



Financial Conflict of Interest Policy on Grants, Contracts, & Sponsored Projects

Preface

“The term conflict of interest... refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator’s professional judgment in conducting or reporting research... conflicts become detrimental when the potential rewards, financial or otherwise, cause deviation from absolute objectivity in the design, interpretation, and publication of research activities or in other academic and professional decisions.” – Association of American Medical Colleges.

[Financial Conflict of Interest Form](#) (Included in our Cayuse SP electronic routing portal)

Background

Research is an important and vital part of the mission of St. John's University (the University or St. John’s). The external sponsorship of research can result in the development of complex relationships between the University, its faculty, and staff, and the external sponsor(s) who support specific programs. To assure that research conducted under the auspices of the University is always of the highest integrity, and in response to regulations issued in 1994 and 1995 by the federal government, St. John's University has developed this policy on Financial Conflicts of Interest in Research and Other Sponsored Programs.

The intention of this policy is to identify and eliminate or manage any possible threat to the integrity of the research and sponsored programs conducted by the St. John’s community.

This policy is applicable to all proposals grants and/or contract support (including federal flow-through funding) of research projects and other sponsored programs submitted on, or after, August 12, 2011.

APPLICABLE FEDERAL REGULATIONS

The following federal regulations inform this policy:

Public Health Service (PHS)

[2011-21633.pdf \(govinfo.gov\)](#)

National Science Foundation (NSF)

http://www.nsf.gov/pubs/policydocs/pappguide/nsf10_1/aag_4.jsp

Food and Drug Administration (FDA) <https://www.fda.gov/RegulatoryInformation/>

In summary, the federal policies and regulations stipulate:

- a. Disclosures of significant financial interests by ALL Investigators;
- b. Institutional certification that all proposed and ongoing sponsored research is either free of financial conflicts of interest, or that such conflicts are managed, reduced, or eliminated, and reported as required by applicable regulations;
- c. The implementation of an institutional mechanism for managing financial conflicts of interest in research;
- d. Notification of sponsors, as required, of management plans and if the University is unable to manage financial conflicts of interest satisfactorily;



- e. Monitoring of compliance, procedures for retroactive review in cases of non-compliance, enforcement mechanisms, and sanctions where appropriate;
- f. Maintenance of records relating to this policy for at least three years following the termination of a given project; and,
- g. Providing information and training to Investigators, as required by applicable regulations.

Policy

Prior to the submission of a research proposal to any agency, all researchers who plan to participate in, or direct, a sponsored research project or other sponsored program (sponsored program) under the auspices of the University must disclose to the University any significant financial interests which they or any members of their immediate family have in any commercial enterprise that will in any way participate in the sponsored program or that potentially may be affected by the performance or completion of the proposed sponsored program. Disclosure is accomplished through completion of a "Financial Conflict of Interest Disclosure Form" (Disclosure Form) which is subject to review by the individual's dean and the Office of Grants and Sponsored Research (OGSR). Each Disclosure Form will be reviewed to determine the existence of, or potential for, any financial conflicts of interest.

For purposes of this policy statement, the following definitions are provided:

- *Business* means any corporation, partnership, sole proprietorship, firm, franchise, association, organization, holding company, joint stock company, receivership, business or real estate trust, or any other legal entity organized for profit or charitable purposes.
- *Clinical Investigation (PHS)* means any experiment in which a drug is administered or dispensed to, or used, involving one or more human subjects. An experiment here is any use of a drug, except for the use of a marketed drug in the course of medical practice.
- *Clinical Investigation (FDA)* means any experiment that involves a test article and one or more human subjects, and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of the chapter, regarding non-clinical laboratory studies.
- *Financial Conflict of Interest (FCOI)* means a situation in which significant financial interests in a business, or other personal considerations provided by a business, may compromise, or have the appearance of compromising, an Investigator's professional judgment in conducting or reporting research, the results of which could affect the aforementioned business, either directly or indirectly. An FCOI exists when the University, through its designated official(s), reasonably determines that an Investigator's Significant Financial Interest is related to a research project and could directly and significantly affect the design, conduct or reporting of the research.
- *Human Subject* (PHS regulations "Protection of Human Subjects" 45 CFR Part 46, as administered by OHRP) means a living individual about whom an Investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information.



