



Financial Conflict of Interest Policy

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I. Purpose

A non-profit organization dedicated to conducting research, Research for Development ("RD Rwanda"), is responsible for ensuring that each member of the research community meets their institutional responsibilities with the highest level of ethical behavior and without any conflicts of interest. The Research for Development ("RD Rwanda") has formed this policy to prevent, manage, and resolve any type of Conflict of Interests (whether substantial or not), as one of the region's research institutes for medical education, fundamental research, and clinical inquiry.

Discovering, developing, and applying new knowledge aimed at enhancing health is one of RD Rwanda's primary research activities, in addition to providing worldwide research education. RD Rwanda has prepared for a leadership position in the field of conflicts of interest by maintaining its policy statements and disclosure standards. All research undertaken by RD Rwanda is required to adhere to this financial conflict of interest policy, which is intended to be compliant with all applicable international and US federal laws as well as social considerations. It also strives to ensure the professional independence and research independence of RD Rwanda's scientists, trainers, clinical practitioners, sponsored students, and staff as part of the self-regulation of science, medical education, and clinical practice. (42 CFR, Vol 1, § 50.604, 2020, P250-253).

II. Training of Investigators and other involved individuals

(Reference: 42 CFR, Vol 1, § 50.604(b), 2020, P251)

- Each covered individual at RD Rwanda is informed of the content and implementation of the Institution's policy on financial conflicts of interest;
- Each covered individual at RD Rwanda has a responsibility to disclose significant financial interests;
- Each covered individual is required to complete a certified training regarding FCOI at least every four years;

If the project is funded by PHS, the above requirements will be applied in the following circumstances:

- (1) The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of covered individual;
- (2) A covered individual is new in RD Rwanda; or
- (3) RD Rwanda finds that a covered individual is not in compliance with the Institution's financial conflict of interest policy or management plan.

III. Scope

(Reference: 42 CFR, Vol 1, § 50.603, 2020, P253-257)

A. Comprehensive Policy

The whole conflict of interest policy statement for RD Rwanda's entire institutional activity is intended to be contained in one document. The policy statements that are attached deal with specific issues of concern and are crucial components of our overall policy.

B. Covered Individuals

All individuals employed by RD Rwanda in roles such as Principal Investigators (PI), Co-Principal Investigators (Co-PI), lead authors/co-authors of studies, researchers, whether in permanent positions, part time, acting as consultants, or engaged in other research projects or grants, and whose compensation or financial support is provided by external organizations or through donations to RD Rwanda, are all obligated to adhere to the comprehensive conflict of interest policy delineated in this document.

C. Institution

It is accepted that RD Rwanda may be in a position where the results of a research project being conducted in its facilities and/or by its research members could plausibly appear to have an impact on its financial interests.

The following has been implemented to lessen that chance:

- It is accepted that RD Rwanda may be in a position where the results of a research project being conducted in its facilities and/or by its research members could plausibly appear to have an impact on its financial interests. The following has been implemented to lessen that chance
- Protocols in which RD Rwanda may have a financial interest shall be reviewed for the protection of human subjects by an outside National Research Board (NRB), formally known as the "Rwanda National Ethics Committee" (RNEC), if necessary to reduce any institutional conflicts of interest.

D. Institutional Governance

To avoid any institutional conflicts of interest, protocols in which RD Rwanda may have a financial interest must be examined for protection of human subjects by an external National Research Board (NRB), officially known as the "Rwanda National Ethics Committee" (RNEC).

E. Administrative COI Management

RD Rwanda adheres to policies and procedures pertaining to purchasing and procurement and to oversight of potential COI for non-researchers' employees have been published by RD Rwanda.

F. Clinical Research

(Reference: 42 CFR, Vol 1, § 50.606(c), 2020, P257)

All research carried out under RD Rwanda's supervision must adhere to the guidelines in this policy. Human subject research is particularly troubling. Because of this, all submitted protocols, modifications, and annual progress reports must undergo thorough an assessment of the RD Rwanda's Institutional Conflict of Interest Committee before being submitted for ethical approval

G. Conflict of Commitment

Covered Individuals may benefit from participating in extracurricular activities that develop their professional networks and showcase public service, as well as RD Rwanda. In order to participate in leadership positions in panels, committees, professional organizations, and other broadly construed public and professional service opportunities, Covered Individuals are encouraged. These interactions could fortify ties with numerous governmental, commercial, and nonprofit entities and pave the way for COI. Here is where this policy is supposed to protect the honorable use of federal funds for their intended purposes.

