

Texas Woman's University University Regulation and Procedure

Regulation and Procedure Name: Financial Conflict of Interest in Research and Sponsored Projects

Regulation and Procedure Number: URP: 02.470

Policy Owner: Academic Affairs

POLICY STATEMENT

Proposed, awarded, or ongoing research conducted at TWU that is funded by the U.S. Public Health Service (“PHS”) and the National Science Foundation (“NSF”) shall not be biased by any significant financial interest of any investigator responsible for the design, conduct, or reporting of that research or activity. The purpose of this URP is to outline procedures to assure that proposals made to and sponsored projects supported by PHS, NSF, and other federal agencies as necessary comply with regulations, or other funding entities as necessary to maintain objectivity in research.

APPLICABILITY

This policy is applicable to TWU Faculty, Staff, and Students.

DEFINITIONS

1. “Designated Official” means the Designated Official, appointed by the Executive Vice President for Academic Affairs and Provost (“EVPAA/Provost”), serves as the TWU administrator who solicits and reviews disclosures of significant financial interests from each investigator who is planning to participate in, or is participating in, PHS or NSF-funded research. The Designated Official shall ensure that TWU meets its responsibilities under 42 CFR 50 and the most current NSF Grant Policy Manual. The Designated Official shall also establish and oversee procedures in accordance with this policy.
2. “Financial conflict of interest (FCOI)” means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of research funded by federal agencies designated in this URP.
3. “FCOI report” means the University’s report of a financial conflict of interest to a PHS funding agency.

4. “Financial interest” means anything of monetary value, whether or not the value is readily ascertainable.
5. “HHS” means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.
6. “Institutional responsibilities” means an investigator’s professional responsibilities on behalf of TWU, such as teaching, professional, scholarly, research, or creative activities, administrative duties, University, disciplinary, and/or community service, or any other activity for which an investigator is compensated by TWU.
7. “Investigator” means 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 or proposed for such funding by PHS or NSF. This may include co-investigators or a subrecipient PD/PI.
8. “Manage” means taking action to address a financial conflict of interest, which can include reducing or eliminating the financial conflict of interest to ensure, to the extent possible, that the design, conduct, and reporting of research will be free from bias.
9. “PD/PI” means a project director or principal Investigator of a PHS or NSF-funded research project; the PD/PI is included in the definitions of senior/key personnel and Investigator.
10. “PHS” means 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”).
11. “Research” means research is a systematic investigation designed to test hypotheses, evaluate programs, draw conclusions, or contribute to generalizable knowledge. Research is usually described in a formal protocol that sets forth objectives and a set of procedures designed to reach those objectives.
12. “Senior/key personnel” means the PD/PI and any other person identified as senior/key personnel in the grant application, progress report, or any other report submitted to the PHS or NSF agencies.

13. “Significant financial interest as defined by 42 CFR 50 (PHS)” means:

A financial interest consisting of one or more of the following interests of the investigator (and those of the investigator's spouse and dependent children) that reasonably appears to be related to the investigator's institutional responsibilities:

- a. With regard to any publicly traded entity, a significant financial interest 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. 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 significant financial interest exists if the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest); or
- c. Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.

Investigators on PHS-funded projects must also disclose the occurrence of any reimbursed or sponsored travel (i.e., that which is paid on behalf of the investigator and not reimbursed to the investigator so that the exact monetary value may not be readily available) related to their institutional responsibilities; provided, however, that this disclosure requirement does not apply to travel that is reimbursed or sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education.

REGULATION AND PROCEDURE

I. Procedure

- A. TWU investigators who apply for PHS or NSF funding of research projects or educational activities shall comply with the requirements of this URP. If such research or activities are carried out through a subrecipient (e.g., subcontractor or collaborator), TWU shall take reasonable steps to ensure

that subrecipient investigators are in compliance with this URP policy or a conflict of interest policy that satisfies the requirements of this URP.

- B. An investigator's significant financial interest is related to PHS or NSF-funded research when TWU, through its designated official, reasonably determines that the significant financial interest: could be affected by the PHS or NSF-funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest ("FCOI") exists when the University, through its designated official, reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS or NSF-funded research.
- C. TWU may involve the investigator in the designated official's determination of whether a significant financial interest is related to the PHS or NSF-funded research.
- D. TWU shall inform each investigator of TWU's URP on financial conflicts of interest, the investigator's responsibilities regarding disclosure of significant financial interests, and of applicable Federal regulations, and shall ensure that each investigator completes training regarding financial conflicts of interest prior to engaging in research related to any PHS-funded grant and at least every four years, and immediately when any of the following circumstances apply:
 - 1. TWU revises its financial conflict of interest policies or procedures in any manner that affects the requirements of investigators;
 - 2. An investigator is new to TWU; or
 - 3. TWU finds that an investigator is not in compliance with the financial conflict of interest URP or management plan.
- E. Pursuant to 42 CFR 50.604(c), TWU shall take reasonable steps to ensure that any subrecipient investigator complies with this URP as outlined in the TWU Financial Conflict of Interest Procedures.
- F. The EVPAA/Provost designates the Vice Provost for Research and Innovation and Dean of the Graduate School as the Designated Official. The Designated Official shall ensure that TWU meets its responsibilities under 42 CFR 50 and the NSF Grant Policy Manual V.510. The Designated Official shall review disclosures of significant financial interests and establish and oversee procedures in accordance with this policy.
- G. TWU shall take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient investigator as outlined in the TWU Financial Conflict of Interest Procedures and shall

provide initial and ongoing FCOI reports to the PHS as required pursuant to 42 CFR §50.605(a) and 42 CFR §50.605(b).

