IVAN RESEARCH INSTITUTE

Financial Conflict of Interest Policy

I. POLICY STATEMENT

This policy sets forth the obligations of IVAN Research Institute and its employees, and affiliates ("individuals"), with respect to financial conflicts of interest that involve Institute-affiliated research and sponsored project activities.

Purpose

The Institute encourages professional collaborations with individuals, companies, and other entities ("entities") external to the Institute. Such external relationships can further the Institute's commitment to excellence in research, education, and engagement, but may also result in conflicts of interest. A conflict of interest arises when an individual's external interest(s) may, or could appear to, bias or unduly influence their decision-making during work in the Institute, or compromise their ability to fulfill their obligations to the Institute.

This policy seeks to maintain objectivity across the lifespan of research in the Institute so that the design, conduct, outcomes, and reporting of Institute-affiliated research will not be biased, or perceived as biased, because of financial interests held by a researcher or their family members. Researchers are to conduct their affairs so that they recognize possible financial conflicts of interest, disclose them promptly to the Institute, and maintain their affairs so that they avoid or minimize conflicts of interest when they could or do exist.

Every researcher has an obligation to become familiar with and abide by the provisions of this policy. Questions about financial conflicts of interest in research should be directed to the Research Conflict of Interest (FCOI) program office. IVAN Research Institute researchers are to initially manage potential research conflicts of interest by remaining current with the following requirements:

- **Training.** Researchers are to complete initial and ongoing training on this policy, their Institute responsibilities, and regulations covering Financial Conflicts of Interest in Research (see **Section V**).

- **Disclosures**. Researchers are to submit initial, ad-hoc, and annual disclosures of external financial interests that may constitute a Significant Financial Interest (SFI) (see **Section IV**). Disclosures must include both Nigerian-based and non-Nigerian-based SFIs.

The Research Office and supervisors are to review disclosures and as appropriate, manage, reduce, or eliminate Financial Conflicts of Interest (see **Section VI**).

II. EXPECTATIONS and STANDARDS OF CONDUCT

Research at IVAN Research Institute is to be conducted with high professional standards and expectations for integrity. The standards of conduct below do not encompass all possible situations that could occur but should underpin the activities of IVAN Research Institute researchers

1. Individuals should not accept other employment or engage in external professional activities that would:

   a) Unduly influence their independent judgment as they perform Institute-affiliated work; or
   b) Require them to disclose confidential information acquired during their Institute work, to an external entity.

2. Individuals should not disclose or use confidential information acquired during their Institute work to further their personal or financial interests.

3. Individuals should not engage with an external entity if they have a financial interest in that entity that could reasonably conflict with their research or Institute responsibilities.

4. Individuals should abstain from investing in entities that could benefit from decisions they could make as a representative of the Institute.

5. Individuals should not accept benefits, remuneration, gifts, loans, or otherwise engage with an entity, if circumstances would reasonably infer that those benefit(s) could unduly influence or reward decisions that they could make during Institute work.

III. SCOPE

This policy applies to all individuals (termed "researchers" or "investigators," see definitions in **Sect. IV**) who are materially involved with Institute-affiliated research activities such as those described in protocols, proposals, studies, awards, or other research activity agreements. This policy is based on the Institute's ethical standards, on the requirements of the U.S. Public Health Service regulation and the National Science Foundation policy as they apply to their grantee institutions. These requirements promote objectivity in research by requiring that significant financial interests which arise from relationships with entities external to the Institute are disclosed to the Institute by the investigator with the financial interest, and managed, reduced, or eliminated as appropriate to reduce the risk of bias in research and related activities affiliated with the Institute.

This policy does not address other types of conflicts of interest that may arise for individuals affiliated with the Institute. Other laws and policies may apply to interactions between IVAN Research Institute employees and entities that are external to the Institute.

What Is a Financial Conflict of Interest at IVAN Research Institute?

A financial conflict of interest in research ("Research Conflict of Interest" or "Research Conflict") arises when Institute-affiliated research could be directly and significantly affected by a financial interest held by an investigator or their family member(s) (see **Sect. IV** for definitions). Such financial interests often arise from collaborations and relationships between external entities and Institute members involved in research.

Examples of possible research conflicts include, but are not limited to:

- Provision of funding, materials, products, or other support for Institute research from an external entity in which investigators or their family members have a financial interest.
- Receipt of payments from an external entity that may be interested in or related to your research.
- Holding or selling stock or stock options in an external entity that may be interested in or related to your research.
- Holding a position in an external entity that may be interested in or related to your research.
- Using Institute resources to benefit an external entity.

