FINANCIAL CONFLICT OF INTEREST (FCOI) POLICY

A. GOAL

This document serves to establish a **Financial Conflict of Interest (FCOI)** policy for the **"Institut National de la Recherche Biomédicale" (INRB)** in **the Democratic Republic of the Congo (DRC)**, applicable to all its departments or divisions. The primary goal is to ensure adherence to **the 2011 FCOI regulation**, which advocates for objectivity in research (*42 CFR Part 50 Subpart F*). It supersedes any previous or similar procedures that were in effect prior to its implementation.

B. RATIONALE

The 2011 FCOI regulation (*42 CFR Part 50 Subpart F*) is designed to foster objectivity in research by setting forth standards that ensure a reasonable expectation for the impartiality in the design, execution, and reporting of research financed through National Institutes of Health (NIH) grants or cooperative agreements, thereby mitigating biases stemming from Investigator FCOIs. In order to qualify for NIH funding, INRB is obligated to uphold and enforce an FCOI policy that not only aligns with but also surpasses the stipulated regulatory criteria.

C. KEY DEFINITIONS

1. *Financial Conflict of Interest (FCOI)* refers to a Significant Financial Interest that has the potential to directly and significantly influence the design, conduct, or reporting of research funded by the Public Health Service.

2. *Significant Financial Interest (SFI)* entails one or more of the following interests held by the Investigator (including those of the Investigator's spouse and dependent children), which reasonably appears to relate to the Investigator's institutional responsibilities (defined by the 2011 FCOI regulation 42 CFR 50.603 or NIH's FAQ D.6. as an Investigator's professional responsibilities on behalf of the Institution (e.g., INRB), and as defined by the Institution in its policy on FCOI, which may include, for example, activities such as **research, research consultation, teaching, professional (e.g., clinical) practice, Institutional committee memberships**, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards or **other professional responsibilities included by INRB within the definition, as appropriate**):

For publicly traded entities, an SFI exists if, within **the preceding 12 months of disclosure**, the total value of remuneration received from the entity and the value of any equity interest in the entity **exceed $5,000** when aggregated. Remuneration comprises **salary and any other payments for services (e.g., consulting fees, honoraria, paid authorship)**, while **equity interest encompasses stock, stock options, or any other ownership** interest determined using public prices or other fair market value measures.

For non-publicly traded entities, an SFI exists if the total remuneration received from the entity within **the preceding 12 months exceeds $5,000** when aggregated, or if the Investigator (or their spouse or dependent children) holds **any equity interest (e.g., stock, stock options, or other ownership interest)**.

Income **exceeding $5,000** derived from **intellectual property rights and interests** (e.g., patents, copyrights) **must also be disclosed**.

Reimbursed or Sponsored Travel: Investigators are further required to disclose **any reimbursed or sponsored travel expenses exceeding $5,000 received within the past 12 months** (initial disclosure) related to their institutional responsibilities. This disclosure excludes travel sponsored by Federal, state, or local government agencies in the United States, United States institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with United States institutions of higher education.

NOTE: **Travel expenses reimbursed or sponsored** by **a foreign government**, including local or provincial governments or foreign institutions of higher education, must be disclosed **if exceeding $5,000.**

Details of travel disclosure must include the purpose of the trip, sponsor/organizer identity, destination, and duration.

Also, the term SFI excludes certain types of financial interests: **Salary, royalties, or other remuneration from the Investigator's current employment or appointment**, including intellectual property rights assigned to the company and agreements to share royalties related to such rights.

Any interest in a commercial or for-profit organization held by the Investigator. Income from investment vehicles such as mutual funds and retirement accounts, provided the Investigator does not
directly control investment decisions. **Income from seminars, lectures, or teaching engagements sponsored by Federal, state, or local government agencies in the United States**, United States institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with United States institutions of higher education.

