



Financial Conflict of Interest (FCOI) Policy

Persons Covered by this Policy

The Windward Islands Research & Education Foundation (“WINDREF”) encourages its research fellows, research scientists, and collaborators to participate in and conduct research activities with the highest ethical standards. While the potential for conflicts of interest is understandable, collaborators must prevent the introduction of bias into their research.

This Financial Conflict of Interest (“FCOI”) Policy (“Policy” or “FCOI Policy”) applies to WINDREF and its Boards, Administrative Staff, Research Fellows, Research Scientists, contractors, temporary employees, agents, and family members of those within the categories listed, who are in a position to exercise substantial influence over the research or business affairs of the institution, or with the ability to influence or bind the institution into a contract or agreement for services or goods (“Interested Persons”).

This includes, but is not limited to:

1. All **Officers** of the Institution;
2. All members of the **WINDREF Administration** (Director, Deputy Director, Treasurer, Legal, Program Manager, Grants Administrator, Assistants, Administrators, Finance Officer);
3. All members of the **WINDREF Boards** (Grenada/USA Board of Directors, UK Board of Trustees, Scientific Advisory Board);
4. All **Research Personnel** (Research Fellows, Research Scientists, Research Program Leads, Project Managers, Data Managers, Research Assistants);
5. **Substantial contributors** to the Institution; and
6. Members of the **immediate family** of any of the above-mentioned persons.

Applicability

This policy applies to all Interested Persons (as defined in this policy). Additionally, the actions of vendors, agents and other third parties who work with WINDREF can have an impact on the Foundation’s reputation. For this reason, WINDREF strives to work only with third parties that share the Foundation’s commitment to avoiding and disclosing conflicts of interest, and WINDREF expects them to act in a way that is consistent with this Policy.

This Policy applies to all Institution affiliates, everywhere WINDREF operates.

Definitions

Conflicts Administrators means the individuals within WINDREF who has been designated to solicit and review disclosures from Investigators of Significant Financial Interests related to the Interested Persons institutional responsibilities. For the purposes of this policy, the Conflicts Administrators shall be the Treasurer, Grants and Finance Officer and Assistant Grants Coordinator, acting together, or his, her, or their designee(s).

Investigator means the principal investigator, co-principal investigators, co-investigators, collaborators, consultants, contractors, and any other person affiliated with WINDREF who is responsible for the design, conduct, or reporting of research, educational, or service activities funded, or proposed for funding, by a sponsor.

Significant Financial Interest means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria), equity interests (e.g., stocks, stock options or other ownership interests), and intellectual property rights (e.g., patents, copyrights and royalties from such rights) that reasonably appears to be related to the Investigator's institutional responsibilities:

- (i) With regard to any publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;
- (ii) With regard to any non-publicly traded entity, a Significant Financial Interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- (iii) Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Investigators also must disclose the occurrence of any reimbursed or sponsored travel (*i.e.*, that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. Investigators should provide information about reimbursed or sponsored travel including: the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration. WINDREF allows for up to \$5,000 to reimbursed or sponsored travel disclosure . The Conflict Administrators will determine if further information is needed, including a

determination or disclosure of monetary value, in order to determine whether the travel constitutes an FCOI with the PHS-funded research.

A new Significant Financial Interest is a different type or nature of Significant Financial Interest (e.g., royalty payment versus consulting fees) than what had previously been disclosed from the same source that meets or exceeds the threshold of \$5000. In addition, a “new” Significant Financial Interest is also considered to be the same type or nature of Significant Financial Interest (e.g., royalty payment) from a different source (e.g., company A versus company B).

Significant Financial Interests do not include:

- I. Salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties related to such rights, not expected to exceed \$5,000 USD during the next twelve months.
- II. An equity interest that, when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests: (a) does not exceed \$5,000 USD in value as determined through reference to public prices or other reasonable measures of fair market value.
- III. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
- IV. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.
- V. Income from service on advisory committees or review panels for a Federal, state, or local government agency, an Institution of higher education as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education. However, Investigators are required to disclose all financial interests received from a foreign Institution of higher education or the government of another country.

Policy Purpose and Objectives

The purpose of this FCOI Policy is to protect the interests of WINDREF and ensure objectivity in research implementation when considering entering into (i.e., applying for) an external funding arrangement and/or after entering into an arrangement or transaction with a funder. The goal is to prevent conflicts of interest that might interfere with a Research Investigators' performance of his/her duties to the Institution, or result, or appear to result in personal financial, professional, or political gain on the part of such Interested Persons at the expense of the Institution or its staff, directors, boards and researchers. This policy also serves to protect the credibility and integrity of WINDREF and to ensure public trust and confidence in the Institution's research and educational activities by identifying, understanding, and responding to conflicts of interest.

Research Investigators, given their position, may influence the outcome of any decision(s) affecting the provision of goods and services to the Institution.

