

Procedures for Compliance with the U.S. Public Health Service Financial Conflict of Interest Regulations

Research and Scholarly Activities

Responsibility: Associate Vice-President, Research

Approval Date: Oct 3, 2017

Purpose

These Procedures are made under the University of Saskatchewan's Conflict of Interest Policy.

Effective August 24, 2012, research funded by the U.S. Public Health Services, which includes the National Institutes of Health, must follow the U.S. Public Health Service Financial Conflict of Interest Regulations (the "Regulations"), which includes 42 CFR Part 50 Subpart F *Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought* and 45 CFR Part 94 *Responsible Prospective Contractors*. The purpose of the Regulations is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under the U.S. Public Health Service grants, cooperative agreements and contracts will be free from bias resulting from Financial Conflict of Interest.

The Regulations apply to all Institutions, both U.S. and foreign, applying for or receiving the U.S. Public Health Service funding, including funding that is received as a sub-award from another Institution, and to each Investigator (and their immediate family members) participating, or planning participate, in such research. All contracts and grants from the U.S. Public Health Service, such as the National Institutes of Health, now require the University to agree to be bound by the Regulations as a condition of funding. Failure to comply can mean risk of serious consequences, including suspension or termination of funding.

Definitions

"Designated Official" is defined as the individual appointed to this position by the University and who is responsible for the review of Significant Conflict of Interest, determination of whether a Financial Conflict of Interest exists, and approval of the University Regulations management plan(s) under these Procedures.

"Financial Conflict of Interest" is defined as a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of U.S. Public Health Service-funded research.

"Financial Interest" is defined as anything of monetary value, received or held by an Investigator or any member of Investigator's immediate family (specifically, any dependent children, spouse, common law partner), whether or not the value is readily ascertainable. Financial Interest includes salary or other payments for services (e.g., consulting fees, honoraria, or paid authorships for other than scholarly works), equity interests (e.g., stocks, stock options, or other ownership interests), and intellectual property rights and interests (e.g., patents, trademarks, service marks, and copyrights) upon receipt of royalties or other income related to such intellectual property rights and interests.

“Institutional Responsibilities” means an Investigator’s professional responsibilities on behalf of the University, and include activities such as:

- participation in teaching programs, including classroom teaching, supervision of graduate students and personal interactions with and advising students;
- participation in research (defined as including the preparation or performance of creative works and reflective inquiry) and the dissemination of the results of research by means appropriate to the discipline;
- provision of service to the discipline of the Investigator; participation in the governance of the University, the Faculty / College and the Department; and dissemination of knowledge to the general public by making available the staff member’s expertise and knowledge of the discipline all of which shall be carried out according to the standards of professional conduct expected of an Investigator;
- clinical service, if identified in the Investigator’s job description; and
- any other responsibility outlined in the Investigator’s job description, employment agreement or appointment letter with the University, in policies applicable to the post-doctoral fellows, or as identified as a responsibility of a student to the University (as applicable).

“Investigator” is defined as any person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the funding U.S. Public Health Service (whether or not they are paid from these funds). This includes, but is not limited to the Project Director (PD), Principal Investigator (PI), Senior/ Key Personnel (as identified in the grant application, research contract, progress report), and may include post-doctoral associates, research staff, students, collaborators, consultants.

“Significant Financial Interest” means 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:

- 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;
- 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
- Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income to such rights and interests.
- Investigator(s) 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 an U.S. federal, state, or local government agency, an U.S. institution of higher education, an U.S. academic

teaching hospital, an U.S. medical center, or an U.S. research institute that is affiliated with an U.S. institution of higher education. This disclosure will include, at a minimum: the purpose of the trip, the identity of the sponsor/ organizer, the destination, and the duration.

The Designated Official (or delegate) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a Financial Conflict of Interest with the U.S. Public Health Service-funded research.

The term Significant Financial Interest does not include the following types of financial interests:

- salary, royalties, or other remuneration paid by the University to the Investigator if the Investigator is currently employed or otherwise appointed by the University, including intellectual property rights assigned to the University and agreements to share in royalties related to such rights;
- 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 an U.S. federal, state, or local government agency, an U.S. institution of higher education, an U.S. academic teaching hospital, an U.S. medical center, or an U.S. research institute that is affiliated with an U.S. institution of higher education; similar income from non-U.S. equivalents of these entities where the annual aggregated amount paid to the specific Investigator does not exceed \$5,000 per entity; or
- income from service on advisory committees or review panels for an U.S. federal, state, or local government agency, an U.S. institution of higher education, an U.S. academic teaching hospital, an U.S. medical center, or an U.S. research institute that is affiliated with an U.S. institution of higher education.

