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University of Regina's Financial Conflict of Interest (FCOI) Procedures for U.S. Public Health Service and National Science Foundation Funded Research Effective: 29 Oct, 2026

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I. INTRODUCTION

The University of Regina ("UofR") adopts these Procedures to meet the requirements of the United States' Public Health Service and National Science Foundation Funded Research Financial Conflict of Interest Requirements to implement and to comply with:

- Public Health Service (PHS) regulations on Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought (42 C.F.R. Part 50, Subpart F) and Responsible Prospective Contractors (45 C.F.R. Part 94) for PHS-funded research for grants, cooperative agreement, and research contracts, respectively. The regulations and this guidance policy do not apply to SBIR or STTR Phase I applications or awards.
- National Science Foundation (NSF) Proposal & Award Policies & Procedures Guide for NSF-funded research

These procedures are complementary to the University's existing policies, especially GOV-022-010 Conflict of Interest and Conflict of Commitment Policy and GOV-022-025 Research and Scholarly Integrity Policy. These specific Procedures are intended to demonstrate compliance with U.S. regulatory requirements and their goal of promoting objectivity in U.S. Federally-funded research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research from U.S. Federally-funded grants, cooperative agreements and contracts will be free from bias resulting from Investigators' Conflict of Interest (COI), including Financial Conflict of Interest (FCOI).

The UofR adopts these procedures/requirements for all Investigators (as defined below) engaged in PHS and/or NSF-funded research. These procedures establish the processes to identify, disclose, and manage Investigator financial conflicts of interest to protect research integrity, ensure the safety of human and animal subjects, and maintain public trust in PHS/NSF-supported research.

II. APPLICABILITY

These Procedures apply to each Investigator that is part of any application for, or in receipt of, research funding from PHS and/or NSF, whether such funding is by means of a grant, cooperative agreement, or contract.

III. DEFINITIONS

Financial Conflict of Interest (FCOI): A Significant Financial Interest (SFI) that could directly and significantly affect the design, conduct, or reporting of U.S. Funded Research.

Financial Interest: Anything of monetary value, whether or not its value is readily ascertainable.

FCOI Committee: Associate Vice-President, Research, and Directors, Office of Research Services and ORPI, as appointed by the Vice-President, Research. The FCOI Committee may include the FCOI Official where warranted.

FCOI Official: UofR's Vice President, Research.

Disclose: An Investigator's submission of a completed Disclosure and Consent Report, defined herein, to the university.

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Disclosure and Consent Report: A tool for Investigators to Disclose the absence or presence of SFIs and to consent to the release of their information according to this procedure, provincial laws and the FCOI Regulation. This reporting tool can be accessed on the UofR website.

FCOI Appeal Review Committee: This committee is assembled on a case-by-case basis when an Investigator challenges decisions made by the Designated Official. The Associate Vice-President (AVP) Research will convene the committee with independent assessors. The chair of the committee will be named by the AVP Research or equivalent position. In order to call this committee to assembly, contact the university's AVP Research.

FCOI Conflict Review Committee: This committee is assembled on a case-by-case basis for complex and unique SFI and FCOI decisions, identified by the Designated Official. It will be a five-member committee chaired by the Designated Official.

FCOI Regulation: The US Federal Department of Health and Human Safety Final Rule found at 42 CFR Part 50, Subpart F and 45 CFR Part 94, Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors. Also known as the 2011 NIH FCOI Regulations.

Institution: Any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, U.S. Federal Research funding.

Institutional Responsibilities: The professional responsibilities of an Investigator on behalf of UofR, including, without limitation

- 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 staff member; participation in the governance of the university, the Faculty 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 a staff member;
- clinical service, if identified in the staff member's job description;
- and any other responsibility outlined in the staff member's job description, employment agreement or appointment letter with the UofR.

Designated Official (DO): The individual appointed by UofR to solicit and review disclosures of significant financial interests, determine FCOIs in accordance with 42 CFR 50.604(f) and these procedures, and develop management plans for identified FCOI.

Investigator: The Project Director (PD) or Principal Investigator (PI), and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by PHS/NSF or proposed for such funding, which may include, for example, collaborators or consultants. The UofR determines who is responsible for the design, conduct, or reporting of PHS/NSF-funded research. The UofR will consider the individual's role, rather than the title (e.g., senior/key personnel, faculty, MD, PhD, etc.),

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of those individuals involved in the research and the degree of independence in carrying out the work when determining who is responsible for the design, conduct, or reporting of the PHS and/or NSF-funded research.

