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# Financial Conflict of Interest for Research Conducted Under United States (US) Public Health Services (PHS) Grants or Agreements



# Financial Conflict of Interest for Research Conducted Under United States (US) Public Health Services (PHS) Grants or Agreements

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Validity:	The English version of this regulation is the operative version, and the Afrikaans version is the translation.

<sup>1</sup> Rules Owner: Head(s) of Responsibility Centre(s) in which the rules functions.

<sup>2</sup> Rules Curator: Administrative head of the division responsible for the implementation and maintenance of the rules

## 1 Introduction

- 1.1. Stellenbosch University ("the University") regulates its Conflict of Interest through the *Institutional Rule: Conflict of Interest* approved by Council and recognises that funders might have specific requirements to ensure that the integrity and judgement of stakeholders are not compromised when designing, conducting and reporting their research activities.
- 1.2. Due to the additional regulatory requirements for compliance with United States federal funding regulations and all institutions subject to the Department of Health and Human Services' regulations applicable to the Public Health Service<sup>1</sup> (such as the National Institutes of Health) grants and cooperative agreements, this *Rule: Financial Conflict of Interest for Research Conducted Under U.S. Public Health Services (PHS) Grants or Agreements* ("Rule"), will apply in addition to the *Institutional Rule: Conflict of Interest*.
- 1.3. This *Rule* must apply to research activities related to PHS grants and agreements and must be read in conjunction with the *Institutional Rule: Conflict of Interest*.
- 1.4. This *Rule* will not repeat aspects that are already included in the *Institutional Rule: Conflict of Interest*, which sets out the University's stance and management of conflict of interest in general.
- 1.5. Stakeholders (as defined in the *Institutional Rule: Conflict of Interest*) involved in U.S. Public Health Services (PHS) grants or agreements, will henceforth be referred to as "*Investigators*" in this *Rule: Financial Conflict of Interest for Research Conducted Under U.S. Public Health Services (PHS) Grants or Agreements*, and must adhere to the additional requirements as stipulated in the relevant U.S. federal funding regulations and subsequent amendments, dealing with *Promoting Objectivity in Research* (42 CFR Part 50 Subpart F)<sup>2</sup>. The financial conflict of interest disclosure (Annexure A) applies to all such Investigators as defined by the PHS.
- 1.6. This *Rule* is intended for internal use only and does not confer any rights or privileges on any third party.

## 2 Definitions

- 2.1. The definitions in the *Institutional Rule: Conflict of Interest* will also be applicable here as and when relevant. Some of the definitions in this *Rule* expand on the original definitions in the *Institutional Rule*. There will also be further definitions that address specific regulatory requirements.
- 2.2. **"Financial Conflict of Interest (FCOI)":** The U.S. federal funding regulations (42 CFR Part 50 Subpart F and subsequent amendments) define a Financial Conflict of Interest (FCOI) as "a significant financial interest that could directly

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<sup>1</sup> The U.S. Public Health Services (PHS) is defined as "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)". The NIH is the biomedical research agency of the PHS. Several non-PHS agencies adopted the PHS regulations.

<sup>2</sup> <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>

and significantly affect the design, conduct, or reporting of Public Health Services (PHS)-funded research".

- 2.3. **"Financial Interest"**: Anything of monetary value, whether or not the value is readily ascertainable.
- 2.4. **"Investigator"**: The U.S. federal funding regulations (42 CFR Part 50 Subpart F and subsequent amendments) define an **Investigator** as the "Project Director or Principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the Public Health Service (PHS) (e.g. NIH), or proposed for such funding, which may include, for example, collaborators or consultants". The University will consider the individual's role, rather than the title, of those involved in the research and the degree of independence with which the individual works when determining who is responsible for the design, conduct, or reporting of the PHS-funded research.
- 2.5. **"Senior/Key Personnel"** as defined meaning: "the Project Director/Principal Investigator (PD/PI) and any other person *identified* as senior/key personnel by the University in the grant application, progress report, or any other report submitted to the NIH/PHS by the University under the regulation". Please refer to the following website for more information: <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>.
- 2.6. **"Institutional Responsibilities"** are defined as an Investigator's professional responsibilities on behalf of the University and as defined by the University in this *Rule* on Financial Conflict of Interest for U.S. federal funded research, which may include, for example, activities such as research, research consultation, teaching, professional practice, Institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards. The University can include other professional responsibilities within the definition, as appropriate" <https://grants.nih.gov/faqs#/>
- 2.7. **"Institutional U.S. FCOI Committee"**: For U.S. federally funded (including funders that adopted the Department of Health and Human Services regulation) research projects, a dedicated **Institutional U.S. FCOI Committee** is established consisting of members from the Division for Research Development (DRD), the Grants Management Office (GMO) of the Faculty of Medicine and Health Sciences, and the Division for Human Resources. This **Institutional U.S. FCOI Committee** has been **designated** by the University to oversee the financial conflict of interest process and is mandated to:
  - 2.7.1. soliciting and reviewing financial disclosures of Investigators' Significant Financial Interests (SFI) that are reasonably related to an Investigator's University responsibilities (e.g., research, clinical, teaching, etc.), including the sub-recipients;
  - 2.7.2. identifying (as per regulatory criteria provided in 42 CFR 50.604(f)) and

determining whether an Investigator's SFI is related to the NIH-funded research (i.e., could the SFI be affected by the research or is the SFI in an entity whose financial interest could be affected by the research) and, if so related, whether the SFI is a financial conflict of interest (FCOI) (i.e., a SFI that could directly and significantly affect the design, conduct or reporting of the PHS-funded research);

