Republic of Rwanda

Ministry of Health

Guidelines for Researchers Intending to Do Health Research in Rwanda

February 2012

List of Abbreviations

HSRP – Health Sector Research Policy

IRB – Institutional Review Board

MoH – Ministry of Health

MOU – Memorandum of Understanding

NISR – National Institute of Statistics of Rwanda

RNEC – Rwanda National Ethics Committee

SOPs – Standard Operating Procedures

SRC – Scientific Review Committee

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I. Introduction

Research is widely acknowledged to play an important role in the socioeconomic development of a nation. Health research is particularly important because it allows for evidence-based decision-making that improves health outcomes. The Government of Rwanda has recently created the Health Sector Research Policy (HSRP), in order to outline a vision for effective and efficient health research in Rwanda.

In accordance with the Ministry of Health's (MoH) desire to facilitate health research in Rwanda, the guidelines presented here have been developed to aid investigators who want to do research with a primary aim of studying health in Rwanda. These guidelines are intended to clarify the processes, expectations, and benefits of doing health research in Rwanda. With the clarity afforded by the guidelines, it is the hope of the Ministry of Health that health research will be a smooth process for investigators, and that it will be a mutually beneficial endeavor for the investigators, the Government of Rwanda, and the communities.

II. Definition of Research

The Ministry of Health of the Government of Rwanda, defines health research as the following:

"Any activity intended to increase the stock of knowledge relating to health that can be generalized and used to draw conclusions, devise new applications, and guide decision-making."

This definition includes a) basic scientific research relating to health, including investigation into fundamental scientific phenomena without a particular application in view; b) applied/operational research, which is generation of new knowledge with a specific practical aim; and c) experimental development, which is research intended to develop new or significantly alter and improve materials, products, systems and services. General-purpose data collection, including statistical surveys and censuses where health data are collected and the primary aim is studying health, are also considered research in the health sector.

Some activities are considered non-research in the health sector unless they are carried out for the purpose of assisting research and development. If not carried out for research-related purposes, these non-research activities do not fall under the jurisdiction of these guidelines. These activities include: standardization procedures, provision of specialized health care, program evaluations (excluding impact evaluations), outbreak investigation/surveillance, and routine software development.

III. Research with Existing Data

Two main types of research are covered by this document: the collection of new data, and additional analysis of existing data. Investigators wishing to conduct health research in Rwanda that requires original data collection are welcome, as new information will help Rwanda to make more informed policy decisions and will help improve health outcomes. This has traditionally been the main form of research in Rwanda.

However, consistent with the principles outlined in the HSRP, the Ministry of Health of Rwanda is also committed to encouraging and facilitating the use of existing data to further knowledge about health in Rwanda. Doing so prevents duplication of work already completed, and thereby prevents waste of limited resources. Use of existing data also allows for meta-analyses, which may yield improved or more generalizeable knowledge than single studies.

The process for carrying out research is largely the same for new data collection as for existing data analysis, and unless otherwise noted, the procedures and expectations outlined in the document apply to researchers wishing to carry out either type of research.

IV. Note on Collaborations

For researchers coming from outside of Rwanda, it is requested to have a Rwandan collaborator involved at all stages of the work with a clear repartition of responsibilities. As such, foreign investigators are requested to partner with a Rwandan researcher who is working in the field of research topic. This will help to ensure relevancy of research

projects for Rwanda, facilitate the approval process (via the institutional affiliation(s) of the Rwandan collaborator or his/her knowledge of the review process), and will additionally help Rwanda build capacity for conducting research of its own. In these guidelines, references to "investigators" or "researchers" are used to refer to the collaboration of foreign and Rwandan investigators, if a foreign investigator is involved.

If any samples, including biological materials and chemicals, are to be removed from Rwanda, it is required that the collaborators develop and sign a memorandum of understanding (MOU) or other material transfer agreement (MTA) prior to initiation of data collection. Such a document will prevent confusion later on, and will strengthen proposals for review by scientific and ethics committees .

V. Process to Begin a Research Project in Rwanda

This section outlines the steps to be taken in order to begin a research project in Rwanda. Researchers should allow three months from the first submission of the proposal to final approval, though in many cases, approval may be obtained much faster. Proposals will usually receive approval for up to one year, though in some cases where more time is clearly needed for the study, a longer approval period may be issued. Note: Rwandan students through the Master's degree will receive approval solely from their institutions of learning according to the institutional standards, with authorization and registration at the institutional level but their research questions will be authorized by the MoH program in which they are related to and then approved by MoH to assure their effectiveness.

