RESEARCH MISCONDUCT POLICY

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I. General Policy

The Misconduct policy of Research for Development (RD Rwanda) serves to maintain the highest standards of integrity in research conducted by Research for Development. Therefore, upholding the highest ethical standards in conducting and reporting research falls on the administration, team, and clients of the organization. This obligation extends not only to the Research for Development community but also to the global research community and to both public and commercial institutions that support research, particularly NIH.

The administration, staff, and clients of the Research for Development also share the responsibility to ensure that misconduct in research, which includes fabrication, falsification, and plagiarism, is reported timely and accurately. At the same time, the organization must ensure that allegations of research misconduct are handled fairly and effectively, while preserving or restoring the reputation of the organization, as well as that of those individuals who in good faith file allegations of misconduct and, to the extent possible, those charged falsely (42 CFR, Vol 1, § 93.100, 2020, P729).

The purpose of the Research for Development Misconduct Policy is to provide the organization with guidelines for reporting and investigating and taking action for allegations of research misconduct(42 CFR, Vol 1, § 93.101, 2020, P729).

II. Applicability

The Research for Development (RD Rwanda) Misconduct Policy involves all individuals and entities linked with the organization engaged in scientific research, including specialists, scientists, technicians, and other staff members and other external researchers affiliated in the organization programs and projects, especially those sponsored by NIH. This policy, under the governance and authority of Research for Development Management committee the Research Integrity Officer implement it according to laws and regulations from NIH to comply with Public Health Service (“PHS”), Office of Research Integrity (“ORI”) and the National Science Foundation (“NSF”) regulations. This Policy does not replace any regulating document but complete them to emphasize the prevention of research related fabrication, falsification and plagiarism .

The Public Health Service and the National Science Foundation administer regulations regarding the investigation of allegations of misconduct involving research-related activities funded by these agencies. The Research for Development Research Misconduct Policy was established in line with these regulations applicable to the Public Health Service, Office of Research Integrity and the National Science Foundation. However, the application of this policy shall

not be limited to allegations of research misconduct arising out of federally funded research but to other research auto-funded or supported by other national and international organization (42 CFR, Vol 1, § 93.102, 2020, P729).

III. Definitions

For the purpose of this Policy, the terms identified below shall have the following definitions (42 CFR, Vol 1, § 93.201-227, 2020, P731-734):

ALLEGATION

Allegation means any written or oral statement or other indication of possible research misconduct made to the Research for Development.

FABRICATION

Fabrication refers to the creation of research data, results, or any other information, as well as recording or reporting it in a way that differs from reality in any way possible.

FALSIFICATION

Falsification indicates modifying research data, materials, equipment, or processes, or findings such that the research conducted no more reflects the existing reality.

GOOD FAITH ALLEGATION

Good faith allegation is an allegation honestly made to the potential research misconduct. An allegation is not in good faith if it is recklessly raised or disregards or ignores the facts that would invalidate the allegation.

INQUIRY

An inquiry is a preliminary phase of information gathering and fact-finding to decide if a claim or apparent incidence of research misconduct calls for further examination.

INVESTIGATION

Investigation is defined as an act that, all pertinent facts and other evidence are formally examined and evaluated in order to ascertain whether research misconduct has taken place, who is to blame, and how serious the misconduct was.

PLAGIARISM

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

IV. Inquiry

(Reference: 42 CFR, Vol 1, § 93.307-309, 2020, P737-738).

A. Initial Notification

The director in charge of research ethics, the chairwoman of RNEC, and the Sponsor, if he requested the opening of the investigation, must all be notified in writing by the Research Integrity Officer before the investigation may commence.

B. Purpose

The intent of the inquiry is to give the inquiry committee the opportunity to conduct a preliminary analysis of the accusation based solely on the written material. To ascertain if the claim is well-founded, the inquiry committee shall examine the allegation and the pertinent research materials. The Inquiry Committee may decide that there is enough proof to conclude that there has been no research misconduct. Alternately, the Inquiry Committee may decide that more factual issues involving the claim need to be investigated in order to make a conclusion about whether or not research misconduct has occurred.

C. Inquiry Committee

A research integrity officer and three additional seasoned experts will be chosen by the director of research ethics in Research for Development to serve as the inquiry committee for each inquiry. The committee will be led by the research integrity officer, who will take reasonable measures to ensure that the members of the inquiry committee are qualified for their positions, free from actual or apparent conflicts of interest or bias, and capable of conducting an unbiased analysis of the

evidence at their disposal.