Manage: means taking action to address a FCOI, which can include reducing or eliminating the financial conflict of interest, to ensure, to the extent possible, that the design, conduct, and reporting of U.S. Funded research will be free from bias.

Management Plan: written plan to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias, when a FCOI is determined. The Designated Official (DO) in consultation with the Investigator creates the Management Plan. The Investigator is required to comply with the Management Plan prescribed by the DO, and the DO will monitor compliance with the plan until the completion of the project as well as provide initial and ongoing FCOI reports to the Funding Source.

Research: means a systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug). As used in the regulation, the term includes any such activity for which research funding is available from a PHS Awarding Component through a grant, cooperative agreement, whether authorized under the PHS Act or other statutory authority, such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project or research resources award.

PHS: The Public Health Service of the U.S. Department of Health and Human Services, and any components of the PHS to which the authority involved may be delegated, including the National Institutes of Health (NIH).

NIH: The biomedical research agency within the Public Health Service (PHS) that funds and conducts research to improve health and advance scientific knowledge.

NSF: the U.S. federal agency that funds fundamental research and education across all non-medical fields of science and engineering.

PHS-Funded Research: Any activity supported by a Public Health Service (PHS) Awarding Component through a grant, cooperative agreement, or contract, whether funded under the PHS Act or other statutory authority.

NSF Funded Research: Any Research funded by the National Science Foundation (NSF).

Senior/Key Personnel: The PD/PI and any other individual identified as senior/key personnel by the UofR in a grant application, progress report, or other submission to PHS/NSF. For this document, the term applies specifically to the public accessibility requirement, which mandates disclosure only of financial conflicts of interest held by these senior/key personnel, as described in Section 9.

Awardee: An institution that receives funding directly from a Funding Source.

Sub-Recipient: An Investigator from the UofR, who is the recipient of funding from a Funding Source via a subgrant from an Awardee institution.

Significant Financial Interest (SFI):

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1.) A financial interest (anything of monetary value, whether or not the value is readily ascertainable) consisting of one or more of the following interests of the Investigator (and those of the Investigator's partner and dependents) that reasonably appears to be related to the Investigator's Institutional Responsibilities:

   a. With regard to any publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the 12 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 CAD. 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.

   b. With regard to any non-publicly traded entity, a SFI exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds $5,000 CAD, or when the Investigator (or the Investigator's partner or dependents) holds any equity interest (e.g., stock, stock option, or other ownership interest); or

   c. Intellectual property (IP) rights and interests (e.g., patents, copyrights): upon receipt of income regarding those rights and interests in excess of $5,000 CAD per year per entity (payor). Includes royalties from such rights, and agreements to share in royalites related to licensed IP rights.

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 when the annual aggregate amount paid to the specific Investigator, exceeds $5,000 CAD per entity. This disclosure also applies to partners and dependents. Such travel includes trips paid on behalf of the Investigator rather than reimbursed directly, where the exact cost may not be known. The disclosure must cover the previous 12 months and include, at minimum, the purpose, sponsor or organizer, destination, and duration of each trip.

   The disclosure requirement does not apply to travel that is reimbursed or sponsored by the following:

   - a federal, state, or local government agency located in Canada or the United States,
   - a Canada or United States Institution of Higher Education,
   - an academic teaching hospital,
   - a medical center, or,
   - a research institute affiliated with a Canada or United States Institution of Higher Education

3.) Exclusions: The term SFI does not include the following types of financial interests

   a. salary, royalties, or other remuneration paid by the UofR to the Investigator if the Investigator is currently employed or otherwise appointed by the UofR, including

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intellectual property rights assigned to the UofR and agreements to share in royalties related to such rights;

b. income from investment vehicles, such as mutual funds and retirement accounts, as long as an Investigator does not directly control the investment decisions made in these vehicles;

c. income from seminars, lectures, or teaching engagements sponsored by an US federal, state, or local government agency, an US institution of higher education, an US academic teaching hospital, an US medical center, or an US research institute that is affiliated with an US institution of higher education;

d. similar income from non-US equivalents of these entities where the annual aggregate amount paid to an Investigator does not exceed $5,000 CAD per entity; or income from service on advisory committees or review panels for an US federal, state, or local government agency, an US institution of higher education, an US academic teaching hospital, an US medical center, or an US research institute that is affiliated with an US institution of higher education; similar income from non-US equivalents of these entities where the annual aggregate amount paid to an Investigator does not exceed $5,000 CAD per entity.