Investigator Obligations

Investigator is required to:

1. Be familiar with these Procedures.
2. Complete the Regulations training web-based tutorial: <https://grants.nih.gov/grants/policy/coi/tutorial2011/fcoi.htm>. Training is to be completed before engaging in any U.S. Public Health Service-funded research and repeated at least every four (4) years. Additional training may be required, including when an Investigator joins the University, the University revises these Procedures, or if an Investigator is not in compliance with these Procedures or the University Regulations management plan. Access to the U.S. Public Health Service funding may be suspended until Investigators have completed the required training.
3. Complete and sign the University Significant Financial Interest(s) Report Form for the Regulations and submit it to Designated Official.
4. Disclose Significant Conflict of Interest(s). Please refer to the definition of Significant Financial Interest(s) to determine what needs to be disclosed. Disclosure must be made at the time of application for funding from the U.S. Public Health Service (or, in case of a sub-agreement, from the Lead Institution), annually during the period of funding, within thirty (30) days of discovering or acquiring a new Significant Financial Interest(s), and when a new Investigator joins an ongoing project. To disclose, an Investigator (and his/ her spouse or common-law partner, and his/ her dependent children) must complete and submit to the Designated Official (or delegate) the Significant Financial Interest(s) Report Form for U.S.

Public Health Service Funding.

5. Comply with these Procedures and the University Regulations management plan. In the event of non-compliance and/ or non-disclosure, the University is required to conduct a retrospective review and mitigation. In addition to these Procedures, an Investigator conducting U.S. Public Health Service-funded research also remain subject to all University's applicable policies and procedures, including but not limited to those with respect to conflict of interest, financial management, and research involving human participants.

University Obligations

University is required by the U.S. Public Health Service to:

1. Appoint the Designated Official to solicit and review disclosures of Significant Financial Interest and determine if a Financial Conflict of Interest exists.
2. Review the Significant Financial Interest(s) Report Form(s) for the U.S. Public Health Service Funding. The Designated Official (or delegate) may consult with the Dean (or delegate) and may request further information from the Investigator and consult (confidentially) with others as necessary.
3. Manage the Regulations at the University, including developing and implementing the University Regulations management plan and, where required, conduct a retrospective review. The University Regulations management plan must specify the actions that have been and will be taken to manage the Regulations, including a mechanism for monitoring compliance with the University Regulations management plan.
4. Conduct a retrospective review in case a Significant Financial Interest was not timely disclosed to the University. Such a retrospective review is to be conducted within sixty (60) days of non-disclosure and will determine whether a Significant Financial Interest is determined to be a Financial Conflict of Interest.
5. Report any Financial Conflict of Interest determined to exist, together with any applicable University Regulations management plan, to the U.S. Public Health Service. These reports will be submitted before any U.S. Public Health Service funds are spent, within sixty (60) days of the identification of new Financial Conflict of Interest(s), annually for the duration of the project, when a new Investigator joins the project, if applicable when a retrospective review is conducted.
6. Make the Financial Conflict of Interest(s) accessible to the public and remain publically available for at least three (3) years (from the date the final expenditure). Written request for information concerning Financial Conflict of Interest(s) needs to be addressed to the Designated Official. The University will provide a written response within five (5) business days. The information will include at minimum: the Investigator's name, title and role on the U.S. Public Health Service-funded research project; the name of the entity in which the Significant Financial Interest(s) determined to be Financial Conflict of Interest(s); the nature and approximate dollar value of that Significant Financial Interest(s).
7. Post these Procedures on the University publicly accessible website.
8. Work with sub-recipients (e.g., sub-contractors, collaborators) and its Investigator(s) to comply with the Regulations.
9. Maintain records relating to Investigator Significant Financial Interest(s) disclosures and reviews, response and actions (whether or not a Financial Conflict of Interest was found to exist).
10. Suspend (in case of non-compliance) the U.S. Public Health Service funding until all requirements are met.

The University is required to submit, or permit on site review of, all pertinent records. To the extent permitted by law, the U.S. Public Health Service will maintain the confidentiality of all records of Significant Conflict of Interest(s). On the basis of its review of records or other information that may be available, the U.S. Public Health Service awarding Agency may decide that further corrective action is needed or that the University has not managed the Financial Conflict of Interest(s) in accordance with the Regulations and may determine that imposition of special award conditions, and/or suspension of funding or other enforcement action, is necessary until the matter is resolved.

Responsibilities

Office of the Vice-President Research, is responsible for the administration of these Procedures and is authorized to modify Procedures.

Related Documents

University's Conflict of Interest Policy: <http://policies.usask.ca/policies/operations-and-general-administration/conflict-of-interest.php>

List of Agencies using the Public Health Service Financial Conflict of Interest Regulations: http://sites.nationalacademies.org/PGA/fdp/PGA_070596

Public Health Service (PHS) U.S. Regulations *Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding is Sought* (42 CFR Part 50 Subpart F): <https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=992817854207767214895b1fa023755d&rgn=div5&view=text&node=42:1.0.1.4.23&idno=42#sp42.1.50.f>

Public Health Service (PHS) U.S. Regulations *Responsible Prospective Contractors* (45 CFR Part 94): <https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=992817854207767214895b1fa023755d&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45>

Sources of research funding which have adopted the Public Health Services and/or any Final Rule at 42 CFR Part 50 Subpart F and 45 CFR Part 94: http://sites.nationalacademies.org/PGA/fdp/PGA_070596

University Significant Financial Interest(s) Report Form for the U.S. Public Health Service Funding (available upon request from the Designated Official)

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