D. Procedure

The Research Integrity Officer shall initiate needed steps to gather all records necessary to conduct the research misconduct proceeding as soon as is reasonably possible after the Research Integrity Officer determines that an inquiry is required, but in no event later than the time the Respondent receives notice of the inquiry. With the exception of scientific instruments that are shared by several users, evidence must be stored securely. As long as the copies have essentially similar evidentiary value to the originals, the Research Integrity Officer may take custody of copies of the evidence contained on such instruments.

The allegation or allegations as well as the pertinent research materials must be examined by the inquiry committee. This written record will be examined by the inquiry committee to see if the complaint or allegation of research misconduct may be well-founded.

E. Inquiry Decision

If the investigation committee finds that the claim of research misconduct is unfounded, it will advise against conducting an investigation.

The Inquiry Committee will suggest that additional investigation is required if it finds that the claim of research misconduct may be well-founded.

F. Inquiry Report

After the inquiry is complete, the inquiry committee must write a thorough inquiry report and submit it to the director responsible for research ethics. A copy of the inquiry report must be given to the respondent by the research integrity officer.

G. Reporting to Sponsors

The Sponsor(s) will be notified by the Research Integrity Officer and given a copy of the final Inquiry Report as well as this Policy if an investigation is decided upon.

The Research Integrity Officer will send a copy of the final Inquiry Report and the decision to the Sponsor if the Director of Research Ethics decides against moving forward with an Investigation and the Inquiry was initiated at the Sponsor's request. If not, the matter might be resolved without giving the Sponsor a heads-up.

V. ORI Requirements (if applicable)

Within 30 calendar days after deciding that an Investigation is required based on the Inquiry Report, the Research Integrity Officer shall inform and give a copy of the Inquiry report to the Director of the ORI if the accusation includes Public Health Service assistance or sponsorship. The organization's decision to launch an investigation must be communicated in writing to the ORI Director on or before the investigation's start date.

VI. Investigation

(Reference: 42 CFR, Vol 1, § 93.307-309, 2020, P737-738).

A. Purpose of the Investigation

The purpose of the Investigation is to make a final decision as to whether research misconduct has occurred or not. The Investigation shall also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human subjects or the general public or affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the Investigation shall be set forth in an Investigation Report.

B. Notification

The Research Integrity Officer shall notify the Respondent as soon as reasonably possible after the Director in charge of research ethics decides that an Investigation is necessary. With notification, the Respondent shall receive the following materials: a copy of the final Inquiry Report; the specific allegations; and a copy of this Policy. The Respondent shall also be notified of the members of the Investigation Committee, the sources of funding, and the opportunity of the Respondent to be interviewed, to provide information, to challenge at any time during the investigation the membership of the Investigation Committee and experts based on bias or conflict of interest, and to comment on the draft Investigation Report.

If the allegation of research misconduct involves Public Health Service support or sponsorship, the Respondent shall also be notified that the ORI will perform an oversight review of the Investigation Report.

C. Formation of Investigation Committee

The Research Integrity Officer may or may not be one of the five persons the Director in charge of research ethics appoints to serve as the Investigation Committee. The

Investigation Committee must include at least one member who is not currently connected to the Research for Development. The Investigation Committee must contain at least one member with knowledge of the specific discipline that is connected to the accusation of research misconduct who is free from any actual conflicts of interest. The day the Investigation Committee is charged is the first day of the investigation.

D. Procedure

The Research Integrity Officer shall collect any additional pertinent research documents that were not already obtained during the Inquiry as soon as an investigation is agreed upon. When the Respondent is informed that an investigation has started, these extra records should be retrieved at the same time or earlier.

E. Investigation Committee

Within 30 calendar days after the date a final finding that an Investigation is necessary, the Investigation Committee shall be charged and the Investigation shall commence. The Investigation Committee will examine the final Inquiry Report as well as any pertinent paperwork and related research materials before beginning its investigation. The Respondent, the Reporting Individual, and any other pertinent witnesses must be questioned by the investigation committee. Interviews with everyone who is either engaged in the accusation or against whom the complaint is made, as well as interviews with anybody else who may know something important about the allegations, should be done whenever deemed important. These interviews will be either recorded or transcribed.

F. Investigation Report

At the conclusion of the Investigation, the Investigation Committee shall prepare a written Investigation Report. A draft Investigation Report shall go through the review and changes may be made. After this review is complete and any changes have been made, the Investigation Committee shall submit the final Investigation Report to the Director in charge of research ethics and give a copy to Research Integrity Officer if he is not part of the committee.