- 2.7.3. developing and implementing management plans to manage FCOIs for Investigators and sub-recipient Investigators, if applicable, and monitoring Investigator compliance with the plan;
- 2.7.4. submitting initial and annual FCOI reports to the NIH via the eRA Commons FCOI Module in accordance with the regulation;
- 2.7.5. completing retrospective reviews when there is noncompliance with the University's *Institutional Rule: Conflict of Interest*, or the *Rule: Financial Conflict of Interest for Research Conducted Under U.S. Public Health Services (PHS) Grants or Agreements*, or the FCOI regulation and updating any previously submitted FCOI report, if required, after the retrospective review is complete;
- 2.7.6. Submitting mitigation reports when bias is found in NIH/PHS-supported research following the completion of the retrospective review;
- 2.7.7. Maintaining certain FCOI-related records and for a prescribed time period per the U.S. federal regulation;
- 2.7.8. If an FCOI for someone listed as a "Senior/Key Personnel" is identified, the University, through this Committee, must make their FCOI information publicly available;
- 2.7.9. To monitor Investigators' FCOI training requirements; and
- 2.7.10. Any other responsibilities that may be relevant.

2.8. **"Significant Financial Interest (SFI)":** The U.S. federal funding regulations (42 CFR Part 50 Subpart F and subsequent amendments) define a Significant Financial Interest (SFI) as:

"(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 (University) 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 the prescribed amount (at the time this *Rule* was approved it was \$5,000 (5 000 US Dollars)<sup>3</sup>). 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

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<sup>3</sup> This amount may vary according as updates to the PHS Policy are made. The Institutional U.S. FCOI Committee will keep Investigators updated with changes.



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 the prescribed amount (at the time this *Rule* was approved it was \$5,000 (5 000 US Dollars)), 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, more than \$5,000 (5 000 US Dollars).
- (2) Investigators also must disclose the occurrence of any reimbursed or sponsored travel above \$5,000 (5 000 US Dollars) (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 University 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 located in the United States, a United States Institution of higher education as defined in 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with a United States Institution of higher education. The details of this disclosure will include, at a minimum, the purpose of the trip, the identity of the sponsor/organiser, the destination, and the duration. The *Institutional U.S. FCOI Committee* 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, and therefore, Investigators are not required to disclose, 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; any ownership interest in the University held by the Investigator, if the University 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 located in the United States, a United States 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 a United States Institution of higher education;

or income from service on advisory committees or review panels for a Federal, state, or local government agency located in the United States, a United States 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 a United States Institution of higher education."

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 foreign government (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for annual disclosure, namely \$5,000 (USD 5 000).

2.9. **"Research"**: Research implies a systematic investigation, study, or experiment designed to develop or contribute to generalisable knowledge relating broadly to public health, including behavioural 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 therapeutic drug).

2.10. **"PHS-Funded Research"**: The term includes any such activity for which research funding is available from a PHS-Awarding Component through a grant, cooperative agreement, or contract, whether authorised under the PHS Act or other statutory authority.

### 3 **Purpose of this Rule:**

This *Rule* elaborates on the *Institutional Rule: Conflict of interest*, to meet the legal obligations in terms of United States Regulatory Requirements related to 42 CFR Part 50 Subpart F and its subsequent amendments and enable compliance with the research conducted under U.S. Public Health Services (PHS) grants or agreements.

The purpose of the U.S. regulation is to promote objectivity of Public Health Service (PHS) (e.g., NIH)- funded research and to protect the design, conduct or reporting of PHS/NIH-funded research from bias resulting from Investigator's financial conflicts of interest.

### 4 **Objective of this Rule:**

The objective of this *Rule* is to build on the *Institutional Rule: Conflict of Interest* and to provide a process for identification, disclosure, determining, managing and monitoring Investigator financial conflicts of interest where research is conducted under U.S. PHS grants or agreements.

## 5 Significant financial interest (SFI) disclosure requirements

At the time of application, the Principal Investigator and all other individuals who meet the definition of 'Investigator' must disclose their SFIs to the University's ***Institutional U.S. FCOI Committee***. Any new Investigator who, after applying to NIH (or any PHS agency) for funding from NIH or during the course of the research project, plans to participate in the project must similarly disclose their SFI(s) to the ***Institutional U.S. FCOI Committee*** promptly and prior to participation in the project.

