

**Financial Conflict of Interest
Disclosure, Review, and Management Procedures**

I. Financial Conflict of Interest Disclosures

A. Mandatory Investigator Disclosures

- i Significant Financial Interest Disclosure for PHS, NSF, and All Other Proposal Submissions:

Investigators, faculty, staff, administrators, and other individuals shall complete and submit to the Office of Grants and Sponsored Research (OGSR) an electronic early notification form for each proposal submission. On the early notification form, investigators, faculty, staff, administrators, and other individuals should disclose any **significant financial interest** (SFI) by completing the significant financial interest disclosure form (see Appendix A) which should be reviewed by the Dean.

The Designated Compliance Officer (DCO) will review each SFI disclosure form for SFI disclosures. If no SFI is disclosed, no further review is required and no additional action will be required unless the proposal is awarded, and/or a significant change occurs prior to the next annual completion and submission of the SFI disclosure form.

If a SFI is disclosed at the time of proposal notification, the DCO will determine if the Significant Financial Interest identified in the disclosure is related to the Investigator's PHS and/or NSF sponsored research. If the SFI is related to the Investigator's PHS and/or NSF or other sponsored Research, the DCO will refer the disclosure to the Sponsored Projects Integrity Officer (SPIO), copying the Sponsored Research Compliance Committee (SRC).

- ii. Annual Significant Financial Interest Disclosure:

The investigator, faculty, staff, administrator, or other individual involved in the implementation and/or management of a current grant award must complete an annual SFI disclosure form (see Appendix B) each year of the grant term for an awarded grant. This form must be completed and returned to the Compliance Administrator (CA) on or before October 1st annually, within 30 days of acquiring a new SFI (e.g., through purchase, marriage, or inheritance), and/or within 60 days of appointment. The investigator, faculty, staff, administrator, or other individual shall disclose all SFIs held by themselves their spouse, and/or their dependent children.

Upon receipt of each annual or updated disclosure form, the CA will ensure all required information and signatures are on the form then forward the form to the DCO. The DCO will review the form for SFI disclosures. If no SFI are disclosed, no further review is required and no additional action will be required unless a change in status occurs prior to the next annual disclosure date. If a change of status occurs prior to the next annual disclosure date, the investigator, faculty, staff, administrator, or other individual must complete the update disclosure

form and email to the CA who will then forward to the DCO for review. The DCO will review the update financial disclosure form for SFI disclosure (see subsection iv). If no SFI are disclosed, no further review is required and no additional action will be required.

The disclosure form will be retained by the CA in the central repository for all initial and annual SFI disclosure forms. If a SFI is disclosed on the annual SFI disclosure form and/or an updated SFI disclosure form, the DCO will determine if the Significant Financial Interest identified in the disclosure is related to the investigator, faculty, staff, administrator or other individual's PHS, NSF, and/or other sponsored research. If the SFI is related to the investigator's PHS and/or NSF sponsored research, the DCO will refer the disclosure to the SPIO and copy the SRC.

iii. Human and/or Animal Subjects:

Investigators, faculty, staff, administrators, and other individuals submitting a human and/or animal subjects protocol for Institutional Review Board (IRB) and/or Institutional Animal Care and Use Committee (IACUC) review must submit an annual SFI disclosure form (see Appendix A) prior to IRB and/or IACUC review on a PHS, NSF, and/or other sponsor funded research project. Any disclosure of SFI should be reported to the DCO.

iv. Change in Significant Financial Interest Status:

Should the investigator, faculty, staff, administrator, or other individual and/or their spouse, and/or their dependent children acquire a SFI (e.g., through purchase, marriage, or inheritance) after the submission of the annual SFI disclosure form to the CA, they shall report same within 30 days by the filing of an updated annual SFI disclosure form, which should be forwarded to the CA.

v. Maintenance of Records.

The CA shall maintain records of all financial disclosures and all actions taken to resolve actual or potential FCIs for 3 years after the later of the termination of the PSH, NSF, or other sponsored contract, completion of the research to which such contracts relate, or the resolution of any government action involving the records.