IV. DEFINITIONS

Aggregate value means the consolidated and summed total, in Nigerian currency, received from a single entity (i.e., remuneration, equity interests, sponsored travel, gifts, etc.) by the discloser and their family member(s).

Disclosure means submitting a completed or updated Institute disclosure form for external financial interests related to research.

Equity means owning shares or stock, or receiving or holding any other type of ownership interest in an entity.

Entity means any person, business, company, organization, institution, agency, or government (other than the Nigerian federal government). An entity may be Nigerian- or non-Nigerian-based, privately- or publicly-held, or hold a for-profit or non-profit tax status.

- "Private entity" refers to a business with stock or other ownership interests which cannot be bought or sold by the public
- "External entity" refers to any entity other than IVAN Research Institute.
- "Foreign entity" refers to any business, organization, agency, Institute, government, or other entity that is not registered or incorporated to do business in Nigeria.

Family Member(s) means an Investigator's spouse or domestic partner, and any dependent child(ren).

Financial Interest means anything of economic value held or received by an Investigator or their Family Member(s), originating from an Entity (other than IVAN Research Institute) regardless of whether the agreed currency value is readily available or ascertainable.

Financial Interests include, but are not limited to:

a) Remuneration
b) Equity or other ownership interests (e.g., stocks, stock options) in an Entity
c) Intellectual property rights and interests (e.g., patents, trademarks, copyrights)
d) Sponsorship or reimbursement of travel- and lodging-related expenses

Financial Interests do **not** include:

a) Remuneration received directly from IVAN Research Institute for carrying out Institute responsibilities
b) Remuneration received for Investigator-provided seminars, lectures, teaching engagements, or services provided to advisory committees or review panels, when provided by: Federal, state, or local governmental agencies; or, Nigerian institutions of higher education and their affiliated research institutes, academic teaching hospitals, and medical centers located within Nigeria.
c) Income or equity held in investment vehicles such as mutual funds or blind trusts, where the Investigator and their Family Member(s) do not directly control the decisions made in those investment vehicles.

Financial Conflict of Interest (FCOI) means the existence of a Significant Financial Interest which could directly and significantly affect the design, conduct, outcomes, or reporting of Research affiliated with the Institute.

Financial Conflict of Interest Officer (FCOI Officer) is the Institutional Official who determines whether a Financial Conflict of Interest exists and directs the implementation of a Management Plan to address it appropriately.

Management plan means an appropriately reviewed and signed document that describes actions taken or that must be taken, to address a Research Conflict of Interest.

Outside or External Professional Activities means those activities undertaken and performed, outside of an Investigator's Institute responsibilities, that utilizes their professional skills and expertise.

Remuneration includes salary, payments for services, in-kind benefits; or receipt of cash, gifts, sponsorship, reimbursements, advances, loans or loan forgiveness, or other types of compensation.

Research encompasses basic research, applied research, and experimental development; and the education and training of others in basic and applied research and experimental development.

Researcher (or Investigator) means an individual who contributes or is expected to contribute, to a significant aspect of the design, conduct, outcomes, or reporting of research & development projects affiliated with the Institute. Principal investigators and senior/key personnel who seek or receive support for IVAN Research Institute-affiliated research activities and programs are always Investigators under this policy, as well as any others who meet the definition above. An active investigator is one who meets the definition above for one or more IVAN Research Institute-affiliated proposals or awards that have not been closed out, or are otherwise active.

Significant Financial Interest (SFI) means financial interests in an entity that (1) are related, or appear to be related, to the Investigator's research or Institute responsibilities; and (2) were received or held by the Investigator or their family members during the 12 months prior to disclosure; and when aggregated across the Investigator and their family members, and for the duration of the previous year, (3) meets one of the thresholds below:

a) Any amount of Equity in a privately-held Entity
b) 1,000,000 Naira or more of Equity in a publicly-traded Entity
c) 1,000,000 Naira or more of Remuneration from an Entity
d) 1,000,000 Naira or more of Financial Interests and Equity received by or held in an Entity

If there is any question about whether a SFI could be related to an Investigator's Research or Institute responsibilities, then that SFI must be disclosed so the FCOI program office can make a determination.