- *Human Subject* (FDA regulations 21 CFR 50) means an individual who is, or becomes, a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.
- *Immediate Family* means the Investigator's spouse/domestic partner and dependent children.
- *Institutional Responsibilities* are an Investigator's professional responsibilities on behalf of the University, which include research, teaching, and service as, e.g., outlined in the Policy on Faculty Professional Responsibilities.
- *Intellectual Property* means a product of the intellect that has commercial value, including copyrighted works, patents, business methods, and industrial processes.
- *Investigator* means the principal investigator and any other person (regardless of title or position) who is responsible for the design, conduct or reporting of research or educational activities. This may include faculty and research staff (research associates and assistants, postdoctoral fellows, graduate students, visiting scientists engaged in research conducted at the University) as well as consultants.
- *Research* (PHS regulation 45 CFR 46.102(d)) means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this Policy, whether or not they are conducted or supported under a program which is considered research for other purposes.
- *Significant Financial Interest (SFI)*
 1. *Significant Financial Interest* means:

For PHS and all sponsors that follow the 2011 PHS FCOI Regulations^[1]

With regard to any **publicly traded entity**, an SFI exists if the value of any **remuneration^[2]** 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**; or With regard to any **non-publicly traded entity**, an SFI 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 Immediate Family) holds **any equity interest** (e.g., stock, stock option, or other ownership interest); or

Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

For NSF and all other sponsors:

An **equity interest** that when aggregated for the Investigator and the Investigator's Immediate Family exceeded **\$5,000** over the **last 12 months**, and/or is expected to exceed **\$5,000** in value over the **next 12 months** as determined through reference to public prices or other reasonable measures of fair market value; or when the Investigator (or the Investigator's Immediate Family) holds a 5% or greater equity interest (e.g., partnership, ownership, stock, stock option, or other ownership interest) in a single publicly traded entity or holds any equity interest in a non-publicly traded entity; or **Salary, royalties or other payments** not from the University for services (e.g., consulting fees or honoraria) that when aggregated for the Investigator and the Immediate Family over the **last 12 months** exceeded **\$5,000** or are expected to exceed **\$5,000** over the **next 12 months**;



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.

For purposes of this policy, Significant Financial Interest does not include:

- salary, royalties, or other remuneration from St. John's University
- income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities

an equity interest in a business enterprise that, when aggregated for the research and immediate family, meets both of the following tests:

(1) A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) 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.

(2) 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. The Institution's FCOI policy will specify the details of this disclosure, which will include, at a minimum, the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the Institution's FCOI policy, the institutional official(s) 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.



- (3) The term *significant financial interest* does not include the following types of financial interests: 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; any ownership interest in the Institution held by the Investigator, if the Institution is a commercial or for-profit organization; 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; 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; or 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 teach The University will not permit the incurring of any expenses on a grant unless, or until, all identified conflicts of interest have been eliminated or properly addressed through a University-approved Resolution Plan.

If over the course of a sponsored program the University finds that it is unable to satisfactorily manage a conflict of interest, the Director of Grants and Sponsored Research will notify the appropriate official at the federal funding agency (e.g. NSF's Office of General Counsel or the relevant PHS Awarding Component) as required by agency regulations.

Procedures

I. Notification

A copy of this policy will be sent to all current Investigators and will be provided to all new Investigators. The policy is also available on the St. John's website under Office of Grants and Sponsored Research "Internal Forms, Policies and Procedures."

II. Training

All PHS-funded Investigators must complete training prior to engaging in PHS-funded research and at least every four years thereafter as well as under the following circumstances (in the timeframes noted in parentheses):

- a. The University's Financial Conflict of Interest policy changes such that Investigator requirements are affected (within 60 days).
- b. An Investigator is new to the University (prior to engaging in PHS-funded research).
- c. The University finds that an Investigator is not in compliance with the Policy or a management plan, as applicable.

III. Disclosure of Significant Financial Interests

Each Investigator must disclose his/her known Significant Financial Interest (SFIs) (including those of the Investigator's Immediate Family) that reasonably appear to be related to the Investigator's Institutional Responsibilities, or that would reasonably appear to be affected by the research for which funding is sought or are in entities whose financial interests would reasonably be affected by the research. In determining whether a financial interest has to be disclosed, the Investigator shall consult the definition of SFI within this policy and, if in doubt, resolve in favor of disclosure.



1. *Disclosure for each Proposal Submission:* At the time of submission of a new proposal, an Investigator must have completed their online financial disclosure in the Cayuse SP Conflict of Interests section. The University will not submit a proposal until such disclosure has been submitted.
2. *Changes in SFI:* An updated disclosure shall be completed and filed within thirty (30) days at any time when an Investigator acquires or discovers a new reportable SFI not disclosed in the last disclosure. For existing Investigators on a project, new or newly identified SFIs will be reviewed promptly to determine if an FCOI exists, create a management plan if necessary and report the newly identified FCOI to the sponsor within 60 days if required.
3. *Human Subject Research:* When research involves human subjects, the Investigator must disclose SFIs to the Institutional Review Board (IRB) with every submission of protocols. If an Investigator has an FCOI, but a management plan is not on file, the IRB will contact the Provost or their designee and hold approval of the protocol until the FCOIR makes a determination.
4. *New Investigators:* If research is ongoing and an Investigator newly participating in the project discloses an SFI related to that research, those SFIs will be reviewed promptly to determine if an FCOI exists, create a management plan if necessary and report the newly identified FCOI to the sponsor within 60 days if required.