4.) In the event that an Investigator has no SFIs to Disclose, the disclosure must still be completed, following the timelines above.

5.) Exclusions related to Foreign (Non-Canadian. Non-American) Financial Interests: Investigators must disclose all foreign financial interests (which includes income from seminars, lectures, or teaching engagements, income from service on advisory committees or review panels, and reimbursed or sponsored travel) received from any foreign entity, including foreign Institutions of higher education or a foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure (e.g., income in excess of $5,000 CAD).

IV. SIGNIFICANT FINANCIAL INTEREST (SFI) DISCLOSURE REQUIREMENTS

Investigators will disclose their SFIs that are related to their "*institutional responsibilities*" as defined in the procedure document herein. The disclosure will not be limited to an Investigator's research responsibilities or their funded research as this is too narrow in scope and not consistent with the 2011 regulation. The Investigator SFI Disclosures will be retained by the UofR as part of the record maintenance requirements. Investigators are required to disclose SFIs at the following times:

1.) At the time of application: The PI and all other individuals who meet the definition of "Investigator" must disclose their SFIs to the DO(s). Any new Investigator who joins the project after the NIH application has been submitted or during the course of the research must also disclose their SFI(s) to the DO(s) promptly and before participating in the project, using the SFI Disclosure Form.

2.) Annual disclosure during the award: Each Investigator participating in research under an NIH award must submit an updated SFI disclosure at least annually as prescribed by UofR (on or before October 1) during the award period on rotating basis - If the form was completed on 30 Nov'2026, they must disclose SFIs on or before 30 No7. '2026The annual disclosure must include:

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a. any new information that was not previously disclosed to the DO under these procedures, including SFIs associated with PHS/NSF - -funded projects transferred from another institution; and

b. updated details for any previously disclosed SFI, such as changes in the value of an equity interest.

3.) Ad-hoc basis during the award: Each Investigator participating in PHS/NSF-funded research must submit an updated SFI disclosure within 30 days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance). Updated disclosure of reimbursed or sponsored travel must also be submitted within 30 days of each occurrence.

V. REVIEW OF SFI DISCLOSURES

At the UofR, the Research Facilitator, the PI's Dean (or immediate supervisor), and the Vice-President Research, will serve as the Designated Officials (DOs) responsible for reviewing all SFI disclosures and making determinations of FCOI. In cases where it is determined that one of the members of this Group has a disclosed SFI related to the research under review, or where additional independence is warranted, the DO team member will recuse themselves from the review and determination. In such cases, the remaining members of this group will serve as the DOs. In situations where a member of this group must recuse themselves, the situation will be documented.

Each SFI will be evaluated in relation to every PHS/NSF research application or award on which the Investigator is responsible for the design, conduct, or reporting of research, to determine whether the SFI is related to the funded research and, if so, whether it constitutes a Financial Conflict of Interest (FCOI). The SFI disclosures will be reviewed as described below:

1.) Prior to the issuance of a new award or before any expenditure of any awarded funds (e.g., during Just-in-Time stage): The DO will review the Investigator's SFIs before NIH issues a new award. If an FCOI is identified, an FCOI report will be submitted to NIH via the eRA Commons FCOI Module prior to any expenditure of funds.

2.) Annual SFI disclosure: As part of the annual disclosure process, Investigators must provide updated information on any previously disclosed SFIs (e.g., revised value of an equity interest). The DO will review these updates to determine whether changes to an existing management plan are needed. Any modifications will be reflected in the next Annual FCOI report submitted to NIH, if applicable.

3.) Ad hoc basis during award period: If a new Investigator joins a project or an existing Investigator acquires or discovers a new SFI during the project, the DO will, within 60 days:

a. review the disclosure;

b. determine whether the SFI is related to the PHS/NSF-funded research;

c. determine whether an FCOI exists; and, if so,

d. implement, on at least an interim basis, a management plan.

An FCOI report will be submitted to NIH within 60 days of identifying the

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FCOI.

VI. RELATEDNESS OF SFIS TO PHS/NSF-FUNDED RESEARCH AND FCOI

The DOs are responsible for assessing the relatedness of SFIs to PHS/NSF-funded research and determining when they constitute a FCOI. Please note that an FCOI exists when the DOs reasonably determine that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NSF- funded research ("significantly" meaning that the financial interest would have a material effect on the research).