G. Finalizing the Investigation Report

The investigation committee will review comments on the investigation report after receiving them, consider the comments, and make any changes to the investigation report that they prove to be necessary before publishing the final investigation report.

The final investigation report and the supporting documentation for the investigation committee's conclusions must be kept in a file by the research integrity officer.

H. Investigation Decision and Notification

1. The Investigation Committee shall recommend such a conclusion to the Director in charge of Research and Ethics if it finds, by a preponderance of the evidence, that no research misconduct has taken place.
2. If the Investigation Committee determines that, by a preponderance of the facts, research misconduct has happened, then it shall recommend such a finding to the Director in charge of Research and Ethics.

The Research Integrity Officer shall provide the Director in charge of Research and Ethics for Research with a complete copy of the final Investigation Report and he shall make the final compilation of facts to help the Director in accepting or not the recommendation of the Investigation Report, its findings, and recommended institutional actions, if any.

The Research Integrity Officer will send written notices to the Respondent and the Reporting Individual when a final decision has been made and approved by all parties involved. The Research Integrity Officer must also inform any Sponsors who are participating in the investigation of the investigation's status and its findings. A funding or sponsoring agency's notification requirements must be complied with at all times, according to the Research Integrity.

I. Time Limit for Completing the Investigation

With the exception of justified extensions, the Investigation must be finished within 120 calendar days. Within 75 calendar days of the date on which it was charged, the Investigation Committee must submit its Investigation Report to the Director in charge of research ethics.
If the Director of Research and Ethics finds that there has been research misconduct, the investigation is over. After receiving the Investigation Report, this decision must be made within 15 days. Any request for a deadline extension or for the Investigation Committee to perform extra research or analysis should be justified and reflected in the investigation report's final version.

J. Requirements for Reporting to ORI (if applicable)

When a claim of research misconduct involves funding or sponsorship from the Public Health Service, the Research Integrity Officer must ensure compliance with the related guidelines and requirements. The Research Integrity Officer may get in touch with the

ORI for assistance and consultation when a research misconduct admission is made.

VII. Administrative Actions and appeal

In order to safeguard the public's health, ensure the safety of human and animal test subjects, and stop the exploitation of research that may have been faked, created, or plagiarized, the organization reserves the right to take reasonable, temporary actions. An inquiry or investigation committee may decide to impose interim measures after consulting with the institutional legal advisor about the best course of action for the investigation. Prior to the action being taken taking effect, the respondent has 15 days to appeal and receive feedback (42 CFR, Vol 1, § 93.314-316, 2020, P739-740).

A. Restoration of the Respondent’s Reputation

The organization shall make all reasonable and practical measures, upon request and if necessary, to restore the Respondent's reputation if it is determined that research misconduct has not taken place. The Research Integrity Officer should think about informing those people who were aware of or participated in the investigation of the final decision and making the final outcome public in the same forums where the complaint of research misconduct was previously made, depending on the specific circumstances.

B. Protection of the Reporting Individual and Others

The Research Integrity Officer shall make all reasonable and practical efforts, if requested and as necessary, to safeguard the positions and reputations of the Reporting Individuals who made allegations of research misconduct in good faith and others who cooperate in good faith with inquiries and investigations, regardless of whether the organization or a Sponsor determines that research misconduct has occurred. During or after the inquiry and investigation, the research integrity officer must also take the necessary precautions to stop any retaliation against the reporting individual.

C. Allegations Not Made in Good Faith

The Director in charge of research ethics will assess whether the claims of research misconduct submitted by the Reporting Individual were made in good faith, if applicable. After giving the Reporting Individual due process if an allegation was not made in good faith, the organization will decide if administrative action against the Reporting Individual is warranted.

VIII. Record Retention

The Research Integrity Officer must create a complete file after a matter is resolved and all subsequent related actions have been taken. This file must include copies of all documents and other materials that were provided to the Research Integrity Officer or the Inquiry and/or Investigation Committees, as well as the records of any Pre-Inquiry, Inquiry, or Investigation. After the incident is resolved, the Research Integrity Officer must maintain the file in a safe place for at least seven years to allow for a later evaluation of the situation. The documents of the case must be made available, upon request, to authorized staff in the U.S. Department of Health and Human Services, if any accusation of research misconduct involves support or sponsorship from the Public Health Service (42 CFR, Vol 1, § 93.317, 2020, P740).