**Annually:** Each Investigator who is participating in research under an NIH (or any PHS agency) award must submit an updated disclosure of SFI at least annually (on or at least 30 days before the next cycle), during the period of the award. Such disclosure must include any information that was not disclosed initially to the University pursuant to this *Rule* or in a subsequent disclosure of SFI (e.g., any financial conflict of interest identified on an NIH-funded project directly as an NIH Grantee and/or indirectly through a sub-award) that was transferred from another Institution, and must include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

**Any New SFI:** Each Investigator participating in PHS/NIH-funded research must submit an updated disclosure of SFI within thirty (30) days of discovering or acquiring a new SFI (e.g., through purchase, marriage, or inheritance). In addition, Investigators must submit an updated disclosure of reimbursed or sponsored travel within 30 days of each occurrence.

Financial conflict of interest relating to research conducted under U.S. PHS grants or agreements is disclosed by completing Annexure A and must also be captured on the Sun-e-HR platform or any other platform or system provided for this purpose.

## 6 Review of significant financial interest disclosures

Apart from the principles identified in the *Institutional Rule: Conflict of Interest*, the following is added with a focus on research conducted under U.S. PHS grants or agreements:

It is the responsibility of the *Institutional U.S. FCOI Committee* to ensure that Investigators and subrecipient Investigators involved in U.S. federal funding or funders follow the PHS regulation and follow the procedures as described in this *Rule*.

The *Institutional U.S. FCOI Committee* will conduct reviews of any SFI that have been identified in a disclosure; these interests will be compared to each PHS/NIH research application and/or award on which the Investigator is identified as responsible for the design, conduct, or reporting of the research to determine if the SFI is related to the PHS/NIH-funded research and, if so, whether the SFI creates a Financial Conflict of Interest (FCOI) related to that research award as explained in Section 7 (Relatedness).

The *Institutional U.S. FCOI Committee* will review the Investigator's SFI(s) prior to the NIH/PHS agency issuing a new award, and if an FCOI is identified, the



University will submit an FCOI report to the NIH (or relevant PHS agency) via the eRA Commons FCOI Module before the expenditure of funds under the new award.

The annual disclosure will require the Investigator to disclose updated values of any previously disclosed SFIs (e.g., the updated value of a previously disclosed equity interest). The *Institutional U.S. FCOI Committee* will review the Investigator's annual disclosure and will use the updated information to determine if any changes are needed to an existing management plan. Any changes to an existing management plan will be reported to the NIH when the next Annual FCOI report is due, if applicable.

The University will also comply with the requirement to review SFIs during the period of an NIH-funded award. Specifically, whenever, in the course of an ongoing NIH-funded research project, an Investigator who is new to participating in the research project discloses a SFI or an existing Investigator discloses a new SFI, the *Institutional U.S. FCOI Committee* will within 60 days: review the disclosure of SFI, determine whether the SFI is related to the NIH-funded research; determine whether an FCOI exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage the FCOI. The University will submit the FCOI report to the NIH within 60 days of identifying the FCOI.

## 7 **Guidelines for determining "Relatedness" of SFI to PHS/NIH-funded research and an FCOI**

The ***Institutional U.S. FCOI Committee*** will determine whether an Investigator's SFI is related to the research under an NIH/PHS award and, if so, whether the SFI is a financial conflict of interest.

An Investigator's SFI is related to the research when the *Institutional U.S. FCOI Committee* reasonably determines the SFI:

- Could be affected by the PHS/NIH-funded research, or
- Is in an entity whose financial interest could be affected by the PHS/NIH-funded research.

The *Institutional U.S. FCOI Committee* may involve the Investigator in determining whether a significant financial interest is related to the PHS-funded research.

A financial conflict of interest exists when the *Institutional U.S. FCOI Committee* reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS/NIH-funded research. ('Significantly' means that the financial interest would have a material effect on the research).

## 8 **Management of SFIs that pose FCOI**

If a financial conflict of interest exists, the *Institutional U.S. FCOI Committee* will determine what management conditions and/or strategies will be put in place to manage the FCOI. Examples of conditions that might be imposed to manage a financial conflict of interest include, but are not limited to:

1. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research, to research personnel working on the study, to the

- University's Ethics Review Boards, etc.);
2. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to human participants in the informed consent document;
  3. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
  4. Modification of the research plan;
  5. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
  6. Reduction or elimination of the financial interest (e.g., sale of an equity interest);
  7. Severance of relationships that create financial conflicts.

If the *Institutional U.S. FCOI Committee* determines that a conflict exists, it will communicate its determination and the means it has developed for managing the FCOI in writing to the individual, to the relevant Principal Investigator/Project Director, and to the appropriate direct line manager.

No expenditures on an NIH/PHS award will be permitted until the Investigator has complied with the Disclosure requirements of this *Rule* and has agreed, in writing, to comply with any plans determined by the *Institutional U.S. FCOI Committee* necessary to manage the Financial Conflict of Interest. The *Institutional U.S. FCOI Committee* of the University will submit the FCOI report to NIH via the eRA Commons FCOI Module.