IV. Policy

(Reference: 42 CFR, Vol 1, § 50.604(a), 2020, P251)

Covered Individuals may benefit from participating in extracurricular activities that develop their professional networks and showcase public service, as well as RD Rwanda. In order to participate in leadership positions in panels, committees, professional organizations, and other broadly construed public and professional service opportunities, Covered Individuals are encouraged. These interactions could fortify ties with numerous governmental, commercial, and nonprofit entities and pave the way for COI. Here is where this policy is supposed to protect the honorable use of federal funds for their intended purposes.

All involved researchers must put first the needs of RD Rwanda and the requirements of the sponsor especially National Institutes of Health (NIH), while performing their Institutional Responsibilities on the organization's behalf. They should abstain from using their positions at RD Rwanda and personal profile to benefit or from taking advantage of the knowledge they acquire via their jobs. In addition, when performing their obligations on behalf of RD Rwanda, Covered Individuals must do so without compromising their impartiality or independence or giving the impression of doing so because of any personal or financial interests, connections, or other activities they may be engaged in.

The primary goal of this policy is to protect the integrity of all research activities at RD Rwanda from any potential or actual relationships between Covered Individuals or the institution and outside parties. RD Rwanda is anticipated to be better able to improve biomedical sciences research and enable its application in patient treatment and the promotion of public health as a result of collaborations that are effectively supervised and managed.

V. Implementation

A. Conflict of Interest Committee

The Executive Director appoints members from the Clinical and/or Paramedical, and Non-Clinical Officers as well as members of the RD Rwanda administration team, to make up the Conflict of Interest Committee (COIC) in charge of prevention, management and efficient treatment of COI mostly financial ones that could affect the decent use of federal funds.

B. Procedures

Disclosure by Covered Individuals

(Reference: 42 CFR, Vol 1, § 50.605(2), 2020, P254)

The purpose of full disclosure and review of potential conflict of interest situations is to reassure Covered Individuals, RD Rwanda, and the general public that business relationships have been looked into and will be managed in line with institutional and societal values and policies. In accordance with federal definitions and regulations, RD Rwanda mandates disclosure of any financial transactions with non-exempt entities, regardless of their cash worth.

All relationships, regardless of financial value or amount, and in particular any such relationships that meet the federal definition of "significant financial interests" (SFI), as defined in federal regulations, must be disclosed by Covered Individuals at the time of appointment or hiring and at specified times ("events") thereafter. Subsequent events which require updated disclosure are:

- Upon submission of a human subject research protocol, amendment, or progress report for a research project in which the staff member is an active participant.
- Upon submission of grant application to the Office of Grant Accounting as required by the funding or reviewing agency or other governmental agencies. This includes compliance with PHS and FDA requirements.
- Upon submission of a contract for industry-sponsored research.

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- Upon appointment as a member of the Institutional Review Board (IRB), the Committee on Conflict of Interest, or the Patent Committee.

Individuals completing the disclosure form must take reasonably diligent steps to determine the scope of their actual and potential interests as they may represent significant secondary interests with respect to their institutional responsibilities. However, the Committee on Conflicts of Interest at RD Rwanda is in charge of figuring out if any declared interests genuinely pose a financial or commitment conflict with regard to a person's institutional obligations. Additionally, individuals required to update disclosure will receive electronic notification when this must be done. The update must be completed and submitted within 10 business days of that notification.