II. Review and Management of SFI associated with a PHS/NSF or Other award

A. Management of Financial Conflict of Interest

Should a SFI related to an investigator, faculty, staff, administrator, or other individual's research be disclosed, the DCO shall, within sixty (60) days of being notified of the SFI, determine if the SFI is related to the investigator's PHS, NSF, and/or other sponsored research. If so, the DCO shall, within thirty (30) days after identifying the SFI refer the disclosure to the SPIO, copying the SRC for review and management.

The DCO will gather further information and supporting documentation from the investigator, faculty, staff, administrator, or other individual and refer the SFI disclosure to the SPIO. If the SPIO determines that the allegation of a FCOI warrants additional inquiries and investigation, he/she will refer the matter to the SRC for review and management. All such documentation and subsequent discussions will be confidential to the extent permitted by applicable law.

The SRC will be comprised of seven voting members (three invited faculty members and one representative from each of the following offices appointed by their respective Vice Presidents; General Counsel, Human Resources, Student Affairs, and a Dean in Academic Affairs) and one nonvoting member (the DCO). The investigator, faculty, staff, administrator, or other individual will have the opportunity to meet with the SRC to discuss the SFI disclosure. Should the SRC find a FCOI, the SRC will recommend action to the Deciding Official (DO), copying the SPIO to effectively manage, reduce, or eliminate the conflict.

Examples of conditions or restrictions that the SRC may impose to manage a FCOI include, but are not limited to:

- Public disclosure of SFI (including but not limited to, when presenting or publishing the results of the research; to staff members working on the project; to College's IRB);
- Disclosure of SFI directly to participants for research projects involving human subjects in research;
- Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the FCOI;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualifications of personnel from participation in the portion of the research that would be affected by the SFI;
- Divestiture of the SFI (including but not limited to, sale of the equity interest and/or stock, withdrawal from a partnership, withdrawal as a member of a limited liability company); or
- Severance of relationships that create actual or potential financial conflicts of interest.

The DO will make the final determination on allegations of conflicts of interest and/or scientific misconduct brought forth and any responsive College actions and notify the SRC, copying the SPIO and DCO of his/her decision. The DCO will notify the investigator, faculty, staff, administrator, or other individual of the DO's decision.

B. Appeal Process

Should the investigator, faculty, staff, administrator, or other individual not agree with the DO's conditions or restrictions, the investigator, faculty, staff, administrator, or other individual can appeal in writing to the DO within ten (10) days after receipt of notification from the DCO, spelling out why such conditions and restrictions are inappropriate. The DO will then consult with the SRC and the SPIO to determine whether a modification of

the conditions and restrictions will be feasible. However, the decision on the appeal by the DO is final.

C. Non-Compliance and Retrospective Review

A FCOI may not be identified or managed in a timely manner due to:

1. Failure of the investigator, faculty, staff, administrator, or other individual to disclose a SFI that is determined to constitute a FCOI;
2. Failure by TCNJ to review or manage a FCOI; and/or
3. Failure by the investigator, faculty, staff, administrator, or other individual to comply with the FCOI unit policy.

D. Management Plan for the Non-Compliance of a Financial Conflict of Interest

In the event of non-compliance, the SPIO and SRC shall, within 120 days of its determination of non-compliance with this policy, complete a retrospective review of the investigator, faculty, staff, administrator, or other individual's activities for the external sponsor funded research project to determine whether the research, or portion thereof, conducted during the time period of non-compliance was biased in the design, conduct, or reporting of such research.

If bias is found, the SPIO and SRC should follow the protocol as stipulated in Section II A of the FCOI procedure. Within 30 days after completing the retrospective review and receiving the final determination from the DO, the DCO shall promptly notify PHS and/or NSF of the findings of the SRC and submit a mitigation report that includes key elements of the retrospective review, a description of the impact of the bias on the research, and TCNJ's plan to impose conditions or restrictions that will eliminate or mitigate the effects of the bias. Thereafter the College's DCO will submit FCOI reports annually to PHS and/or NSF for the investigator, faculty, staff, administrator, or other individual found to be in non-compliance (see section III C of the FCOI procedures).

III. Institutional Compliance and Reporting

A. Prior to Award

Prior to the expenditure of any funds awarded by PHS, NSF, and/or another external sponsor, the College's DCO must report to the NIH the existence of any FCOI and, if needed, ensure that the FCOI has been managed, reduced, or eliminated in accordance with all applicable regulations. The DCO shall also provide a FCOI report to PHS and/or NSF if it is discovered that the Investigator has not timely disclosed a SFI or if the institution failed to determine that a FCOI existed.

