improve its policy and practice of reducing environmental impact of research?

Answer:

We have applied - along with several partners - for funding from the African Academy of Sciences that includes a climate change, development, and human health component that consists of the following research questions: how are climate change and urbanization affecting disease endemicity and outbreaks in Africa; how can spatial-temporal epidemiology inform policies on access to care; what population vulnerabilities drive geographical variation in childhood mortality within and across African countries?

Notes:

None.

14.2.E

Please indicate what priority level your institution assigns indicator 14.2. for improvement

Answer:

Medium - to be dealt with in the next 4 years

Notes:

None.



14.3 Promoting participation of women in science and innovation.

Attachments

Diversity and Equality policy
Professional Development Policy

14.3.A

Does your organisation have a policy or practice in place for both itself and its partners concerning the participation of women in science, at all levels of research?

Answer:

Yes we have a formal (written) policy in place

Notes:

None.

14.3.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

14.3.C

Does your organisation follow any guidelines to act if inequity is found? If yes, please provide a description in the box below. [In cases where there is an under representation of men, the same applies to dealing with this inequity.]

Answer:

With MSF as its parent organization, Epicentre refers to the MSF Policy for Managing Personal Misconduct and Abusive Behavior, all staff may lodge a complaint about abusive behavior or discriminatory or prejudicial treatment of which he/she feels he/she has been the victim, to the personnel representatives and the official legal authorities, or to his/her supervisors or via the MSF 'whistle blowing' reporting mechanism. All

staff must report any abusive behavior or other discriminatory or prejudicial treatment of which he/she has the knowledge, without necessarily having been the victim.

Notes:

None.

14.3.D

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

None.

Notes:

None.

14.3.E

What steps does your organisation intend to take in the next one or two years to improve its policy and practice of increasing women's participation in research collaborations?

Answer:

The Research Department wants to encourage more dialogue between practitioners and researchers from different fields, and provide more networking opportunities for Niger staff, especially women scientists. To this end, one of our goals is to improve the English language skills of Epicentre Niger staff to encourage their participation in the broader scientific community.

Notes:

None.

14.3.F

Please indicate what priority level your institution assigns indicator 14.3. for improvement

Answer:



Medium – to be dealt with in the next 4 years

Notes:

None.

Topic 15: Expectation of All Partners to Adhere to a Best Practice Standard in Research Collaboration

Why is the 'Expectation of All Partners to Adhere to a Best Practice Standard in Research Collaborations' a Reporting Topic?

An institution or national body that adopts and follows nationally and/or internationally accepted best practice standards and guidelines is more likely to deal pro-actively with challenges and potentials of creating solid partnerships, is likely to have more lasting and efficient research relationships, will reduce its reputational risk and will have more credibility within its network of potential collaborators.

Existing Solution(s)

There are several existing guidelines from a variety of organisations and countries covering key aspects of the RFI. Adopt one or more as basis for organisational behaviour and making sure that key staff involved with research collaborations are aware of this. Examples include guidelines like the KFPE53, IRD54 and the CCGHR55 to name a few. More can be found at the RFI Website Resource Page: <http://rfi.cohred.org/relevant-source-documents-papers-books-and-websites/>.

<http://rfi.cohred.org/relevant-source-documents-papers-books-and-websites/>



15.1 Partner Requirements for Fair Research Partnerships

Attachments

Third Party Guide
Human Resources checklist

15.1.A

Please provide a paragraph which describes how your organisation works towards ensuring that all partners and all collaborations are held to a high standard of partnership practice in research collaboration.

Answer:

A third-party guide is provided to all partners to ensure compliance with Epicentre Research Department's minimum standards of integrity and work practices. These include ethical considerations for research, health and safety aspects, equal, free & fair employment, child protection, fraud prevention, corruption, bribery, and other practices. We expect Third Parties to ensure their own contracting parties also comply with this guide if applicable. More stringent rules may apply as agreed between the Research Department and Third Parties on an individual basis. This Guide explains and refers to all minimum standards of integrity and conduct.

Notes:

None.

15.1.B

Does your organisation have policies or practices in place which require its the following stakeholders to produce RFI Reports on their own organisations, or to make explicit statements about adoption and use of existing codes of research practice?

Research Partners

Answer:

Yes we have a formal (written) policy in place

Notes:

None.

15.1.C

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

None.

Notes:

None.

15.1.D

Does your organisation have policies or practices in place requiring itself and its partners to adhere to accepted / available best practice guidelines for fair research partnerships?

Research Funders / Sponsors**Answer:**

Yes we have a formal (written) policy in place

Notes:

None.

15.1.E

Does your organization plan to formalize these practices or make them explicit?

Answer:

Not applicable

Notes:

None.

15.1.F

If you do not have any attachments to share, please describe your practice in the text box below.



Answer:

None.

Notes:

None.

15.1.G

What steps does your organisation intend to take in the next one or two years to improve its policy and practice of requiring research management staff to be trained and remain updated on best practices in fair research contracting?

Answer:

Where appropriate, the Research Department will encourage its partners to produce Research Fairness Initiative reports.