Income from service **on advisory committees or review panels for Federal, state, or local government agencies in the United States**, United States institutions of higher education, academic teaching hospitals, medical centers, or research institutes affiliated with United States institutions of higher education. **Of note, income from similar activities sponsored by foreign governments or foreign institutions of higher education must be disclosed if such income exceeds$5,000. Refer to *NIH's FAQs E.36. and E.37.* for additional information.**

3. *Investigator* refers to **the program director (PD) or principal investigator (PI) and any other individual, irrespective of title or position, who bears**

responsibility for the design, conduct, or reporting of research funded or proposed for funding by the Public Health Service (NIH etc.,), which may include **collaborators** or **consultants.**

D. APPLICABILITY

This INRB policy applies to two main categories: 1) all NIH grants and cooperative agreements, with the exception of **Phase I Small Business Innovative Research (SBIR)** applications and awards, and 2) every Investigator, as defined above, who intends to participate in or is currently involved in research funded by the Public Health Service.

***Regulation Applicability*:**

This policy is a requirement outlined in *42 CFR Part 50 Subpart F*, accessible at *eCFR: 42 CFR Part 50 Subpart F* — **Promoting Objectivity in Research**.

E. PROCEDURES GUIDE

1. Training:

a) All investigators intending to participate in or already involved in PHS-funded research must receive information regarding INRB's FCOI policy, Federal regulation *42 CFR Part 50 Subpart F*, and their obligation to disclose significant financial interests per the policy.
b) Training for Investigators must occur:
    - Before commencing PHS-funded research.
    - Every four years thereafter.
    - Promptly in case of:
        - Revision of INRB's FCOI policy that affects Investigator disclosure requirements.
        - Hiring of a new Investigator.
        - Non-compliance with the FCOI policy or management plan by an Investigator.
c) Training involves Investigators certifying their review and understanding of:
    - INRB's Financial Conflict of Interest Policy.
    - NIH's "FCOI Training" on Regulation *42 CFR Part 50 Subpart F* available at FCOI Training | grants.nih.gov.
d) Implementation of the FCOI Policy includes:
    - Providing each Investigator with a written copy.
    - Adding the FCOI Policy to the INRB's website.

2. ***Disclosure, Review, and Monitoring Requirements:***

a) Each Investigator must disclose SFIs related to their INRB's responsibilities that meet or exceed the SFI definition provided in this policy, using INRB's Significant Financial Interest Form.
    - At the time of application for PHS-funded research.
    - Annually during the award period.
    - Within 30 days of discovering or acquiring a new SFI.

b) INRB's authorized official representative (AOR): **Dr. Stomy Karhemere**, will collect and review Investigator SFIs, determining if they constitute FCOIs.

- An SFI is considered related to PHS-funded research if the SFI could be affected by the research or is in an entity whose financial interest could be affected by the research.
- An Investigator may assist in determining the relationship between an SFI and PHS-funded research.
- An FCOI exists if the AOR reasonably determines the SFI could directly and significantly affect the research's design, conduct, or reporting. The word "significantly" means that the SFI would have a "material effect" on the research (see page 53261 of the Final Rule).

c) If an SFI is deemed to be an FCOI, INRB will manage it accordingly, potentially including public disclosure (e.g., requiring the Investigator to publicly disclose the FCOI in publications, presentations, to research personnel working on the study, to the Institution Review Board, etc.), appointment of an independent monitor, to human research participants on the informed consent, or modifying the research plan, etc. If applicable, additional management strategies will be implemented as per *NIH's FAQ F.1*.

d) Prior to expending PHS funds, INRB's AOR must:
   - Review all Investigator SFI disclosures.
   - Determine if any SFIs are related to PHS-funded research.
   - Determine if an FCOI exists, and if so,
   - Develop and implement a management plan

e) If a new Investigator joins or an existing one discloses a new SFI, the AOR will review the disclosures within 60 days and implement a management plan if needed.

f) If an undisclosed or unreviewed SFI is identified during ongoing PHS-funded research, the AOR will review the disclosure within 60 days and develop a management plan for future action.

g) The INRB will manage FCOIs of all Investigators, including subrecipient Investigators if applicable, and monitor compliance with management plans throughout the project duration.