A. Proposal Generation

The first step in doing research in Rwanda is to generate a research proposal for review. Investigators will develop a research proposal of no more than 15 pages that contains the following:

- Introduction with literature review and rationale behind research;
- Clear description of research question to be addressed;
- Specific objectives of research regarding the research question;

- Detailed protocol including risk assessment, informed consent procedures and methodology;
- A clear link between the protocol and the ability to answer the research question addressed;
- Information about the source of funding;
- Evidence of ethical review at home institution (for foreign researchers);
- Benefits for Rwanda or communities;
- List of researchers and curriculum vitae of each researcher who will be involved in the research process, with declarations of conflicts of interest;
- Clear dissemination strategy

B. Scientific Review

Scientific Review Committees (SRCs) will be established at institutions with health research in their mandates in order to provide scientific review for proposals. After the generation of a proposal, the proposal should be submitted to the scientific review committee (SRC) of the affiliated Rwandan institution, if one exists. If the researcher is not affiliated with an institution which has an SRC, the proposal should be submitted to the SRC of the institution which supervises the original institution, or to any existing SRC which is highly relevant for the research topic. If none of these alternatives fits a given case, the researcher should submit his/her research protocol to the national research committee to review the proposal in question as well as research project from out of Rwanda.

The proposal should be submitted at least two weeks before the meeting of the SRC. Research protocols that require work or data collection nationally or for at least one whole province should be submitted to the National Institute of Statistics of Rwanda instead of another institutional SRC, pursuant to the Visa Instruction Manual found in the references. It is assumed that foreign researchers will also have proposals reviewed by their home institutions, but the additional review in Rwanda is required to ensure relevance to Rwanda.

In special cases where one given institution does not possess the scientific expertise required to review a certain proposal, the institution could seek external expertise. Additionally, for some projects initiated at the Ministry of Health or elsewhere, the Honorable Minister of Health can ask for assembly of an ad hoc SRC, either at one institution or comprising members from many institutions. All scientific review committees in Rwanda will use identical standards as defined by the Ministry of Health, consistent with international standards.

The SRC will review the proposal in a timely manner for issues including but not limited to:

- Qualifications of researchers;
- Relevance of the project and benefit to Rwanda;
- Appropriateness/ability of methodology to answer the study question;
- Conformation of proposed project to the latest international standards for research;
- Added value of knowledge after completion of the project, in Rwanda or in the world.

If the proposal is approved, the research team will receive a letter to that effect, and indicating that the team may seek ethical approval. If the proposal is not approved, the SRC will send a letter containing the strengths and weaknesses of the proposal to allow for revision and resubmission. If the research is not relevant or out of standard it may be refused

C. Ethical Review

After receiving official confirmation of scientific approval, the proposal should be submitted with a copy of the letter of scientific approval to the Institutional Review Board (IRB), or ethics committee associated with the same institution. As with the scientific review, proposals should be submitted at least two weeks prior to the IRB meeting, and proposals that have received IRB approval internationally need to receive it in Rwanda as well. Across all institutions, the IRBs will conform to international ethical research standards and will be overseen by the Rwanda National Ethics Committee (RNEC) to ensure standardization. In especially sensitive cases, an institutional IRB may refer a

proposal to the RNEC for review. The ethics committees will review proposals including but not limited to the following issues:

- Informed consent;
- Confidentiality of patient information;
- Voluntary participation;
- Risk of harm, both to subjects and researchers;

Assuming a favorable review, the research team will receive a letter from the IRB indicating that the proposal has been approved and should be submitted to the Ministry of Health for registration and administrative authorization for data collection. If the ethical review is not favorable, the research team will receive a letter detailing the problems that need to be addressed before the proposal will be approved.

D. Ministry of Health Registration

The Ministry of Health will serve as the central registry for all health research in Rwanda. After proposals have received both scientific and ethical approval, the complete proposals, both hard and soft copies, including the registration form and copies of the letters from the SRC and IRB, should be addressed to the Honorable Minister of Health and submitted to the Ministry of Health , Medical Education and Research Department in one package. Within one week of receiving the necessary documents, the Ministry of Health will issue a letter to the research team confirming their research registration and authorizing them to begin to implement the research. This letter will facilitate data collection and research implementation. The ministerial Instructions N° 003/2010 of 09/12/2010, regulating research activities in Rwanda recognizes national research entities such as MoH and its entities. Proposals for analysis of existing data can expect further communication from the Ministry of Health giving them access to the requested data, which is centralized in the Ministry of Health. At this point, researchers may begin to implement the project which has been approved.

E. Ministry of Health Support to Research Teams

In addition to serving as the final registration center, the Ministry of Health will play several supporting roles to researchers. After registration, the Ministry of Health will provide additional authorization letters as needed to support ease of data collection in health facilities, villages, etc. They will also support the efforts of the research team to other government officials within the rule of law. Finally, they will provide access as needed to national level data sets to inform the study (HMIS, TracNet, etc.). These efforts are intended to facilitate and streamline the research process for research teams whose proposals have been approved.

VI. Implementation of Approved Research

Procedures for implementation of research will vary widely depending on the nature of the study, but some aspects are consistent across all types of research in the health sector.

A. Capacity-Building

Implementation of all proposals should include some aspect of capacity-building for Rwanda. This can take many shapes and forms, but it is crucial that the implementation phase of any project include the training of Rwandan personnel, or the improvements of Rwanda's research facilities or infrastructure.