Relatedness Test: The DOs determine whether an Investigator's SFI is related to research under an PHS/NSF - award. An SFI is considered "related" when the DOs reasonably determine that:

1.) The SFI could be affected by the PHS/NSF-funded research, or

2.) The SFI is in an entity whose financial interests could be affected by PHS/NSF- funded research.

Investigator involvement: The DOs may consult with the Investigator when assessing whether an SFI is related to the research.

VII. MANAGEMENT OF SFI THAT POSE AN FCOI

When an FCOI is identified, the DO will determine and implement management strategies to ensure the research is conducted objectively. Examples of management conditions include, but are not limited to:

1.) Public disclosure of the FCOI (e.g., in publications or presentations, to study personnel, to the Research Ethics Board (REB), President's Committee on Animal Care (PCAC).

2.) For human subjects' research, disclosure of the FCOI to participants in the informed consent document

3.) Appointment of an independent monitor to protect against bias in the design, conduct, and reporting of the research

4.) Modification of the research plan

5.) Change of personnel roles or removal from portions ofthe research

6.) Reduction or elimination of the financial interest (e.g., divesting equity)

7.) Severance of relationships that create financial conflicts.

The DOs will communicate the determination and the management plan in writing to the Investigator and will require the Investigator to certify compliance with the management plan.

No expenditures on an NIH award may occur until the Investigator has met all disclosure requirements and agreed in writing to comply with the management plan. The DOs will submit an FCOI report to NIH via the eRA Commons FCOI Module.

VIII. MONITORING INVESTIGATOR COMPLIANCE

UofR will monitor Investigator compliance with the management plan for the duration of the NIH award. When the Institution's FCOI requirements apply to subrecipient Investigators, the Institution will monitor subrecipient Investigator compliance with the management plan.

As part of this monitoring process, the DO may request and review documentation demonstrating

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compliance with required FCOI disclosures, including publications, presentation materials, abstracts, posters, and written communications to study personnel. Investigators must provide copies of such materials, including relevant emails or other written disclosures, to the DO for recordkeeping. These records will be maintained to document compliance with the management plan and to support institutional review and audit activities.

IX. PUBLIC ACCESSIBILITY OF THE FCOI PROCEDURES AND FCOI HELD BY SENIOR/KEY PERSONNEL

A copy of GOV-022-010 Conflict of Interest and Conflict of Commitment Policy is available on UofR's public website, and a copy of these procedures is posted at here as required by Section 4.1.10 Financial Conflict of Interest of the NIH Grants Policy Statement.

Identified FCOIs held by Senior/Key Personnel: Before any funds are spent under an NIH award, UofR will ensure public accessibility, by providing a written response within five business days to requests for information about any SFI that meets all three of the following criteria:

1.) The SFI was disclosed, is still held by Senior/Key Personnel (the PD/PI and any other individual identified by UofR as senior/key personnel in the application, progress report, or other NIH submission).

2.) UofR has determined that the SFI is related to the PHS/NSF - -funded research.

3.) UofR has determined that the SFI constitutes an FCOI.

When applicable, UofR will make available at least the following information:

1.) Investigator's name

2.) Investigator's title and role with respect to the research project

3.) Name of the entity in which the SFI is held.

4.) Nature of the SFI

5.) Approximate dollar value of the SFI in the following ranges: $0–$4,999; $5,000–$9,999; $10,000–$19,999; amounts between $20,000 and $100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000; or a statement that the value cannot be readily determined by public prices or reasonable fair market value measures.

The written response will note that the information provided is current as of the date of the correspondence and is subject to updates on at least an annual basis and within 60 days of the institution's identification of a new FCOI, which should be requested subsequently by the requestor.

If UofR uses a publicly accessible website to meet this requirement, the information will be updated at least annually and within 60 days of:

1.) Receiving or identifying an additional SFI of Senior/Key Personnel related to the PHS/NSF - -funded research that was not previously disclosed, or

2.) A new SFI being disclosed by Senior/Key Personnel joining the project and determined by the DO to be related and an FCOI. Information on SFIs subject to public accessibility will remain available for at least three years from the most recent update.