Training means completion of the Institute-approved FCOI course (1) upon initial identification as an Investigator, (2) least every four years thereafter, and (3) otherwise upon request by the FCOI Officer, a supervisor, or other Institute official. This fulfills the training standard described in the U.S. Public Health Service regulation on Financial Conflicts of Interest in Research. More information about Institute-approved FCOI training can be found at the NIH training portal. NIH provides online training here: https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html Training must take place prior to engaging in the PHS- or NSF-funded research. Please be sure to print a certificate of completion at the end of the training session and send a copy to the Sponsored Research Office.

Institute responsibilities means the Investigator's obligations and responsibilities associated with their Institute appointment; for example, activities involving research and research consultation, teaching, advising, clinical or professional practice, administrative duties, Institute service on committees and panels, and Institute-based outreach and engagement.

V. REQUIREMENTS FOR DISCLOSURE OF FINANCIAL INTERESTS

Investigators are required to disclose their external financial interests to the Institute accurately, completely, and promptly to the FCOI program for review and assessment of any Significant Financial Interests.

An Investigator must disclose initially:

- Within 30 days of Institute appointment, when the investigator expects to contribute to one or more active research proposals or awards within the first year, or
- Prior to submission of their first research proposal as an Investigator, or
- Upon request by the FCOI Program Office or the FCOI Officer, their supervisor, or other Institute official.

Thereafter, Investigators must complete their research disclosure to the Institute:

- Within 30 days of discovering or acquiring a new SFI,
- On an annual basis, whether or not they have any financial interest(s) to disclose, and
- Upon request by the FCOI Program Office or the FCOI Officer, their supervisor, or other Institute official.

Investigators are to disclose their external financial interests to the FCOI program using the Institute's online disclosure form at the **IVAN RESEARCH INSTITUTE**- website https://ivaninstitute.org/fcoi

During review, additional information may be requested in order to determine whether an SFI or FCOI exists, and if so, determine how to reduce, manage, or eliminate the conflict(s). Additional information may be gathered from the Investigator, and from other sources such as Institute websites, research-related websites, external entity websites, and publicly available databases, on an as-needed basis.

Some conflict of interest information must be made publicly accessible per PHS requirements. Upon written request, the Institute will provide necessary information regarding Significant Financial Interest(s) held by Investigators of NIH-funded research projects when the Institute determines that (1) the SFI(s) are related to NIH-funded projects, and (2) the SFI(s) are Research Conflicts of Interest.

VI. TRAINING

All Researchers must complete Institute-approved training on this policy and the underlying federal regulations:

- Initially upon appointment or qualification as an active Investigator, and
- At least once every four years thereafter.

This training describes regulatory and policy requirements, Investigator responsibilities to the Institute and to research sponsors, and provides examples of conflict-of-interest scenarios. The current Financial/Research COI training module is available online in the CITI Program website here.

VII. REVIEW AND MANAGEMENT

Review. The FCOI program office initially reviews Investigator disclosures and their research activities, on behalf of the Institute, to reasonably determine whether an Investigator has an SFI that could:

1. Be affected by their Institute research,
2. Affect the external entity's financial interests, or
3. Unduly affect or bias Institute research.

The FCOI Officer may identify additional individuals to advise on complex or novel issues of actual, potential, or perceived Financial Conflicts of Interest, such as representatives from IVAN RESEARCH INSTITUTE Administration, Office of Research and Sponsored Projects Administration (ORSPA), Faculty Affairs and Human Resources, the Graduate School, or other relevant units. If there is a possible conflict of interest but the conflict is not a Financial Conflict of Interest, the review will be referred to the individual's supervisor and appropriate administrative unit, as applicable.

When the FCOI program identifies an actual or potential Financial Conflict of Interest, the scenario is further reviewed to determine what conditions or restrictions may be required to reduce, manage, or eliminate the financial conflict.

Management. The FCOI program office drafts a management plan, when necessary, that describes how the Researcher is to manage, reduce, or eliminate the Financial Conflict of Interest.

Examples of conditions that could be applied include but are not limited to:

1. Disclosing the potential conflict to appropriate audiences;
2. Monitoring of research for undue influence or bias from financial interests;
3. Modification of research plans that reduces or eliminates the ability of financial interests to affect the research;
4. Reduction or modification of a researcher's participation in affected research;
5. Reduction or modification of a researcher's duties or appointment;
6. Partial or complete divestiture of the researcher's significant financial interest(s); or
7. Severance of relationships that create the conflict(s).