## 9 **Monitoring Investigator compliance**

The University will monitor Investigator compliance with the management plan for the duration of the NIH (or other PHS) award or until the FCOI no longer exists during the period of an NIH/PHS-funded award. Monitoring of public disclosure requirements will include reviewing publications and presentations to confirm that the Investigator disclosed the FCOI in such communications. To facilitate additional monitoring, Investigators will be required to disclose the FCOI in writing to research personnel in the study and send a copy of the communication to the *Institutional U.S. FCOI Committee*.

## 10 **Public accessibility to information related to FCOI**

The University has published this *Rule* on its publicly accessible website to ensure transparency and compliance with the USA federal regulations, at: [Policies & Guidelines](#).

Prior to the expenditure of any funds under an NIH or PHS award, the University will ensure public accessibility by written response to any requestor within five business days of a request for information concerning any SFI disclosed that meets the following three criteria:

1. The SFI was disclosed and is still held by the senior/key personnel. Senior/key personnel are the PD/PI and any other person identified as senior key personnel by the University in the award application, progress report, or any other report submitted to the NIH or any PHS agency;
2. The University has determined that the SFI is related to the research funded through an award; and

3. The University has determined that the SFI is a financial conflict of interest.

The information that the University will make available via a publicly accessible website or in a written response to any requestor within five days of request will include, at a minimum, the following:

1. The Investigator's name;
2. The Investigator's title and role with respect to the research project;
3. The name of the entity in which the Significant Financial Interest is held;
4. The nature of the Significant Financial Interest; and
5. The approximate dollar value of the Significant Financial Interest in the following ranges: \$0-\$4,999; \$5,000- 9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000, or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

If the University uses a publicly accessible Website to comply with the public disclosure requirements of the U.S. federal regulations, the information posted will be updated at least annually and within sixty days of receipt or identification of information concerning any additional Significant Financial Interest of the senior/key personnel for the NIH/PHS-funded research project that had not been previously disclosed, or upon the disclosure of a Significant Financial Interest of senior/key personnel new to the NIH/PHS-funded research project, if it is determined by the *Institutional U.S. FCOI Committee* that the Significant Financial Interest is related to the research and is a financial conflict of interest.

Information concerning an individual's SFI, as limited by this *Rule* will remain available for responses to written requests or for posting via the University's publicly accessible website for at least three years from the date that the information was most recently updated.

## 11 Reporting of FCOI

The University has assigned an institutional official to serve as the FCOI SO (signing official) within the eRA Commons FCOI Module. The FCOI SO has the authority to submit FCOI reports to the NIH and any other relevant PHS agency. FCOI reports are submitted to the NIH/PHS agency only when a grant or cooperative agreement is active and an FCOI is identified.

The FCOI Module User Guide is available at [https://www.era.nih.gov/files/fcoi\\_user\\_guide.pdf](https://www.era.nih.gov/files/fcoi_user_guide.pdf).

### INITIAL OR ORIGINAL FCOI REPORTS:

When an FCOI is identified upon the issuance of a new NIH/PHS award, the FCOI SO will submit a NIH "2011 FCOI" (Original) report **prior to the expenditure of any funds** under the award as required by the regulation. The Original (initial) FCOI report will include the information required in the U.S. regulation at 42 CFR Part 50.605(b)(3) or as outlined in NIH's FAQ H.5. at <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52888>.

The University will ensure that the Investigator has agreed to and implemented the corresponding management plan prior to submitting the report to the NIH/PHS

agency.

For any Significant Financial Interest that is identified as conflicting subsequent to an initial FCOI report during an ongoing NIH/PHS-funded research project ( e.g., a new SFI is identified for an Investigator who is participating in the NIH-funded research, upon the participation of an Investigator who is new to the research project, etc.), the University will provide to NIH/PHS agency ***within 60 days of identifying an FCOI***, an FCOI report regarding the financial conflict of interest and ensure that the University has implemented a management plan and the Investigator has agreed to the relevant management plan.

#### **ANNUAL FCOI REPORTS:**

While the award is ongoing (including any extensions with or without funds), the University will provide NIH/PHS agency with an annual FCOI report that addresses the status of the FCOI (i.e., an indication whether the FCOI is still being managed or if it no longer exists) and any changes in the management plan, if applicable. The Annual Report will be submitted at the same time as when the Research Performance Progress Report or multi-year progress report is due and at the time of grant extension, if applicable, per the NIH guidance (see NIH's FAQ H.2. at <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52860>).

#### **REVISION (or Mitigation) FCOI REPORTS:**

Following the completion of a retrospective review, the University will provide NIH/PHS agency with a Revision if new information is discovered or a Mitigation Report if bias is found.