Notes:

None.

15.1.H

Please indicate what priority level your institution assigns indicator 15.1. for improvement

Answer:

Low – to be dealt with in the next 6 years

Notes:

None.

15.2 Expectations to adhere to accepted or available best practice for responsible research collaborations.

Attachments

Third Party Guide

15.2.A

Does your organisation have policies or practices in place requiring itself and its partners to adhere to accepted / available best practice guidelines for fair research partnerships?

Answer:

Yes we have a formal (written) policy in place

Notes:

None.

15.2.B

Does your organization plan to formalize these practices or make them explicit?

Answer:

None.

Notes:

N/A

15.2.C

If you do not have any attachments to share, please describe your practice in the text box below.

Answer:

None.

Notes:

None.



15.2.D

What steps does your organisation intend to take in the next one or two years to improve its policy and practice of requiring research management staff to be trained and remain updated on best practices in fair research contracting?

Answer:

Epicentre's Research Department plans to formalize in research collaboration agreements our requirement that all partners adhere to internationally accepted best practice guidelines for equitable research partnerships.

Where appropriate, the Research Department will encourage its partners to produce Research Fairness Initiative reports.

Notes:

None.

15.2.E

Please indicate what priority level your institution assigns indicator 15.2. for improvement

Answer:

Low - to be dealt with in the next 6 years

Notes:

None.

Summary of Short Term actions for ERD

Main short-term activities:

Epicentre Research Department aims to perform research to help speed up development & access to new and adapted healthcare innovations and improve care strategies. As commercial “pull” that may drive innovations is often absent in resource-poor settings, our focus is and will remain on projects which aim to fill this gap, allowing for the efficient testing, development, and scale-up of approaches that can improve medical practice. Understanding the research and innovation landscape in the areas where we work is also essential to ensuring successful projects.

The Research Department wants to encourage dialogue between practitioners and researchers from different fields and provide increasing networking opportunities for Niger and Uganda staff, especially women scientists. To this end, one of our goals is to improve the English language skills of Epicentre Niger staff to support and encourage their participation in the broader scientific community. In addition, Epicentre Research Department’s Professional Development Policy is designed to establish a large pool of competent supervisors and increase the visibility and prominence of our research centers in Niger (Niamey, Maradi) and Uganda (Mbarara). This promotes an internationally and locally relevant research agenda by ensuring that the issues and concerns of populations where we work are included. The overall goal is to ensure that high-quality and ethical epidemiology and research are conducted with consistency and continuity.

Epicentre Research Department has the knowledge necessary to anticipate the potential need for technological and research innovations. Therefore, we intend to seize opportunities for new partnerships to reinforce our international positioning and provide a wider bandwidth for innovation and take part in specific consortiums to respond to the needs of patients and communities. We also aim to promote our innovative research model to improve access to new tools and information. As mentioned above in the foreword, ERD aims to have the capacity to conduct all aspects of study initiation, operations oversight, and result dissemination.

Epicentre Research Department has formalized the implementation of local Community Advisory Committees that will actively participate in the studies conducted by the Research Department. Successful biomedical and behavioral research requires the active participation of all stakeholders, including the communities in which studies are conducted. Community involvement builds trust and mutual understanding of the research questions and ensures respect for community values and cultural sensitivities. Community participation also generates important contextual information about the setting and acceptance of the study.

The Research Department has also begun to set up scientific committees composed of technical and operational representatives from several institutions. We actively and closely collaborate with most local ethics committees in the countries where we



conduct research. In addition, the Research Department brings support to the SEA-RAFES project through IP Dakar. This project aims to build a functional collaborative platform between French-speaking African National Ethics Committees (NECs), other French-speaking or non-French speaking ethics committees, the research community, populations, national authorities, and international organizations. This network will play a key role in exchanges with other NECs to extend this approach to non-French-speaking countries.

The Research Department commits to a gender integration process, i.e., “the process of assessing the implications for [all] of any planned action, including policies, in all areas and at all levels. It is a strategy for making [the diversity of] concerns and experiences an integral dimension of the design, implementation, monitoring, and evaluation of policies and guidelines in all spheres so to ensure equity and address the perpetuation of [visible and invisible] inequalities.” (ECOSOC). Gender integration encompasses not only our staff composition but also the conduct of our activities and research in terms of their design and implementation.

Finally, ERD is currently being certified for working in compliance with Good Financial Grant Practice (GFGP). GFGP is an international quality standard used in 43 countries, developed in collaboration with the African Organization for Standardization (ARSO) and a global community of grantors and grantees. Being listed as a GFGP-certified organization includes the Research Department in a community in which both public and corporate funders are searching to find trusted partners to fund. After having received its GFGP certification, the Research Department is committed to encouraging all partners to achieve GFGP certification.

Documentation development and revision:

Epicentre Research Department guidelines, policies, procedures, and practices – including guidance documents and quality manuals – are continually updated, to improve its practices and meet high international standards. For example, Epicentre Research Department's legal team continuously reviews, updates, and/or refines standardized contracts and partnership agreements, to add elements and/or comply with new requirements and standards.