C. Exclusions from Required Disclosure

Exclusions from required disclosure include:

- Earnings from investment vehicles (mutual funds, retirement accounts), as long as the individual has no direct influence over the decisions taken in relation to the investments made in these vehicles.
- Income from seminars, lectures, or teaching engagements sponsored by the primary research grant recipient, a local government agency, a higher education institution, an academic teaching hospital, a medical facility, or a research institute connected to an institution of higher education; or
- Income received as a result of participation in advisory committees or review panels for federal, state, or municipal government agencies, educational institutions, academic teaching hospitals, medical centers, or research institutes connected to educational institutions.

D. Disclosure of Travel

Any travel connected to their institutional obligations that is sponsored (i.e., not reimbursed but funded on the individual's behalf so that the precise monetary value may not be easily identifiable) or reimbursed by a non-excluded organization must be disclosed by Covered Individuals. As mentioned above, excluded entities include the principal awardee, local government agencies, academic teaching hospitals and medical facilities, and research institutes connected to higher education institutions.

1. Any trip that was sponsored or paid within the previous 12 months should be disclosed in the initial disclosure of a covered individual.
2. Within 30 days of the travel event, any sponsored or reimbursed travel that takes place after the original disclosure must be recorded.

Travel reimbursement disclosure must at least include:

- a. The purpose of the trip,
- b. The identity of the sponsor or organizer,
- c. The destination,

- d. The duration.

To properly examine a travel declaration, the Institutional Official must decide if more details are needed.

E. Timeliness of Disclosure

Within thirty (30) days of establishing a new business relationship, getting increased compensation in an existing partnership, or experiencing one of the aforementioned travel events, Covered Individuals are required to file an updated disclosure. A disclosure is deemed "up-to-date" if it is dated less than six months after the Conflict of Interest review date.

F. COI Committee Action

The COI Committee will set up a system to quickly analyze all COI declarations, identify those that could point to possible conflicts of interest, and determine the best course of action to take in each case.

- a. The Director and Administrator of the COI committee conduct an initial review of all COI disclosures. The first screening may find that there are no unacceptable conflicts of interest or that any possible conflicts may be resolved via disclosure in a consent form or at the time of publishing or presentation.
- b. The item will be forwarded to the full committee for evaluation and recommendation if the preliminary screening finds that an unacceptable COI may exist and may need more comprehensive mitigation. This referral might be made electronically.
- c. The committee must give recommendations about the steps necessary to resolve or appropriately lessen the issue within 7 days.
- d. The rationale for such recommendations should be explained and justified in writing to the covered individual.

The determined outcome and/or recommendations of the screening committee may be contested by the covered individual in writing or in person.

1. If a covered individual and or disagrees with the decision and/or suggestions of the first screening committee, he is free to speak with the COI committee Director about it. If a solution cannot be found, the issue will be brought up before the whole COI Committee. The complete COI Committee will make a final decision and, if necessary, set the conditions for its mitigation.

After receiving a decision from the COI Committee, the covered person has thirty (30) days to submit any new information that may have an impact on the decision and ask for the Committee to reconsider its decision.

2. The Committee shall promptly and thoroughly analyze such documents before determining whether the original decision should be carried out or whether a change in the decision is necessary.
3. In the event that a prohibited conflict of interest is found, the Committee on Conflict of Interest shall report its findings and recommendations for the management and/or mitigation of the conflict of interest to the Director of Administration and Finance, with copies, as necessary, to the Executive Director, the department Head of the Covered Individual, the IRB (if related to human research, internal if any otherwise to the external IRB with mandate to review and approve the researches being conducted under RD Rwanda), research sponsors, and any governmental agencies that may be involved in the matter.
4. The person (s) shall immediately abide by any instructions for monitoring, modifying, or ceasing such conduct where the Conflict of Interest Committee concludes that such reported activity is restricted or banned.
5. Even when a scenario including a conflict of interest is accepted, the conflict may need to be reported to public or private organizations who are funding or contemplating funding the study.
6. The disclosure of the conflict of interest may also be required when results related to the conflict of interest are presented in journals, professional forums, or other open settings.
7. In addition, disclosures to potential subjects must be made in line with instructions from the Committee on Clinical Investigations if any disclosed action is connected to a human subject research protocol.
8. The Institution shall require the Investigator to disclose the financial conflict of interest in any instance where the HHS determines that a PHS-funded research project or clinical research with the aim of assessing the safety or effectiveness of a drug, medical device, or treatment has been planned, carried out, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution as required by this regulation.