#### **Types of FCOI Reports Summary Chart for NIH (similarly for other PHS agencies):**

##### **REQUIRED FCOI REPORTS TO BE PROVIDED TO NIH THROUGH eRA COMMONS FCOI MODULE**

<b>Report</b>	<b>Content</b>	<b>Required When?</b>
New FCOI Report (Initial submission)	Grant Number, PI, Name of Entity with FCOI, Nature of FCOI, Value of financial interest (in increments), Description of how FI relates to research, Key Elements of Management Plan	Prior to the expenditure of funds; Within 60 days of any subsequently identified FCOI.
Annual FCOI Report	Status of FCOI (i.e., whether FCOI is still being managed or no longer exists) and Changes to Management Plan, if applicable.	Annual report due at the same time as when the University is required to submit annual progress report, multi-year progress report, or at time of extension.
Revised FCOI Report	If applicable, update a previously submitted FCOI report to describe actions that will be taken to manage FCOI going forward or make changes to the originally submitted FCOI report.	Following the completion of a retrospective review when there is noncompliance with the regulation, if needed.
Mitigation Report	Project Number, Project Title, Contact PI/PD, Name of Investigator with FCOI, Name of Entity with FCOI, Reason for review, Detail Methodology, Findings, and Conclusion.	When bias is found in retrospective review.

## **12 Training requirements**

All Investigators (including subrecipient Investigators) must undergo training as prescribed by the U.S. funding regulations (42 CFR 50.604(b)). For University Investigators, there are two training streams, and for each, a certificate will be issued after successful completion of the training, and the certificates must be submitted

to the *Institutional U.S. FCOI Committee*. Both streams of training are required to be done before engagement in NIH/PHS-funded research, and at least every four (4) years, and immediately under the following circumstances:

- a. If the University's *Institutional Rule: Conflict of Interest* or this *Rule: Financial Conflict of Interest for Research Conducted Under U.S. Public Health Services (PHS) Grants or Agreements* changes in a manner that affects the requirements placed on the Investigator;
- b. An Investigator is new to the University; or
- c. When it is found that an Investigator does not comply with the University's *Institutional Rule: Conflict of Interest*, including this *Rule: Financial Conflict of Interest for Research Conducted Under U.S. Public Health Services (PHS) Grants or Agreements*.

**Stream 1 compulsory training:** The NIH FCOI training module is available [https://grants.nih.gov/grants/policy/coi/tutorial2018/story\\_html5.html](https://grants.nih.gov/grants/policy/coi/tutorial2018/story_html5.html).

**Stream 2 compulsory training for University Investigators:** The University's Conflict of Interest training sessions are offered by the *Institutional U.S. FCOI Committee*.

This training requirement is to train Investigators on the U.S. regulations, the University's *Institutional Rule: Conflict of Interest*, this *Rule: Financial Conflict of Interest for Research Conducted Under U.S. Public Health Services (PHS) Grants or Agreements* and the University's disclosure requirements.

**13 Failure to comply with the University's Rule: Financial Conflict of Interest for Research Conducted Under U.S. Public Health Services (PHS) Grants or Agreements, applicable to PHS-funded awards**

Whenever the University identifies an SFI that was not disclosed, identified, reviewed or managed in a timely manner, the *Institutional U.S. FCOI Committee* shall within 60 days: review the SFI, determine whether the SFI is related to research; determine whether an FCOI exists, and, if so: implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such FCOI going forward. The University will also submit an FCOI report to the PHS/NIH via the eRA Commons FCOI Module.

In addition, whenever an FCOI is not identified or managed in a timely manner, including:

- failure by the Investigator to disclose an SFI that is determined by the University to constitute an FCOI,
- failure by the University to review or manage such an FCOI; and
- failure by the Investigator to comply with a management plan;

then the University will within 120 days of determining noncompliance:

1. Complete a retrospective review of the Investigator's activities and the PHS/NIH-funded research project to determine whether any NIH/PHS-funded research, or portion thereof, conducted during the period of the noncompliance was biased in the design, conduct, or reporting of the research;
2. Document the retrospective review consistent with the regulation at 42 CFR 50.605(a)(3)(ii)(B) or as described in NIH's FAQ 1.2. at <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52895>.

If bias is found, the University shall notify NIH/PHS agency promptly and submit a mitigation report per the regulation at 42 CFR 50.605(a)(3)(iii) or as described in NIH's FAQ 1.3. at <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=52896> to NIH via the eRA Commons FCOI Module that shall address the following:

1. Impact of the bias on the research project, and
2. The University's plan of action or actions taken to eliminate or mitigate the effect of the bias.

Thereafter, the University will submit FCOI reports annually to NIH/PHS agency in accordance with the NIH/PHS agency's guidance as provided in the summary chart above. Depending on the nature of the Financial Conflict of Interest, the University may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS/NIH-funded research project between the date that the Financial Conflict of Interest is identified or the Investigator's noncompliance is determined and the completion of the University's retrospective review.

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 NIH/PHS agency. If applicable, update the existing FCOI report to specify the actions that have been and will be taken to manage the FCOI going forward or update 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.