X. REPORTING IDENTIFIED FINANCIAL CONFLICTS OF INTEREST

Prior to spending any funds under an PHS/NSF - funded award, UofR will submit an identified FCOI report to NIH, in accordance with the FCOI regulations, for any Investigator's SFI determined to be an FCOI. UofR will also ensure that the Investigator has agreed to and begun implementing the associated management plan.

UofR will designate an institutional official to act as the FCOI Signing Official (FCOI SO) in the eRA Commons FCOI Module. The FCOI SO is authorized to submit FCOI reports to NIH. FCOI reports are submitted only when an award is active and an FCOI has been identified (i.e., no award means no FCOI report, and no FCOI means no FCOI report). The NIH eRA Commons FCOI Module User Guide, available at the following location, provides instructions for preparing and submitting FCOI reports. The institution will submit the following types of reports as explained below:

1.) Initial (Original) FCOI Reports: The report must include all information required under 42 CFR 50.605(b)(3) or as outlined in NIH's FAQ currently numbered H.5 linked herein.

When an FCOI is identified, the Original Report will be submitted as described below:

a. Prior to the expenditure of funds: If an FCOI is identified at the time a new NIH award is issued, the FCOI SO will submit an "Original" FCOI report (2011 FCOI) through the eRA Commons FCOI Module before any funds are spent. This requires the following content to be submitted: Grant number; PI; name of entity with FCOI; nature of FCOI; value of the financial interest (in required increments); description of how the financial interest relates to the research; key elements of the management plan.

b. Within 60 days of Identifying a New FCOI during the award: If an FCOI is identified during the award period (e.g., a new SFI is disclosed or a new Investigator joins the project), the Institution must submit an Original FCOI report within 60 days of identifying the FCOI.

2.) Annual FCOI Reports: For the duration of an award, including any extensions with or without funds, the Institution must submit an annual FCOI report to NIH. This report will indicate whether each previously reported FCOI is still being managed or no longer exists and describe any changes to the management plan, if applicable. At this stage, the following contents need to be submitted: Status of the FCOI (whether it is still being managed or no longer exists) and any changes to the management plan, if applicable.

a. The annual report must be submitted at the same time as the Research Performance Progress Report (RPPR) or multi-year progress report, and at the time of any grant extension, following NIH guidance (see here). NIH creates the opportunity for the FCOI SO to submit the Annual report 75 days prior to the next budget period start date for continuation awards. NIH will notify the Institution by email when an annual report is due.

b. Annual FCOI reports are not required at grant closeout.

3.) Revision (or Mitigation) FCOI Reports: If applicable, updates to a previously submitted FCOI report to describe actions that will be taken to manage the FCOI going forward or to revise the original report. After completing a retrospective review, the Institution will submit a Revision report to NIH if new information about the FCOI is discovered, or a Mitigation report if the review finds that bias has occurred. These reports will require the following information to be submitted again: Project number; project title; contact PI/PD; name of Investigator with FCOI; name of entity with FCOI; reason for review; detailed methodology, along with findings, and conclusions.

Summary Chart for FCOI Report Types

Required FCOI Reports to NIH via eRA Commons FCOI Module		
REPORT	**CONTENT**	**REQUIRED WHEN**
New FCOI Report (Initial Submission)	Grant number; PI; name of entity with FCOI; nature of FCOI; value of the financial interest (in required increments); description of how the financial interest relates to the research; key elements of the management plan	1) Prior to the expenditure of funds on a new award; or 2) Within 60 days of identifying any new FCOI during the award period
Annual FCOI Report	Status of the FCOI (whether it is still being managed or no longer exists) and any changes to the management plan, if applicable.	Submitted annually at the same time as the annual progress report, multi-year progress report, or at the time of a grant extension.
Revised FCOI Report	If applicable, updates to a previously submitted FCOI report to describe actions that will be taken to manage the FCOI going forward or to revise the original report.	Following a retrospective review when noncompliance with the regulation is identified, if applicable.
Mitigation Report	Project number; project title; contact PI/PD; name of Investigator with FCOI; name of entity with FCOI; reason for review; detailed methodology, findings, and conclusions.	After a retrospective review when bias is found.

XI. TRAINING REQUIREMENTS FOR INVESTIGATORS

Each Investigator will be informed of this procedure and trained on their responsibility to disclose foreign and domestic SFIs under this guidance and the FCOI regulation. Training must be completed before an Investigator engages in PHS/NSF-funded research, at least once every four years, and promptly (as described below) when any of the following occur:

1.) UofR revises this guidance or related procedures in a way that affects Investigator requirements.