IV. Determination, Resolution, and Management of a Conflict of Interest

1. The PI's Dean along with the Director of the Office of Grants and Sponsored Research (OGSR) will review Research Financial Conflict of Interest Form (RFCOI) and, if an FI is disclosed, the Dean and OGSR to conduct the required explicit review for possible financial conflicts of interest.

A conflict of interest exists when the reviewers reasonably determine that a significant financial interest could directly and significantly affect the design, conduct or reporting of funded research or educational activities.

2. If the Dean or the OGSR determines that a researcher (or any member of his/her immediate family) has a significant financial interest in a commercial enterprise connected with the proposed sponsored program, the principal investigator and/or researcher will be required to prepare a Resolution Plan to reduce, minimize or eliminate the conflict of interest. This Resolution Plan must be approved by the University before any expenditure is incurred against the award.

As in the case of Disclosure Forms, the initial review of Resolution Plans will be conducted by offices of the Dean and OGSR.

If the Resolution Plan accepted and the project is funded, a Memorandum of Understanding between the University and researcher will be issued.

If the Resolution Plan is rejected by the dean and/or OGSR, the matter may be submitted by the principal investigator and researcher to the Committee for Resolution of Financial Conflicts (CRFC). The CRFC will consist of three members designated by the Provost.

The CRFC should review the Resolution Plan and devise alternatives to mitigate the Conflict of Interest.

- In the event circumstances change regarding the significant financial interest of a researcher engaged in a sponsored program (or regarding the significant financial interest his/her immediate family), the researcher must notify the University as soon as the change becomes known. Revised Disclosure Forms are subject to the same review process as an original submission.
- If a researcher fails to provide or update the Disclosure Form, or provides false information, the University reserves the right to take appropriate actions.



- OGSR will maintain the confidentiality of the Disclosure Statements, except as may be required by federal law or agency award terms. In no case will a Disclosure Statement be released to a federal agency without prior notification to the affected individual.
- OGSR will maintain all Disclosure Statements and approved Resolution Plans for a period of three years beyond the termination or completion of the grant to which they relate, or until resolution of any action involving those records, whichever is longer.

V. Notification/Reporting

If an FCOI is identified, the CRFC is responsible for:

- 1. Notification of the Investigator of the management plan designed by the Committee for his/her FCOI;
- 2. Notification of the Office of Grants and Sponsored Research (OGSR) to assure that no spending of funds from related grants occurs without prior approval of the CRFC.
- 3. Notification of the IRB of FCOI management plan when the research involves human subjects.
- 4. Notification of research sponsors, as required, of any FCOIs, including any measures taken to reduce, manage, or eliminate such conflicts. The elements of such a report shall include, at least, the items enumerated under the FCOI Regulations.
- The Provost or his/her delegate will notify the above individuals, offices, and sponsors on behalf of the CRFC. Reasonable efforts will be made to maintain the privacy of information gathered in the CRFC's deliberations, within the limits imposed by applicable laws and regulations.

VI. Maintenance of Records

All records related to the implementation of this policy (e.g., *Individual Financial Disclosure Forms*, minutes of the meetings of the *COI in Research Management Committee*, notifications to funding agencies, actions taken to resolve or mitigate FCOIs, etc.) will be maintained securely by the OGSR for a period of at least three (3) years beyond the termination or completion of the sponsored award to which they relate, or until the resolution of any action involving those records, whichever is longer. FCOI records shall be subject to periodic review for compliance with this policy by the Provost or by any agency per applicable regulations.

VII. Subrecipients

If a subrecipient carries out a portion of the work, University shall take reasonable steps to ensure that any subrecipient and subrecipient Investigator complies with the applicable FCOI regulation.

University will establish, via a written agreement, the governing FCOI policy.

1. Sub-recipient will certify that its FCOI policy complies with the respective regulations and, further, sub-recipient will report identified FCOIs for its investigators in a time frame that allows University to report identified FCOIs to the awarding agency.
2. Alternatively, if a sub-recipient lacks a compliant FCOI policy, the subrecipient will be governed by the University's FCOI policy; University will solicit and review sub-recipient Investigator disclosures and identify, manage and report FCOIs to the sponsor.