#### **14 Clinical research requirements**

If the Department of Health and Human Services determines that one of its funded clinical research projects 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 a Financial Conflict of Interest that was not managed or reported, the University shall require the Investigator involved to disclose the Financial Conflict of Interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

#### **15 Subrecipient requirements**

A subrecipient relationship is established when federal funds flow down from or through the University to another individual or entity, and the subrecipient will be conducting a substantive portion of a PHS/NIH-funded research project and is accountable to the University for programmatic outcomes and compliance matters. Subrecipients, who include but are not limited to collaborators, consortium members, consultants, contractors, subcontractors, and sub-awardees, are subject to the University's terms and conditions, and as such, the University will take reasonable steps to ensure that any subrecipient Investigator complies with the U.S. federal FCOI regulation at 42 CFR Part 50 Subpart F.

The University will incorporate, as part of a written agreement with the subrecipient, terms that establish whether the University's *Rule: Financial Conflict of Interest for Research Conducted Under U.S. Public Health Services (PHS) Grants or Agreements* or the FCOI Policy of the subrecipient's institution will apply to the subrecipient Investigator(s). See the NIH Grants Policy Statement Section 15.2.1 Written



If the subrecipient's FCOI policy applies to the subrecipient Investigator, the subrecipient institution will certify as part of the agreement with the University that its policy complies with the U.S. federal FCOI regulation. In this situation, the agreement shall specify the time period for the subrecipient to report all identified FCOIs to the University in sufficient time to enable the University to provide timely FCOI reports, as necessary, to the PHS/NIH as required by the U.S. regulation (i.e., prior to the subrecipient's expenditure of funds and within 60 days of the subrecipient's identification of an FCOI during the period of an award). Therefore, the written agreement may establish a reporting requirement of FCOIs identified during the period of an award to be submitted to the University within 50 days of the subrecipient's identification of an FCOI to allow the University to report the FCOI within the 60-day period. The University's assigned FCOI Signing Official (SO) will submit the FCOI report (subrecipient report) to the NIH via the eRA Commons FCOI Module.

If the subrecipient cannot provide the certification of compliance with the U.S. FCOI regulation, the agreement shall state that the subrecipient Investigator is subject to the University's *Rule: Financial Conflict of Interest for Research Conducted Under U.S. Public Health Services (PHS) Grants or Agreements* for disclosing SFI(s) that are directly related to the subrecipient's work for the University. Therefore, the University will require the submission of all Investigator disclosures of SFIs to the University. The agreement will include sufficient time period(s) to enable the University to comply timely with its review, management, and reporting obligations under the U.S. regulation. When an FCOI is identified, the University will develop a management plan, monitor subrecipient Investigator compliance with the plan, and submit an FCOI report (subrecipient report) to the NIH through the eRA Commons FCOI Module for any FCOIs identified for a subrecipient Investigator.

## 16 **Maintenance of records**

The University will keep all records of all Investigator disclosures of financial interests and the University's review of, or response to, such disclosure (whether or not a disclosure resulted in the University's determination of a Financial Conflict of Interest), and all actions under the University's *Rule: Financial Conflict of Interest for Research Conducted Under U.S. Public Health Services (PHS) Grants or Agreements* or retrospective review, if applicable. Records of financial disclosures and any resulting action will be maintained by the University for at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 C.F.R. 75.361 for different situations. The University will retain records for each competitive segment as provided in the U.S. regulation.

## 17 **Enforcement, actions, sanctions: Failure to comply with this Rule**

Compliance with this *Rule: Financial Conflict of Interest for Research Conducted Under U.S. Public Health Services (PHS) Grants or Agreements* is a condition of employment and/or participation for all applicable Investigators. Therefore, such Investigators who fail to comply with this *Rule* are subject to discipline, including letters of reprimand, restriction on the use of funds, termination of employment, or

disqualification from further participation in any PHS/NIH-funded research, etc., as may be deemed appropriate.

## 18 Resolution of dispute

Apart from the steps identified in the *Institutional Rule: Conflict of Interest*, the additional consideration for research conducted under U.S. PHS grants or agreements must be applied as required. For Investigators involved in U.S. federal funding or funders that follow the Department of Health and Human Service's regulation, the resolution of the dispute will be dealt with as prescribed in 42 CFR Part 50 Subpart F.

## 19 Rule governance

### 19.1 Owner and Curator

19.1.1 The owner is the Senior Director: Research and Innovation. The Owner oversees the development of the *Rule* and consultation and recommendation to Council. The Owner is responsible for ensuring that the necessary supporting documents exist, that the Curator functions effectively; and appoints a task team for the periodic revision of the *Rule*, as required.

19.1.2 The Curator of the *Rule* is the Director: Research Contracts and Compliance. The Curator is responsible for the *Rule* formulation, approval, review, communication, training, availability and monitoring. The Curator of the *Rule* is also responsible for interpretation and guidance with respect to the implementation of the *Rule*. The Curator is assisted by Conflict of Interest advisors as and when appropriate.