G. Final Reporting FCOI Pertaining to PHS-Funded Research

According to federal laws, the PHS Awarding Component must receive an FCOI report if a FI or SFI is found to have a financial conflict of interest (FCOI) with regard to a PHS-funded research project Reporting of financial conflicts of interest (42 CFR, Vol 1, 50.605(b), 2020, P253-257).

Regarding grant-funded research, any conflicting interests discovered after the institution submitted its initial report under the grant are required to be disclosed to the PHS Awarding Component and managed, reduced, or eliminated, at least temporarily, within sixty days of discovery.

The Institution should quickly notify the PHS Awarding Component of the remedial action taken or to be taken if the design, conduct, or reporting of the PHS-funded research has been influenced by an Investigator's failure to abide by the Institution's conflict of interest policy. The PHS Awarding Component will evaluate the circumstance and, if necessary,

take appropriate action or refer the problem to the Institution for further action.

H. Sub-Recipients

A written agreement between RD Rwanda and the subrecipient must include provisions stating whether the subrecipient's investigators will be subject to RD Rwanda's financial conflicts of interest policy or that of the subrecipient. This is true for any research where there is a subrecipient relationship with an investigator at another institution.

The written agreement must specify that the subrecipient Investigators are subject to RD Rwanda's financial conflicts of interest policy for disclosing material financial interests that are directly related to the subrecipient's work for RD Rwanda if the subrecipient is unable to provide such certification. The written agreement must specify the deadline(s) by which the subrecipient must provide RD Rwanda with all disclosures of material financial interests. The deadline(s) must be long enough to allow RD Rwanda to meet its legal obligations for timely review, management, and reporting (42 CFR, vol 1, 50.604(c), 2020, P252).

I. Monitoring

The COI committee must continuously check on the Investigator's adherence to the management plan after a COI management plan has been put into place until the research project is over. If funding runs out, RD Rwanda will keep an eye on all relevant studies until they are finished in order to make sure that the COI standards have been completed.

J. Retrospective Review

(Reference: 42 CFR, Vol 1, § 50.605(a)(3), 2020, P254)

According to federal regulation, in the event that the COI Committee discovers a FI or SFI that was not disclosed by an Investigator in a timely manner or, for whatever reason, was not previously reviewed during an ongoing PHS-funded research project (for example, was not timely reviewed or reported by a subrecipient), the COI Committee shall, within sixty days: review the significant financial interest; determine whether it is related to PHS-funded research; determine what the potential conflicts of interest are; and, if so:

Put into place, at least temporarily, a management strategy outlining the steps that have been and will be done to handle future financial conflicts of interest; and

1. To ascertain whether any PHS-funded research, or a portion thereof, carried out during the period of the noncompliance was biased in the design, conduct, or reporting of such research, the Investigator shall, within 120 days of the determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project.

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2. RD Rwanda will document the recorded review of occurred FCOI. Such documentation will include, but not necessarily be limited to, all of the following key elements (42 CFR, vol 1, 50.604(B), 2020, P252):
 - a. Project number
 - b. Project title
 - c. PD/PI or contact PD/PI if a multiple PD/PI model is used
 - d. Name of the Investigator with the FCOI
 - e. Name of the entity with which the Investigator has a financial conflict of interest
 - f. Reason(s) for the retrospective review
 - g. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed)
 - h. Findings of the review
 - i. Conclusions of the review
 3. The Institution should amend the previously submitted FCOI report, where necessary based on the findings of the retrospective review, outlining the steps that will be taken to address the financial conflict of interest moving forward.
 4. If prejudice is discovered, the Institution must tell the PHS Awarding Component as soon as possible and submit a mitigating report. The mitigation report must include the crucial components that were noted in the retrospective evaluation, an explanation of how the bias affected the research project, and the Institution's action plan or steps taken to reduce or eliminate the bias's effects. (For instance, the effect on the research project; the degree of harm caused, including any evidence—qualitative or quantitative—to support any current or potential harm; a determination of whether the research project can be saved.
 5. Thereafter, RD Rwanda will submit FCOI reports annually.
 6. RD Rwanda may decide that between the time the financial conflict of interest or the investigator's noncompliance is discovered and the end of RD Rwanda's retrospective review, additional interim measures are required with regard to the investigator's participation in the PHS-funded research project. This depends on the nature of the FCOI.