This Policy is therefore to ensure that Research Investigators perform their duties in an open, impartial, ethical and unbiased manner. This Policy also provides guidance on how to manage actual, potential or perceived conflicts of interest, and is intended to supplement any existing policy on the subject, as well as any applicable laws and regulations.

In order to ensure open, impartial and ethical decision making, full disclosure of all conflicts of interest is required. Prompt and full reporting of all conflicts of interest is intended to prevent any actual, potential or perceived appearance of bias in the decision-making process.

The objectives of the FCOI Policy are to:

- Ensure that all Interested Persons are made aware of their obligation to report any conflict of interest, make decisions free of bias and to commit to carrying out their official responsibilities at a high ethical standard;
- Remove any perception of bias;
- Facilitate the record keeping of all declared conflicts of interest by Research Investigators, the Conflicts Administrators and WINDREF's Directors;
- Explain the process of identifying and managing FCOI;
- Explain the process of reporting of identified FCOI.

Training

Each Investigator will be provided with the WINDREF FCOI policy, as well as the regulations outlined in Subpart F—Promoting Objectivity in Research no later than at the time of application for externally-funded research, including PHS-funded research. Each investigator will then be required to complete an online training module in FCOI offered by the NIH-
https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html. WINDREF requires that investigators complete the training prior to engaging in NIH-supported research and at least every four years, and immediately under the designated circumstances:

- Institutional FCOI policies change in a manner that affects Investigator requirements
- An Investigator is new to WINDREF
- WINDREF finds an Investigator noncompliant with the Institution's FCOI policy or management plan.

All externally supported-supported Investigators will also be required to complete this FCOI training prior to engaging in research.

Policy

I. Conflicts of Interest

A potential conflict of interest occurs when there is a divergence between an individual's private interests and his or her professional obligations to WINDREF such that an independent observer might reasonably question whether the individual's professional actions

or decisions are made by considerations of personal gain, financial or otherwise. An actual conflict of interest depends on the situation and not on the character or actions of the individual. For the purposes of this policy, a conflict of interest exists when WINDREF, through the procedures described in this policy, reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of sponsored projects.

II. Significant Financial Interest Disclosure

Each Interested Person is required to disclose the following Significant Financial Interests:

- A. Any Significant Financial Interest of the Interested Person that would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by a sponsor; or
- B. Any Significant Financial Interest of the Interested Person in an entity whose financial interest would reasonably appear to be affected by the research or educational activities funded, or proposed for funding, by a sponsor.

The disclosure must be submitted by email to administrators listed at the end of this document no later than at the time of application for all funded research, including PHS-funded research, and if the funds are awarded, at least annually during the period of the award or within 30 days of discovering or acquiring a new SFI.

Regardless of the above minimum requirements, any Interested Person, in his or her own best interest, may choose to disclose any other financial or related interest that could present an actual or potential conflict of interest or be perceived to present a conflict of interest. Disclosure is a key factor in protecting one's reputation and career from potentially embarrassing or harmful allegations of misconduct.

No later than at the time of application for externally-funded research, including PHS-funded research, each Investigator shall complete a Conflict of Interest Attestation form and attach all required supporting documentation, if any. An Investigator must also submit an attestation form even if he or she does not have any Significant Financial Interests. Supporting documentation that identifies the business enterprise or entity involved and the nature and amount of the interest should be submitted in a sealed envelope marked confidential and accompanying the disclosure form. All financial disclosures must be updated by Investigators during the period of the award, either on an annual basis or as new reportable Significant Financial Interests arise or are acquired.

All attestation forms and supporting documentation are to be submitted to the Conflicts Administrators. Additional information may be requested by the Conflicts Administrators and shall be furnished upon request. The Conflicts Administrators are responsible for the receipt, processing, review, and retention of all disclosure forms.

III. Review of Financial Conflicts of Interest

The Conflicts Administrators shall review all financial disclosures to determine whether a conflict of interest exists. If the Conflicts Administrators determine that there is potential for a conflict of interest covered by this policy, then the Conflicts Administrators shall determine what conditions or restrictions, if any, should be imposed by WINDREF to manage actual or potential conflicts of interest arising from the disclosed Significant Financial Interests within sixty days. Such conditions or restrictions include, but are not limited to, the following:

- A. Public disclosure of Significant Financial Interests;
- B. Monitoring of research by independent reviewers;
- C. Modification of the research plan;
- D. Disqualification from participation in all or a portion of the research;
- E. Divestiture of the Significant Financial Interest; or
- F. Severance of the relationships that create actual or potential conflicts of interest.

The Conflicts Administrators may require that a plan for reducing or eliminating conflicts of interest be incorporated into a Memorandum of Understanding between WINDREF and the Investigator.