3. Reporting Requirements to NIH:

a) INRB must submit initial, annual, and revised FCOI reports, if applicable, including all necessary information defined in *42 CFR 50.605(b)(3) or NIH's FAQ H.5.*, to the NIH via the eRA Commons FCOI Module for the Institution and its subrecipients if applicable.
   - Before fund expenditure.
   - Within 60 days of new or newly identified FCOIs for new or existing Investigators.
   - Annually, coinciding with the submission of the annual progress report. The report will detail FCOI status and any changes to the management plan until project completion.
   - After a retrospective review to update a previously submitted report if new information arises post-review.

b) INRB must promptly notify NIH of any bias found in the research's design, conduct, or reporting. A Mitigation Report outlining actions taken will be submitted in compliance with *42 CFR Part 50.605(b)(2)*.

c) INRB must promptly inform NIH if an Investigator fails to comply with the FCOI policy or if an FCOI management plan appears to bias the research.

4. Maintenance of Records:

- INRB will retain all FCOI-related records, including Investigator disclosures and the company's responses, for at least 3 years from the final expenditure report submission to NIH or other specified dates as per *45 CFR 75.361*.

5. Enforcement Mechanisms, Remedies, and Noncompliance:

- In cases of Investigator noncompliance with INRB's FCOI policy or management plan, appropriate employee sanctions or administrative actions will be enforced as defined by *42 CFR Part 50.504(i)*.
- Whenever a Financial Conflict of Interest is not identified or managed in a timely manner, including:
    a) Failure by the Investigator to disclose a Significant Financial Interest that is determined by the Institution to constitute a Financial Conflict of Interest ;
    b) Failure by the Institution to review or manage such a Financial Conflict of Interest ; or
    c) Failure by the Investigator to comply with a Financial Conflict of Interest management plan ;

  the Institution shall, within 120 days of the Institution's determination of noncompliance, complete a "retrospective review" of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance was biased in the design, conduct, or reporting of such research .
- In a case in which the Department of Health and Human Services determines that a PHS-funded research project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by an Investigator with an FCOI that was not managed or reported by the Institution as required by the regulation, the Institution shall require the Investigator involved to: a) Disclose the FCOI in each public presentation of the results of the research, and; b) To request an addendum to previously published presentations as defined by *42 CFR 50.606(c)*

6. Subrecipient Requirements:

- INRB will comply with all subrecipient requirements per *42 CFR 50.604(c)* and NIH Grants Policy Statement 15.2.1.
- Written agreements will establish whether subrecipients follow INRB's FCOI policy or their own, ensuring compliance with regulatory standards for disclosure of SFI and reporting identified FCOIs to the NIH for the time period prescribed in the regulation (e.g., prior to the expenditure of funds under the subaward, within 60 days of identifying a new SFI, and on an annual basis).

7. Public Accessibility Requirements:

a. INRB's FCOI policy will be made publicly accessible on its website.

b. Information concerning identified FCOIs held by senior/key personnel, as defined by *42 CFR Part 50.603*, will be made publicly accessible prior to the expenditure of funds. The publicly accessible information will :

- Include the minimum elements as provided by 42 *CFR Part 50.605(a)(5)(ii*).
- Be made available within 5 business days of a written request.
- Be updated at least annually, but a response to a written request will be current.
- Be updated within 60 days of a newly identified FCOI, but a response to a written request must will current.
- Remain available for 3 years from the date the information was most recently updated.

E. FORMS

INRB Significant Financial Interest Form (enclosed)

F. ELIGIBILITY FOR TRAINING

All employees or agents of the company falling under the following category must familiarize themselves with this procedure and provide their signature to signify their comprehension and commitment to compliance :

- All Investigators involved in current or prospective PHS-funded research projects.

G. DATE OF IMPLEMENTATION

This policy becomes effective as of the date of the most recent approval signature.

Expiration or Review :

This procedure and its accompanying forms remain in effect indefinitely, except if :

1. It undergoes revision as per the outlined procedures.
2. It becomes redundant due to the introduction of a procedure that explicitly replaces it.