K. Records Maintenance

(Reference: 42 CFR, Vol 1, § 50.604(i), 2020, P253)

The Conflict of Interest Committee will maintain records of all FCOI, and of all actions taken by the Institution to mitigate or eliminate any such conflicting interest for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified for different situations.

In accordance with federal standards, RD Rwanda must submit yearly FCOI reports relevant to PHS-funded research.

1. RD Rwanda must submit an FCOI report to the PHS Awarding Component before

any funds from a PHS-funded research project are used.

2. with relation to any major financial interest that an Investigator may have that the Institution determines to be in conflict, and confirm that a management plan has been put in place.

L. Remedies and Sanctions for Non-Compliance

(Reference: 42 CFR, Vol 1, § 50.606, 2020, P257 for remedies and 42 CFR, Vol 1, § 50.604(j), 2020, P253 for sanctions)

All Covered Individuals are required to adhere to this policy to the letter by RD Rwanda. The involved covered individual may face sanctions if there is a knowing or deliberate violation of the policy, such as the failure to file or the knowing filing of an incomplete, inaccurate, or misleading disclosure form or the failure to promptly comply with monitoring, modification, or termination requirements. The researcher against whom written charges have been made may be suspended from all or part of their duties by the Dean pending a decision on the charges in cases where doing so threatens immediate harm to themselves or others or may result in irreparable harm to RD Rwanda. In the case of a staff member such suspension by could be with salary pending final action upon such charges.

The COI Committee is responsible for reviewing all instances of non-compliance with this policy and to recommend appropriate measures to the Executive Director of RD Rwanda. Included in possible sanctions if the non-compliance is significant (otherwise the research will be called for advice followed by remedial action), are the following:

- i. Formal admonition including possible inclusion in the individual's file of a letter indicating that the researcher's good standing has been called into question;
- ii. Ineligibility of the researcher to apply for grants, sponsored research agreements, to seek Committee on Clinical Investigation (CCI) approval, conduct animal or other research, or to teach or supervise students;
- iii. Notice to appropriate parties (including government and private agencies) of the conflict of interest activity found to exist;
- iv. Dismissal from the Institution.

M. Non-Retaliation

No individual will be subjected to retaliation by the institution, or by individuals under its direction or control, for good faith reporting of any actual or perceived violation of this policy.

N. Public Accessibility

In compliance with federal regulations (42 CFR, Vol1, 50.605(a)(5)(i)-(iii),2020,P256) , RD Rwanda shall ensure public accessibility by responding, within 5 business days, to a signed request for information concerning any significant financial interest disclosed to the institution that meets the following criteria:

- a. The FI or SFI was disclosed and is still held by the investigator;
- b. RD Rwanda has determined that the FI or SFI is related to PHS-funded research; and
- c. RD Rwanda has determined that the FI or SFI is an FCOI.

Requests must be made in writing and include the name of the specific investigator and the name or identifying number of the PHS-funded research project that the request relates to. Information regarding significant financial interests of an individual shall be available, for responses to written requests, for three years from the date that the information was most recently updated. Address requests for information to:

*Boniface Nsengiyumva MSc., Chair,
Conflict of Interest Committee for Research for
Development
KG 8 Avenue
Kibagabaga, Kigali city*

VI. Definitions

(Reference: 42 CFR, Vol 1, § 50.603, 2020, P249-250)

Conflict of Interest (COI): A conflict of interest is a collection of circumstances that raises the possibility that a secondary interest would improperly influence a professional's judgment or conduct with regard to a primary interest.