The Conflicts Administrators shall notify the Director of WINDREF of the conditions or restrictions to be imposed. If the Director determines that imposing the above referenced conditions or restrictions would be ineffective or inequitable, or that the potential negative impacts that may arise from a Significant Financial Interest are outweighed by interests of scientific progress, technology transfer, or the public health and welfare, then the Director may recommend that, to the extent permitted by the applicable regulations/laws, the research go forward without imposing such conditions or restrictions. In these cases, the Director shall make the final decision regarding resolution of any actual or potential conflicts of interest.

The Conflicts Administrators shall review all initial and updated disclosures of Significant Conflicts of Interest in accordance with this policy.

IV. Managing and Monitoring Conflicts of Interest

Actual or potential conflicts of interest shall be satisfactorily managed, reduced, or eliminated in accordance with this policy. Additionally, all required reports regarding the conflict of interest shall be submitted to the sponsor prior to expenditure of any funds under an award in accordance with the applicable regulations/laws. All actual or potential conflicts of interest shall be monitored until completion of the associated project.

V. Noncompliance of Financial Conflict of Interest Policy

Whenever an Interested Party has violated this policy or the terms of any resolution plan required by the Conflicts Administrators (including failure to file or knowingly filing incomplete, erroneous, or misleading disclosure forms) the Conflicts Administrators shall notify the Director who may impose sanctions or institute disciplinary proceedings against the violating Interested Party. If the violation results in a collateral proceeding under

WINDREF's policies, then the Director may defer his or her decision on sanctions until such other proceeding is completed.

In addition, WINDREF shall comply with all applicable regulations/laws regarding the notification of the sponsor in the event an Interested Party has failed to comply with this policy. The sponsor may take its own action as it deems appropriate, including the suspension of funding for the research until the matter is resolved.

The Conflicts Administrators will complete and document retrospective reviews within 120 days of the Institution's determination of noncompliance for SFIs not disclosed timely or previously reviewed or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulation.

In any 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, WINDREF shall require the Investigator involved to:

- Disclose the FCOI in each public presentation of the results of the research, and
- To request an addendum to previously published presentations.

VI. Maintenance of Records

Records of Investigator financial disclosures and of actions taken to manage actual or potential conflicts of interest shall be retained by the Conflicts Administrators for 3 years following the date the final expenditures report is submitted to the PHS (NIH).

VII. Subrecipient Requirements

Collaborators, sub-recipients, and subcontractors from other organizations will receive a copy of this FCOI policy, receive FCOI training and must comply with this policy.

Reporting Requirements to NIH

Reports will be shared with NIH on an annual basis by WINDREF's Compliance Officers. Reports will include initial, annual (i.e., ongoing) and revised FCOI reports, including all reporting elements required by the regulation, to the NIH for the Institution and its subrecipients, if applicable, as required by the regulation:

- Reports will be shared prior to the expenditure of funds.
- Reports will be shared within 60 days of identification for an Investigator who is newly participating in the project.
- Reports will be shared within 60 days for new, or newly identified, FCOIs for existing Investigators.
- Reports will be shared at least annually (at the same time as when the Institution is required to submit the annual progress report, multi-year progress report, if applicable, or

at time of extension) to provide the status of the FCOI and any changes to the management plan, if applicable, until the completion of the project.

- Reports will be shared following a retrospective review to update a previously submitted report, if appropriate.
- WINDREF will notify NIH promptly if bias is found with the design, conduct or reporting of NIH-funded research and to include the requirement to submit a Mitigation Report in accordance with the regulation.
- Reports will include all reporting elements as required by the regulation.
- WINDREF will promptly notify the NIH if an Investigator fails to comply with the Institution's FCOI policy or if a FCOI management plan appears to have biased the design, conduct, or reporting of the NIH-funded research.

Public Accessibility

WINDREF's FCOI policy, FCOI attestation form and reports of identified FCOI are available on its website: <https://www.windref.sgu.edu/>. All reports of FCOIs by the key personnel will be made available on the website within 30 days of a FCOI disclosure. All reports posted on the website will not posted to the website will be made available within 5 calendar days of a written request, the report will include the elements described in the regulation, will be updated at least annually, will be updated within 60 days of a newly identified FCOI and will remain available for three years from the date the information was most recently updated.

All WINDREF investigators and affiliated individuals will be directed to this website when hired and/or appointed as a WINDREF Research Fellow/Research Scientist. The hiring/appointment letter will include the following statement, and each hiring/appointment letter is signed by the hiree/appointee:

"I understand and agree that conflicts of interest, including financial conflicts of interest, can impact the objectivity of research findings. By signing this appointment letter, I agree to read and comply with the WINDREF Financial Conflict of Interest (FCOI) Policy, which can be found here: <https://www.windref.sgu.edu/>."

Additional Information can be obtained from the following contacts:

- Conflict Administrators: Ms. Margaret Lambert (mlambert@sgu.edu)
Ms. Nakita Francis (nakitafrancis@windref.gd)
Mr. Kareem Coomansingh (kcoomans@sgu.edu)
- Legal: Mr. Michael Cahill
- Director: Dr. Calum Macpherson