2.) An Investigator is new to UofR research under a PHS/NSF - award (training must be completed before participating in the research).

3.) UofR determines that an Investigator has not complied with this guidance or with a management plan issued under it (training must be completed within 30 days as directed by

the DO).

To supplement the regulatory training requirements, UofR will utilize NIH's training programs to train Investigators on the FCOI regulation. UofR requires Investigators to complete either:

1.) The NIH Training module at https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training and print and retain the Completion Certificate for audit purposes. Certificate should be shared with the DO, OR

2.) Review the NIH Virtual Seminar presentation on FCOI compliance from the following location: https://www.youtube.com/watch?v=D292YZ6BX24. Send DO the date of completion through email for audit purposes.

XII. NON-COMPLIANCE WITH FCOI PROCEDURES AND CORRECTIVE ACTIONS

If UofR identifies an SFI that was not disclosed, reviewed, or managed in a timely manner, the DO will, within 60 days: review the SFI; determine whether it is related to PHS/NSF - funded research; determine whether it constitutes an FCOI; and, if so, implement an interim management plan describing actions that have been and will be taken to manage the FCOI going forward. UofR will also submit an FCOI report to NIH via the eRA Commons FCOI Module. In addition, whenever an FCOI is not identified or managed in a timely manner, including:

1.) Failure by the Investigator to disclose an SFI that is later determined to constitute an FCOI.

2.) Failure by the institution to review or manage an FCOI.

3.) Failure by the Investigator to comply with an established management plan.

UofR will, within 120 days of identifying noncompliance:

1.) Complete a retrospective review of the Investigator's activities and the PHS/NSF - -funded research to determine whether the research, or any part of it, was biased in the design, conduct, or reporting.

2.) Document the retrospective review in accordance with 42 CFR 50.605(a)(3)(ii)(B) or as described in NIH's FAQ I.2. at https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52895. Based on the results of the retrospective review, if appropriate, the Institution shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward.

If bias is found, UofR will promptly notify NIH and submit a mitigation report as required by 42 CFR 50.605(a)(3)(iii) or as described in NIH's FAQ I.3. at https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52896 to NIH via the FCOI Module. The report will include:

1.) The impact of the bias on the research project, and

2.) The plan of action or corrective steps taken to eliminate or mitigate the effect of the bias.

UofR will thereafter submit FCOI reports annually to PHS/NSF - as required by the regulations and the terms and conditions of the award. Depending on the circumstances, UofR may implement additional interim measures regarding the Investigator's participation in the research until the retrospective review is complete.

If bias is not found following completion of the retrospective review, no further action will be taken unless new information is discovered that needs to be reported to the PHS/NSF -. If applicable, the Institution will update an existing FCOI report to specify the actions that have been, and will be, taken to manage the FCOI going forward or update a previously submitted report information (e.g., increase in value

of the SFI or add any newly identified SFIs) following the completion of the retrospective review.

If the failure of an Investigator to comply with an UofRs FCOI or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS/NSF-funded research, the Institution shall promptly notify the PHS/NSF Awarding Component of the corrective action taken or to be taken. The PHS/NSF Awarding Component will consider the situation and, as necessary, take appropriate action, or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the PHS/NSF-funded research project. PHS may, for example, require Institutions employing such an Investigator to enforce any applicable corrective actions prior to a PHS/NSF award or when the transfer of a PHS/NSF grant(s) involves such an Investigator.

XIII. CLINICAL RESEARCH REQUIREMENTS

If HHS determines that a PHS-funded clinical research project evaluating the safety or effectiveness of a drug, medical device, or treatment was designed, conducted, or reported by an Investigator with an unmanaged or unreported FCOI, UofR will require the Investigator to disclose the conflict in every public presentation of the research results and to request an addendum to previously published presentations.

XIV. SUBRECIPIENT REQUIREMENTS

A subrecipient relationship exists when federal funds flow from or through UofR to another individual or entity that will carry out a substantive portion of a PHS/NSF-funded research project and is accountable to UofR for programmatic outcomes and compliance.