In the event that a sub-recipient notifies University of an FCOI for sub-recipient Investigators for which University is the prime awardee, University will promptly notify the sponsor.

VIII. Public Accessibility



Prior to expending any funds under a PHS-funded grant, cooperative agreement or contract, the Provost shall ensure public accessibility of information about the FCOI, via a written response to any requestor within five (5) business days of a request, of information concerning an SFI which was disclosed and is still held by the senior/key personnel on the project, which is determined to be related to the PHS-funded research, and which is determined to be a FCOI. The information shall consist of the information required to be provided under the FCOI Regulations.

IX. Monitoring Compliance /Mitigation

1. The Dean of the associated school and the OGSR will monitor for compliance with the policy.
2. If the Dean and/or the OGSR learns of an SFI that was not timely disclosed or was not timely reviewed, the Provost, or his/her delegate, shall, in consultation with the CRFC and no later than the sixtieth (60th) day after learning of the SFI:
 - a. determine whether the SFI is an FCOI; and
 - b. if an FCOI exists, implement an interim management plan or implement other interim measures to ensure the objectivity of the research going forward.
3. If an FCOI was not timely identified or managed or if an Investigator fails to comply with a management plan, the Provost shall no later than the 120th day after determining noncompliance:
 - a. complete and document a retrospective review and determination as to whether research conducted during the period of noncompliance was biased in the design, conduct, or reporting of the research; and
 - b. implement any measures necessary with regard to Investigator's participation in the research between the date that the noncompliance is identified and the date the retrospective review is completed.
4. For PHS-covered research projects, the retrospective review shall cover key elements as specified by federal regulations and may result in updating the Financial Conflict of Interest Report, notifying the PHS awarding component, and submitting a mitigation report as required by federal regulation.
5. University will notify the PHS of instances in which the failure of an Investigator to comply with this policy or a management plan appears to have biased the design, conduct, or reporting of funded research. The University will make information available to HHS or the PHS awarding component as required by federal regulation.

X. Appeals

1. In situations where an Investigator disputes the decision of the CRFC, the Investigator may request to present the case to the CRFC in person. An Investigator who disagrees with the CRFC's determination may appeal in writing to the Provost. An appeal may be made in regard to whether the professional judgment of the Investigator is likely to affect his or her conduct of research, but Investigators may not contest the terms and conditions of this.
2. The Provost may agree with the CRFC's findings and/or recommendations, or may amend such findings and/or recommendations. The Provost shall promptly notify the Investigator and the CRFC in writing of the conclusions of his/her review, including the actions that must be taken by the Investigator to comply with this policy.
3. Upon receipt of the Provost's written report, the Investigator must promptly comply with the actions specified in that report.

XI. IMPLEMENTATION AND ENFORCEMENT

The Provost is the senior administrator responsible for overseeing the implementation of this Policy. The Provost has delegated the disclosure/review/management process to the Director of the Office of Grants



and Sponsored Research (OGSR) or his/her designee. The Provost, in consultation with the Dean of the appropriate School and the Investigator(s) Department Head, will review all breaches of the policy, including:

- a. failure to comply with the process (by refusal to respond, by responding with incomplete or knowingly inaccurate information, or otherwise);
- b. failure to remedy conflicts; and
- c. failure to comply with a prescribed management plan

Sanctions and penalties for those who knowingly and willfully disregard this policy, or refuse to comply with its terms, will be determined by the Provost, in consultation with the Dean of the appropriate School, with advice from the Investigator(s) Department Head and the Department of Faculty and Staff Labor Relations. Sanctions include, but are not restricted to:

- Letter of reprimand
- Notification to professional and/or scientific societies, funding agencies and/or professional journals
- Reassignment of duties
- Termination of grant support
- Adjustment of research space allocation
- Adjustment of salary
- Suspension
- Dismissal

XII. Audit Procedures

In order to ensure that all declarations are being made and financial conflicts managed, the University will implement a relevant audit program through the University's Office of Business Affairs.

Effective October 1, 1995, the National Institutes of Health and National Science Foundation required grant recipients to establish a Financial Conflict of Interest Policy. All persons who play a key role in the performance of a project funded either directly or indirectly by NIH or NSF are required to complete a [Financial Conflict of Interest Form](#) at the time of proposal submission. The completed form(s) should be submitted to the Office of Grants and Sponsored Research.

Effective August 24, 2012, in the case of investigators working on NIH grants, there is a more stringent requirement that the aggregate financial benefit cannot exceed \$5000 for the prior 12-month period for the investigator as well as family members or those living in the same household.