The management plan is reviewed and signed by the Researcher, their academic supervisor and dean, and the FCOI Officer. Supervisors oversee the implementation of a management plan for researchers who report to them, and Researchers are responsible for managing their conflict(s) in accordance with the terms of their current conflict management plan. When the Institute identifies a significant financial interest that was not disclosed in a timely mannerfor whatever reason, within 60 days the Provost's/Dean's Office will review the significant financial interest; determine whether it is related to specified funded research; determine whether a FCOI exist and, if so, implement a management plan for the FCOI. Furthermore, whenever a FCOI is not identified or managed in a timely manner, the Institute will complete a retrospective review of theInvestigator's activities and the funded research project to determine whether any portion of the funded research conducted during the noncompliance time period was biased inthe design, conduct or reporting of such research. This review will be completed within 120 days of the noncompliance determination. The Institute will follow funders regulations regarding reporting of a FCOI or non-compliance with the regulations.

VIII. ENFORCEMENT

Failure to comply with this policy may lead to disciplinary action, up to and including termination of appointment in accordance with applicable disciplinary procedures. Possible violations that may lead to disciplinary action include, but are not limited to:

1. Failure to complete required training or disclose in a timely manner;
2. Failure to fully disclose a potential conflict;
3. Failure to fully comply with a required conflict management plan;

4. Failure to respond to inquiries from the FCOI program office or Officer.

Researchers will receive automated reminders to submit their disclosures and complete their training. The FCOI program office may notify researchers with significantly delinquent disclosures to trainings and request that they complete their obligations. The FCOI Officer will provide a final notification of delinquency and indicate the potential consequences of inaction. The FCOI Officer may, as the Institutional Official, suspend relevant activities or impose other sanctions to help resolve the Financial Conflict of Interest(s), or noncompliance with policy and program obligations.

Examples of actions or sanctions that could be applied include but are not limited to:

1. Requiring the completion of additional training or coursework regarding conflicts of interest
2. Involvement of a relevant supervisor
3. Review of whether the research was biased in its design, conduct, outcomes, or reporting
4. Review of whether information about the research was inappropriately shared with one or more external entities
5. Notification of Research sponsor(s) regarding policy noncompliance and Institute plan to resolve the issue(s)
6. Suspension of researcher from participating on one or more Research project(s)
7. Suspension of a researcher from submitting additional Research funding applications
8. Recommendation of disciplinary action(s), including postponement of promotion activities, suspension of employment, or termination from the Institute

If sanctions are imposed on an Investigator because they failed to comply with: (1) this policy, (2) their current FCOI management plan, or (3) a decision made by the FCOI Officer, then a written explanation will be provided to the Researcher and their supervisor

IX. INSTITUTIONAL REQUIREMENTS FOR PHS and NSF FUNDED PROJECTS

The Public Health Service (PHS) of the U.S. Department of Health and Human Services (DHHS) and the National Science Foundation (NSF) have specific requirements regarding identification, disclosure, and resolution of financial conflicts of interest that arise in research. The Institute will meet these sponsor requirements as defined in 42 CFR Part 50, Subpart F (Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought, or “FCOI Regulations”) and in NSF’s current Proposals and Award Policies and Procedures Guide (PAPPG) by the implementation and enforcement of this policy.

If sanctions are imposed on an Investigator because they failed to comply with: (1) this policy, (2) their current FCOI management plan, or (3) a decision made by the FCOI Officer, then a written explanation will be provided to the Researcher and their supervisor

X. RECORDS RETENTION

The FCOI program office is responsible for the receipt, processing, review, and retention of FCOI disclosures and related records, and follows the Institute’s policies for Data Management and Classification and Records Retention.

XI. SUBRECIPIENT MONITORING

The Institute is responsible for ensuring that subrecipients comply with its FCOI policy.The Institute will execute a written agreement with the subrecipient that establishes whether the Institute’s FCOI policy or the FCOI policy of the subrecipient institution will be followed. If it is the latter, the agreement will specify the time period for the subrecipient to report all identified FCOI to the Institute.

Additional Resources

Financial Conflict of Interest (FCOI) regulation (42CFR Part 50 Subpart F – Grants): https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50#subpart-F
Financial Conflict of Interest (FCOI) regulation (45CFR Subtitle A Subchapter A Part 94 – Responsible Prospective Contractors): https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-94
Frequently Asked Questions: https://grants.nih.gov/grants/policy/coi/coi_faqs.htm

NSF Financial Conflict of Interest: https://www.nsf.gov/pubs/policydocs/pappg22_1/pappg_9.jsp