Subrecipients (e.g. collaborators or consortium members) are subject to UofR's terms and conditions. UofR will take reasonable steps to ensure that all subrecipient Investigators comply with the federal FCOI regulations. UofR will include in each written agreement with a subrecipient term specifying whether UofR's FCOI procedures or the subrecipient's own FCOI requirements will apply to subrecipient Investigators (see NIH Grants Policy Statement Section15.2.1 Written Agreement at https://grants.nih.gov/grants/policy/nihgps/html5/section_15/15.2_administrative_and_other_requirements.htm).

1.) If the subrecipient's FCOI guidance applies: The subrecipient institution must certify in the agreement that its requirements comply with federal FCOI regulations. The agreement will specify the timeframe for the subrecipient to report identified FCOIs to UofR in time for UofR to meet NIH reporting deadlines (i.e., before funds are spent and within 60 days of the subrecipient identifying an FCOI). Typically, this means requiring subrecipients to report FCOIs to UofR within 50–55 days of identification. UofR's DO will then submit the subrecipient FCOI report to NIH through the eRA Commons FCOI Module.

2.) If the subrecipient cannot certify compliance: The agreement will specify that UofR's FCOI procedure applies. In this case, subrecipient Investigators must disclose their SFIs to UofR. The SFI disclosure must include SFIs that are directly related to the subrecipient's work for UofR. The agreement will allow sufficient time for UofR to review, manage, and report any resulting FCOIs. When an FCOI is identified, UofR will implement a management plan, monitor compliance by the subrecipient Investigator, and submit the required FCOI report to NIH via the eRA Commons FCOI Module.

XV. MAINTENANCE OF RECORDS

UofR will maintain records of all Investigator financial interest disclosures, UofR's review and response to those disclosures (whether or not they resulted in a determination of an FCOI), and any actions taken under this guidance or through retrospective review. These records will be retained for at least three years from the date of submission of the final expenditures report, or for longer periods as specified in 2 CFR 200.334 (https://www.ecfr.gov/current/title-2/subtitle- A/chapter-II/part-200/subpart-D/subject-group-

ECFR4acc10e7e3b676f/section-200.334) for different situations. UofR will retain these records for each competitive segment as required by regulation.

Copies of management plans will be retained as part of the record maintenance requirements and **not submitted to NIH** as per NIH's FAQ guidance.

XVI. ENFORCEMENT ACTIONS FOR INVESTIGATOR NONCOMPLIANCE AND REMEDIES FOR NONCOMPLIANCE

In addition, the PHS/NSF Awarding Component and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests and the Institution's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the UofR's determination of an FCOI. The Institution will submit, or permit on site review of, all records pertinent to compliance with the regulation and this procedure. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests. On the basis of its review of records or other information that may be available, the PHS/NSF Awarding Component may decide that a particular FCOI will bias the objectivity of the PHS/NSF-funded research to such an extent that further corrective action is needed or that the Institution has not managed the FCOI in accordance with the regulation or this document. The PHS/NSF Awarding Component may determine that imposition of specific award conditions under 2 CFR 200.208 (https://www.ecfr.gov/current/title-2/section-200.208), or suspension of funding or other enforcement action under 2 CFR 200.339 (https://www.ecfr.gov/current/title-2/section-200.339) is necessary until the matter is resolved.

XVII. USEFUL FCOI AND NIH RESOURCES

1.) NIH e-mail address for FCOI-related inquiries: fcoicompliance@mail.nih.gov

2.) FCOI Regulation 42 CFR Part 50 Subpart F - Promoting Objectivity in Research at https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F

3.) Financial Conflict of Interest at https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi

4.) FCOI Training at https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training

XVIII. POINT OF CONTACT

If you have a question related to the FCOI Procedure of UofR, or would like to disclose a financial interest, contact us using the information below:

Contact Information
Office of Research Services
Centre for Kinesiology, Health and Sport, Floor 2A, Room 227
University of Regina
Treaty 4 and Métis Homeland
3737 Wascana Parkway Regina, Saskatchewan S4S 0A2
Phone: 306-585-4269
Fax: 306-585-4893
Email: Research.Services@uregina.ca
www.uregina.ca/research/

The University of Regina is located on Treaty 4 lands with a presence in Treaty 6. These are the territories of the nêhiyawak (nay-hi-yuh-wuk, Cree), Anihšināpēk (uh-nish-i-naa-payk, Saulteaux), Dakota, Lakota, Nakoda, and the homeland of the Métis/Michif Nation. Today, these lands continue to be the shared territory of many diverse peoples. Recognizing this is an important part of our culture and our values as members of this community.