B. Ongoing Projects

For research projects that have already commenced and are ongoing, the DCO shall submit a FCOI report to the NIH within sixty (60) days after it determines that a FCOI exists.

C. Annual Financial Conflict of Interest Report

For any FCOI previously reported by the College, the DCO shall provide an annual FCOI report that includes the status of the SFI and any changes to the College's plan to manage it. Annual FCOI reports shall identify whether the FCOI is being managed or provide an explanation of why the FCOI no longer exists. Annual FCOI reports must be submitted to the PHS and/or NSF for the duration of the grant contract term or performance of the research, whichever is later, on the date when the College is required to submit its annual progress report (i.e., two months prior to the start date or 45 days prior to the start date of the noncompeting continuation award), including a multi-year funded progress report, or at the time of the extension (e.g., submission of an extension notification in the NIH eRA Commons or submission of a PHS and/or NSF prior approval request, whichever is applicable.) When a FCOI ceases to exist during the ongoing project period, the DCO shall update the status of the FCOI at the time of the next annual FCOI report submission deadline.

D. Subrecipients

Prior to submission of a proposal to PHS, NSF, and/or another sponsor, or the issuance of a subaward agreement, the College shall ensure that the proposed recipient of any subaward distributed from a PHS and/or NSF sponsored research agrees to comply with PHS and/or NSF policies on FCOI. If the proposed subrecipient does not have a publicly posted FCOI Policy in compliance with PHS and/or NSF policy, the subrecipient will be required to comply with the College's Financial Conflict of Interest policy.

Subrecipients will be required to report FCOI to the College's CA within 45 days of discovering the FCOI. Should a sub-awardee investigator, faculty, staff, administrator, or other individual report a FCOI, the College's DCO will report the FCOI to the PHS and/or NSF on the subrecipient's behalf.

IV. Training Requirements

Investigators, faculty, staff, administrators, and other individuals shall attend financial conflict of interest training offered by the College prior to engaging in research funded by PHS, and again thereafter at least every four years. In addition, Investigators shall undergo training offered by the College immediately under the following circumstances:

1. College financial conflict of interest policies change in a manner that affects investigator, faculty, staff, administrator, and other individual requirements;
2. An investigator, faculty, staff, administrator, other individual was recently hired by the College and has received PHS funding; or,
3. The College determines the investigator, faculty, staff, administrator, or other individual has failed to comply with this policy, and/or any condition or restriction imposed due to the presence of a financial conflict of interest.

The College of New Jersey will provide access to FCOI training (<https://www.citiprogram.org/>) for personnel identified on PHS funded research. College employees who are conducting NSF and/or other sponsored research are not

required to complete the training, but are encouraged to do so since the PHS revised requirements are very similar to current NSF requirements.

V. Public Accessibility to Financial Conflict of Interest information

A. Written Response to Requests

In the event of a public request for information on a FCOI, in compliance with PHS Policy, prior to the expenditure of any funds under a PHS-funded Research project, College counsel will make reasonable efforts to provide accessibility by written response within five business days of a request.

VI. Federal References

A. OMB Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR Part 200)

- 2 CFR 200.112
- 2 CFR 200.317
- Office of Executive Councils, Chief Financial Officers Council: Counsel on Financial Assistance Report (COFAR)

B. U.S. Department of Health and Human Services (Including Public Health Service and National Institutes of Health)

- 42 CFR Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought
- National Institutes of Health Financial Conflict of Interest Page
- NIH Tutorial on Financial Conflict of Interest

C. National Science Foundation

- NSF "Investigator Financial Disclosure Policy"
- NSF "Frequently Asked Questions Concerning the DHHS Objectivity in Research Regulations and the NSF Investigator Financial Disclosure Policy"
- NSF Proposal and Award Policies and Procedures Guide, January 2011, Part II - Award & Administration Guide, Chapter IV, A. Conflict of Interest Policies
- NSF Proposal and Award Policies and Procedures Guide, January 2011, Part I - Grant Proposal Guide, Chapter II, C.1.e. Proposal Certifications