19.1.3 The Owner of this *Rule*, in conjunction with and supported by the Curator, the conflict of interest advisor, and the ***Institutional U.S. FCOI Committee***, are responsible for managing and monitoring the implementation of this *Rule*. They will also deal with breaches of this *Rule* and decide on reporting instances of a possible or actual financial conflict of interest on a regular basis, and for reporting on an Institutional level.

### 19.2 Approval

19.2.1 This *Rule* will be approved by the Council.

## 20 Useful FCOI and NIH records

- FCOI Regulation 42 CFR Part 50 Subpart F – Promoting Objectivity in Research: <https://www.ecfr.gov/current/title-42/chapter-I/subchapter-D/part-50/subpart-F>
- Financial Conflict of Interest: <https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi>
- FCOI Training: <https://grants.nih.gov/policy-and-compliance/policy-topics/fcoi/fcoi-training>

- FCOI Frequently Asked Questions (FAQs): <https://grants.nih.gov/faqs#/financial-conflict-of-interest.htm?anchor=3875>
- Information for Foreign Grants: <https://grants.nih.gov/new-to-nih/information-for/foreign-grants>
- NIH's Welcome Wagon letter at NIH 'WELCOME WAGON' LETTER Information for New Recipient Organizations: <https://grants.nih.gov/policy-and-compliance/welcome-wagon>

## 21 Point of Contact

If you have any questions related to this Rule, you can contact Dr. Cornelia Malherbe ([cvdm2@sun.ac.za](mailto:cvdm2@sun.ac.za)) or Ms Naseema Sonday ([naseema@sun.ac.za](mailto:naseema@sun.ac.za)).

## 22 Supporting documentation

This section might be updated from time to time to include any relevant and the latest supporting documentation related to U.S. Public Health Services (PHS) Grants or Agreements relevant to Financial Conflict of Interest. This *Rule: Financial Conflicts of Interest in Research Conducted Under U.S. Public Health Services (PHS) Grants or Agreements* is supported by the annexure provided below:

Annexure A	Financial Conflict of Interest Disclosure Form applicable to U.S. federally funded research subject to 42 CFR Part 5, Subpart F and subsequent amendments, and also applies to subrecipients who do not have their own compliant FCOI Policy.
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## Annexure A: Disclosure Form and Considerations

### First Step:

Investigator must determine their institutional responsibilities:

- For Stellenbosch University Investigators, please complete Stellenbosch University in all the sections where the Name of the Applicant and/or Recipient Institution is required.
- For Subrecipients using this disclosure form, please complete your institution's name in all the sections where the Name of the Applicant and/or Recipient Institution is required.

The Investigator must determine the responsibilities they perform on behalf of (*Name of Applicant and/or Recipient Institution*) (e.g., activities such as research, research consultation, teaching, professional practice, institutional committee membership, and service on panels such as Institutional Review Boards or Data Safety and Monitoring Boards).

### Second Step:

Investigator must determine all domestic and foreign Significant Financial Interests (SFI) related to their institutional responsibilities received from or held in entities *outside* the applicant and/or recipient institution:

The Investigator must disclose all SFIs (including those of the Investigator's spouse and dependent children) *that are related to the Investigator's institutional responsibilities* per the categories and the dollar thresholds indicated within the definition of SFI and as provided below.

**Note: SFI "exclusions" – Investigators are **not** required to disclose these Financial interests:**

- Salary, royalties, or other remuneration paid by the Institution (i.e., *Name of Applicant and/or Recipient Institution*) to the Investigator if the Investigator is currently employed or otherwise appointed by the (i.e., *Name of Applicant and/or Recipient Institution*), including intellectual property rights assigned to the Institution (i.e., *Name of Applicant and/or Recipient Institution*) and agreements to share in royalties related to such rights;
- any ownership interest in the Institution (i.e., *Name of Applicant and/or Recipient Institution*) held by the Investigator, if the Institution (i.e., *Name of Applicant and/or Recipient Institution*) is a commercial or for-profit organisation;
- 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 *located in the United States*, a *United States* Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a *United States* Institution of higher education; or
- income from service on advisory committees or review panels for a federal, state, or local government agency *located in the United States*, a *United States* Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a *United States* Institution of higher education.

## Disclosure Form

Disclosing Investigator's Name: \_\_\_\_\_

Principal Investigator's Name (if different from Investigator): \_\_\_\_\_

Grant Application or Funded NIH Grant Number(s): \_\_\_\_\_

Project Dates: \_\_\_\_\_

Project Title(s): \_\_\_\_\_

Name of funder (e.g., National Institutes of Health): \_\_\_\_\_

Definitions	
Remuneration	includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship).
Intellectual property rights and interests (e.g., patents, copyrights)	upon receipt of income related to such rights and interests (e.g., royalties) not from the recipient Institution
Equity interest	includes any stock, stock options, or other ownership interest as determined through reference to public prices or other reasonable measures of market value.