B. Monitoring for Misconduct

The Ministry of Health and its agencies reserve the right to monitor the implementation of approved proposals to ensure that the projects are being carried out in accordance with the approved protocols. It is first and foremost the responsibility of the researchers and their sponsors and sponsoring institutions to ensure that implementation occurs as described in the approved proposal. Researchers are additionally expected to submit quarterly reports to the ethics committee that approved the research. Further monitoring and inspection may be done by a body authorized by the Ministry of Health. Researchers found to be non-compliant with approved methodology will be subject to consequences, and may have their research approval terminated. Consistent with Ministry of Health monitoring is the expectation that unforeseen issues that arise during the project will be reported to the IRB or RNEC by the researcher, including but not limited to unanticipated adverse events, clear

results that may suggest the need to stop the study, a need to modify the approved methodology, or a significant change in research personnel. Such changes will not necessarily impede the research, but must be reported and will be addressed as necessary by the, SRC, and IRB that approved the initial proposal.

C. Availability, Use , and Publication of Data and Research Findings

Consistent with the HSRP, it is of utmost importance that data generated through research carried out in Rwanda be used to ensure maximum public benefit in Rwanda, as well as in the broader international research community. To that end, data and results from a study must be shared with the community in which the research was carried out and must be published in Rwanda. The publication in Rwanda may be done after the international one.

The Ministry of Health will maintain a registry of both datasets and research reports. To this end, datasets, data documentation, and research reports must be shared with the National institution which the PI is coming from as a co-owner of the data and MoH data warehouse within three months of the conclusion of the data collection. This will facilitate future research utilizing data previously collected, and future research wishing to build off of previous work. Two years after the conclusion of data collection, the dataset can be shared by the National Institution with other researchers on written demand for secondary analysis. In case of negative answer from this institution a researcher can appeal to national research committee which will judge adequacy of the negative answer and take the final decision. In special circumstances, an MOU can be signed between the Ministry of Health and the research team or research institution, which will detail the ownership and use of data. Additionally, the investigator may send a formal request to keep data private beyond two years, with reasons detailed.

Timely publication of results in peer-reviewed academic journals is highly encouraged. Peer review helps to maintain the quality of research in Rwanda, and publication ensures that the results of research in Rwanda are recognized internationally, and can be used to influence policy and future research around the globe. In the event that the PI is foreign, it is important the Rwandan collaborator be a co-PI on any publication, consistent with the guidelines for authorship addressed in the Roles and Responsibilities of Investigators

document. . For research done in Rwanda that is initiated by a foreign PI, it is encouraged that at least four Rwandans be collaborators.

D. Renewal of Approval

Researchers who wish to extend their periods of data collection must renew the approval for the projects. The PI is required to compile a report on the work already completed, and write a letter detailing the rationale and need behind extending the data collection. If the extension is within the same research methods, these materials should be submitted to the IRB or RNEC at least one month prior to the expiration of the original approval. The IRB or RNEC will respond within one month, and renewal may be approved for up to an additional one year, except in special circumstances. At this point, a "renewal of research" form should be submitted to the Ministry of Health. If the research methods for the extension differ from those originally approved, the request for an extension must be submitted to the SRC prior to the renewal approval by IRB or RNEC, and before final renewal is registered at the Ministry of Health. This more extensive renewal process may take up to two months, so researchers should therefore plan ahead accordingly so as not to have to suspend data collection.

VII. Provisions for the Transition Period

It is understood that many of the structures described above are not yet implemented, and that while they are being created, it is important to have provisions in place to guide research. These provisions will be removed from this document when all structures exist. To that end, if SRCs and IRBs do exist for an institution, researchers affiliated with those institutions should follow the protocol described above. If they do not, or a researcher is not affiliated with an institution, the following procedures should be followed:

1. Scientific review will happen in 3 ways. For projects covering at least one whole province, proposals should be submitted to NISR for scientific review. Proposals treating HIV/AIDS, Non communicable diseases,Malaria, Mental health should be submitted to IHDPC . All other proposals should be submitted directly to the RNEC, which will provide scientific review.

2. Ethical review will happen at the RNEC. Proposals should be submitted in accordance with the SOPs of the RNEC.
3. All proposals (approved by scientific and ethical review) will be addressed to the Honorable Minister of Health and submitted to the Ministry of Health Medical Education and Research Department. They will be registered and the PI will receive a letter of authorization from the Minister of Health to facilitate implementation of the research, as above.

VIII. Additional Resources

1. Health Sector Research Policy (HSRP), Ministry of Health website.
2. Standard Operating Procedures, Rwanda National Ethics Committee <http://www.moh.gov.rw/index.php?option=com_docman&Itemid=81>
3. Visa Instruction Manual, National Institute of Statistics of Rwanda <http://www.statistics.gov.rw/images/PDF/Visa%20Instruction%20manual.pdf>
4. <http://www.rrrs.gov.rw:8080/ResearchProject/faces/faces/Login.jsp>
5. Ministerial Instructions on Research, Ministry of Education <http://www.mineduc.gov.rw/IMG/tif/Research_Law0001.tif>