Epicentre Research Department's legal team will update the standardized Research collaboration agreement regularly and improve the quality of legal advice provided to partners. In addition, we will formalize our requirement that all partners adhere to internationally accepted best practice guidelines for equitable research partnerships in research collaboration agreements. When appropriate, the Research Department will encourage its partners to produce Research Fairness Initiative reports.

We are currently developing a grant tracker, that will allow us to track all pending and obtained grant applications. This system will allow for better time management in terms of financial and administrative deliverables for awarded grants, better planning in the development of grant proposals through the ability to visualize upcoming grants, and better follow-up of pending grant applications. ERD will also

develop a Sustainable Development Goals Tracking Tool to track and visualize progress toward the UN Sustainable Development Goals. This will allow for better planning in the development of grant proposals that include components aimed at achieving these goals.

Report Summary

DOMAIN 1: FAIRNESS OF OPPORTUNITY

Topic 1

Relevance to Communities in which Research is done

INDICATOR

STATUS PRIORITY

1.1 Research priorities in communities where research is being conducted.

Approved High

1.2 Actions if there are no research priorities.

Approved High

1.3 Justification to research low priority topics.

Approved Low

Topic 2

Early Engagement of Partners

INDICATOR

STATUS PRIORITY

2.1 Relationship between the 'main/lead/sponsoring' and 'other' partners

Approved Medium

2.2 SOPs for supportive actions to partners

Approved Medium

Topic 3

Making Contributions of Partners Explicit

INDICATOR

STATUS PRIORITY

3.1 Role clarification in research partnerships

Approved Low

3.2 Making potential beneficial impact explicit before starting research.

Approved Low

Topic 4

Ensuring That Matching and Other Co-Financing Mechanisms Do Not Undermine Opportunities for Fair Participation of All Partners

INDICATOR

STATUS PRIORITY

4.1 Equal co-financing.

Approved

4.2 Alternatives to equal co-financing.

Approved

4.3 Research outside national priorities and co-financing.

Approved



Topic 5

Recognition of Unequal Research Management Capacities Between Partners and Providing for Appropriate Corrective Measures

INDICATOR	STATUS	PRIORITY
5.1 Research Management Capacity	Approved	Medium
5.2 Financial Management Capacity	Approved	Medium
5.3 Contracting and Contract Negotiation capacity	Approved	Medium

DOMAIN 2: FAIR PROCESS**Topic 6**

Minimising Negative Impact of Research Programmes on Systems

INDICATOR	STATUS	PRIORITY
6.1 Assessing potential or actual harm of research.	Approved	Medium
6.2 Reducing negative impact of research	Approved	High
6.3 Compensation for unintended (negative) consequences of research	Approved	Low

Topic 7

Fair Local Hiring, Training and Sourcing

INDICATOR	STATUS	PRIORITY
7.1 Local staffing and sourcing of consumables and services.	Approved	High
7.2 Support for local capacity development.	Approved	High

Topic 8

Respect for Authority of Local Ethics Review Systems

INDICATOR	STATUS	PRIORITY
8.1 Research Ethics Approval	Approved	Medium
8.2 Supporting local Research Ethics Review capacity	Approved	High

Topic 9

Data Ownership, Storage, Access and Use

INDICATOR	STATUS	PRIORITY
9.1 Data Ownership and Accessibility Agreements.	Approved	Low
9.2 Material Transfer Agreements	Approved	Low

Topic 10

Encouraging Full Cost Recovery Budgeting and Compensation

INDICATOR	STATUS	PRIORITY
10.1 Full Cost Recovery Budgeting	Approved	Medium
10.2 Improving/Standardising Budgeting	Approved	Medium

DOMAIN 3: FAIR SHARING OF BENEFITS, COSTS & OUTCOMES

Topic 11

Research System Capacities

INDICATOR	STATUS	PRIORITY
11.1 Training	Approved	Medium
11.2 Increase (Predictable) Funding.	Approved	High

Topic 12

Intellectual Property Rights and Tech Transfer

INDICATOR	STATUS	PRIORITY
12.1 Technology Transfer	Approved	Low
12.2 Sharing Intellectual Property Rights	Approved	Low
12.3 Contracting Support for IPR	Approved	Low

Topic 13

Innovation System Capacities

INDICATOR	STATUS	PRIORITY
13.1 Ensuring Socio-Economic benefits for Local Communities	Approved	Low
13.2 Support Innovation Culture	Approved	Medium

Topic 14

Due Diligence

INDICATOR	STATUS	PRIORITY
14.1 Achieving International Development Goals.	Approved	Low
14.2 Negative environmental impact	Approved	Medium
14.3 Promoting participation of women in science and innovation.	Approved	Medium

Topic 15

Expectation of All Partners to Adhere to a Best Practice Standard in Research Collaboration

INDICATOR	STATUS	PRIORITY
15.1 Partner Requirements for Fair Research Partnerships	Approved	Low
15.2 Expectations to adhere to accepted or available best practice for responsible research collaborations.	Approved	Low