Disclose all domestic and foreign Significant Financial Interests (SFI) (including those of your spouse and dependent children) **that are related to the Investigator's institutional responsibilities** per the categories and dollar thresholds provided below:

**SFIs RELATED TO A PUBLICLY TRADED ENTITY** – Disclose any *remuneration* (e.g., salary and any payment for services, consulting fees, honoraria, paid authorship) received over the preceding 12 months and any *equity interest* held in a publicly traded entity as of the date of disclosure, that when aggregated, exceeds \$5,000 that is related to your *institutional responsibilities* performed on behalf of the (INSERT NAME OF APPLICANT AND/OR RECIPIENT INSTITUTION).

*NOTE: The threshold for disclosure is a value greater than \$5,000 for remuneration and equity interest that is related to the Investigator's institutional responsibilities.*

**As part of the disclosure, provide the following information for each entity in which an SFI is identified:**

- The Value of SFI: \_\_\_\_\_
- Entity Name as it appears on the entity's public website: \_\_\_\_\_
- Nature of the SFI (e.g., salary, consulting fees, honorarium, paid authorship, payment for services, equity interest): \_\_\_\_\_

*Although this is an institutional determination, in your opinion:*

- *could the SFI be affected by the NIH-funded research? YES\_\_\_\_\_ No\_\_\_\_\_ Or;*
- *is the SFI in an entity whose financial interest could be affected by the NIH-funded research? Yes\_\_\_ No\_\_\_\_\_*

**SFI RELATED TO A NON-PUBLICLY TRADED ENTITY** – Disclose any *remuneration* received over the preceding 12 months that exceeds \$5,000 and any *equity interest* held in a non-publicly traded entity as of the date of disclosure that is related to your *institutional responsibilities* performed on behalf of the (INSERT NAME OF APPLICANT AND/OR RECIPIENT INSTITUTION).

*NOTE: A \$5,000 threshold for remuneration and a \$0 threshold for equity interest that is related to the Investigator's institutional responsibilities.*

**As part of the disclosure, provide the following information for each entity in which an SFI is identified:**

- The Value of SFI:\_\_\_\_\_
- Entity Name as it appears on the entity's public website:\_\_\_\_\_
- Nature of the SFI (e.g., salary, consulting fees, honorarium, paid authorship, payment for services, equity interest):\_\_\_\_\_

*Although this is an institutional determination, in your opinion:*

- *could the SFI be affected by the NIH-funded research? YES\_\_\_\_\_ No\_\_\_\_\_ Or;*
- *is the SFI in an entity whose financial interest could be affected by the NIH-funded research? Yes\_\_\_\_\_ No\_\_\_\_\_*

**SFI RELATED TO IP RIGHTS AND INTERESTS** – Disclose any income received regarding **intellectual property rights and interests** (e.g., patents, copyrights), upon the receipt of income *greater than \$5,000* over the preceding 12 months that is related to such rights and interests and related to your *institutional responsibilities* performed on behalf of the (INSERT NAME OF APPLICANT AND/OR RECIPIENT INSTITUTION).

**NOTE:** Disclosure does not include income related to IP rights assigned to the (*Name of applicant and/or recipient Institution*) and agreements to share in royalties related to such rights as noted above.

**As part of the disclosure, provide the following information for each entity in which an SFI is identified:**

- The Value of SFI:\_\_\_\_\_
- Entity Name as it appears on the entity's public website:\_\_\_\_\_
- Nature of the SFI (e.g. royalties, licensing fees):\_\_\_\_\_

*Although this is an institutional determination, in your opinion:*

- *could the SFI be affected by the NIH-funded research? YES\_\_\_\_\_ No\_\_\_\_\_ Or;*
- *is the SFI in an entity whose financial interest could be affected by the NIH-funded research? Yes\_\_\_\_\_ No\_\_\_\_\_*

**SFI RELATED TO REIMBURSED OR SPONSORED TRAVEL** - Disclose any reimbursed or sponsored travel received from an entity that exceeds \$5,000 over the preceding 12 months that is related to your ***institutional responsibilities*** performed on behalf of the (INSERT NAME OF APPLICANT AND/OR RECIPIENT INSTITUTION).

**Note:** You are not required to disclose reimbursed or sponsored travel that is received from a federal, state, or local government agency located in the United States or a United States Institution of Higher Education, an academic teaching hospital, a medical center, or a research institute that is affiliated with a U.S. Institution of higher education.



**As part of the travel disclosure, provide the following information for each entity in which reimbursed or sponsored travel is identified:**

- Value of the reimbursed or sponsored travel \_\_\_\_\_
- Purpose of the trip:\_\_\_\_\_
- Identity of the sponsor/organizer:\_\_\_\_\_
- Destination:\_\_\_\_\_
- Duration:\_\_\_\_\_

*Although this is an institutional determination, in your opinion:*

- *could the SFI be affected by the NIH-funded research? YES\_\_\_\_\_ No\_\_\_\_\_ Or;*
- *is the SFI in an entity whose financial interest could be affected by the NIH-funded research? Yes\_\_\_\_\_ No\_\_\_\_\_*