Covered Individuals: This policy applies to all individual researchers employed by RD Rwanda, individuals employed by clinical affiliates of RD Rwanda when participating in RD Rwanda's research Programs, and sponsored students involved in RD Rwanda's internship Programs. The covered individuals mainly include the Principal Investigators (PI), Co-Principal Investigators (Co-PI), lead authors/co-authors of studies, researchers, whether in permanent positions, part time, acting as consultants.

Financial Conflict of Interest (FCOI): A financial interest (FI) for covered individuals (described above) or a significant financial interest (SFI) that could adversely influence a covered individual's institutional obligations or directly and materially alter the design, conduct, or reporting of research.

Financial Interest (FI): If the Covered Individual received ANY compensation from a third party in the year prior to the disclosure or held any equity interest in the third party as of the disclosure date, FI is present. For the purposes of this definition, compensation includes a

salary as well as any payment for services that aren't otherwise classified as wages (such as consulting fees, honoraria, or payments for writing), and equity interests include any stock, stock options, or other ownership interests that are valued according to the market or other reasonable methods to reflect fair market value. Additionally, upon receipt of ANY revenue associated with any Intellectual Property Rights (IP) (such as patents, copyrights), FI exists.

Institutional Official: The individual appointed by RD Rwanda to oversee the implementation and management of the Conflict of Interest (COI). This person also serves as the COI compliance officer for RD Rwanda.

Institutional Responsibilities: Activities like research, research consultation, teaching, professional practice, participation in institutional committees, and service on boards like Institutional Review Boards or Data and Safety Monitoring Boards are just a few examples of the professional responsibilities a covered person performs on behalf of RD Rwanda.

Primary Concerns: In the context of an academic medical facility, primary concerns include the safety of patients, the reliability of research, and the standard of instruction. These fit the definition of "Institutional Responsibilities" given above. **Secondary Interests:** In addition to monetary gain, secondary interests also include the desire for professional growth, praise for one's accomplishments in the workplace, and favors done for friends, family, pupils, and coworkers.

Any financial interest of a Related Party that logically seems to be connected to the covered individual's institutional responsibilities is referred to as a Significant Financial Interest (SFI). SFI comprises:

- **For publicly traded companies:** If the total value of all compensation received from the company in the year prior to the disclosure and the value of all equity interests held by the company as of the disclosure date exceeds \$5,000. Salary and any payments for services that aren't classified as salaries (including consultancy fees, honoraria, and rewards for writing) are all considered to be remuneration. Stocks, stock options, or other ownership interests are examples of equity interests.
- **In non-publicly traded entities:** If the covered individual (or their spouse or dependent children) holds any equity interest (e.g., stocks, stock options, or other ownership interests), or if the value of any compensation received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000.
 - **Intellectual property (IP) rights:** These cover copyrights, patents, and any revenue derived from such rights or interests.

Financial Interest (FI) and Significant Financial Interest (SFI) do not include the following kinds of financial interests: salaries, royalties, or other compensation paid to the covered person by RD Rwanda if they are currently working for or being appointed by RD Rwanda, including intellectual property rights assigned to RD Rwanda and agreements to share in royalties associated with such rights.

The income earned from participation on advisory committees or review panels for federal, state, local government agencies or institutions of higher education is also excluded, as is the income from seminars, lectures, or teaching engagements sponsored by RD Rwanda as the Organization.

- **Primary Interests:** The well-being of patients, the integrity of the research, and the standard of instruction are the academic medical center's three main priorities. These are equivalent to the concept of "Institutional Responsibilities" as it is used here.
- **Secondary Interests:** In addition to financial gain, secondary interests might also include the desire for professional growth, recognition for professional accomplishment, and favors for friends, family, pupils, and coworkers.

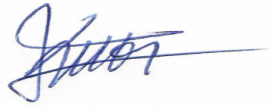
VII. Effective Date

Effective as of October 01, 2023.

VIII. Policy Management and Responsibilities

RD Rwanda's Conflict of Interest department is the Responsible Office under this Policy. RD Rwanda's Associate Research is the Responsible Executive, and RD Rwanda's Director of Conflict of Interest is the Responsible Officer for the management of this policy.

VIII. Approved (or Revised)



Gallican Kubwimana
Responsible Executive

September 29, 2023

Date