H. TWU shall certify, in each application for funding to PHS or NSF that the University:

1. Has in effect an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received;
2. Shall promote and enforce investigator compliance with the requirements of the TWU FCOI URP, including those pertaining to disclosure of significant financial interests;
3. Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS funding agency as required by 42 CFR 50 and the TWU FCOI URP;
4. Agrees to make information available, promptly upon request, to the PHS or NSF relating to any investigator disclosure of financial interests and TWU's review of, and response to, such disclosure, whether or not the disclosure resulted in the University's determination of a financial conflict of interest; and
5. Shall fully comply with the requirements of 42 CFR 50 as applicable.

I. The University shall maintain records relating to all investigator disclosures of financial interests and the review of, and response to, such disclosures (whether or not a disclosure resulted in the University's determination of a financial conflict of interest) and all related actions or retrospective reviews, if applicable, for at least three years from the date the final expenditures report is submitted to PHS or NSF, or, where applicable, from other dates specified in 45 CFR 74.53(b) and 92.42 (b) regarding retention and access requirements for records.

II. Investigator Responsibilities

- A. Each TWU investigator who plans to participate in PHS or NSF-funded research is required to disclose significant financial interests (and those of the investigator's spouse and dependent children) to the Designated Official no later than the time of application for funded research.
- B. TWU investigators who are participating in PHS or NSF-funded research are also required to submit an updated disclosure of significant financial interests upon receipt of the award and at least annually during the period of the award. Such disclosure shall include any information that was not

disclosed initially, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

- C. Each investigator who is participating in PHS or NSF-funded research is required to submit an updated disclosure of significant financial interests within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

III. Management of Financial Conflicts of Interest

- A. Prior to the expenditure of any funds under a PHS or NSF-funded research project, TWU's designated official shall review all investigator disclosures of significant financial interests; determine whether any significant financial interests relate to PHS or NSF-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest are listed in the TWU Financial Conflict of Interest Procedures.
- B. The TWU designated official shall, within 60 days of reviewing the disclosure of a significant financial interest by an investigator who is new to participating in an ongoing PHS or NSF-funded research project or an existing investigator discloses a new significant financial interest: determine whether it is related to PHS or NSF-funded research; determine whether a financial conflict of interest 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 financial conflict of interest. The designated official may determine that additional interim measures are necessary with regard to the investigator's participation in the PHS or NSF-funded research project between the date of disclosure and the completion of the University's review.
- C. If the designated official identifies a significant financial interest that was not disclosed timely by an investigator or, for whatever reason, was not previously reviewed by the University during an ongoing PHS or NSF-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official shall, within 60 days: review the significant financial interest; determine whether it is related to PHS or NSF-funded research; determine whether a financial conflict of interest 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 financial conflict of interest going forward;

IV. Noncompliance with FCOI URP and Retrospective Reviews

- A. If a financial conflict of interest is not identified or managed in a timely manner including failure by an investigator to disclose a significant financial interest that is determined to constitute a financial conflict of interest; failure by the University to review or manage such a financial conflict of interest; or failure by the investigator to comply with a financial conflict of interest management plan, the designated official shall, within 120 days of the University's determination of noncompliance, complete a retrospective review of the investigator's activities and the PHS-funded research project to determine whether any funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.
- B. TWU is required to document the retrospective review including elements pursuant to 42.CFR 50.605(a)(3)(ii)(B) and as detailed in the TWU Financial Conflict of Interest Procedures.
- C. TWU shall, based on the results of the retrospective review and if appropriate, 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, the University shall notify the PHS funding agency promptly and submit a mitigation report pursuant to 42 CFR 50.605(a)(3)(iii) and as detailed in the TWU Financial Conflict of Interest Procedures. Thereafter, TWU will submit FCOI reports as specified by this URP.
- D. The University may determine that additional interim measures are necessary with regard to the investigator's participation in the PHS-funded research project between the date that the financial conflict of interest or the investigator's noncompliance is determined and the completion of the retrospective review, depending on the nature of the financial conflict of interest.
- E. If TWU implements a management plan in conjunction with a retrospective review and mitigation report, the University shall monitor investigator compliance with the management plan on an ongoing basis until the completion of the PHS or NSF-funded research project.

V. Public Access

Prior to the expenditure of any funds under a PHS-funded research project, TWU shall ensure public accessibility, via a written response to any requestor within ten business days of a request, of information concerning any significant financial interest disclosed to the University that meets the following three criteria:

- A. The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart;

- B. TWU determines that the significant financial interest is related to the PHS funded research; and
- C. TWU determines that the significant financial interest is a financial conflict of interest.

The information that TWU makes available via a written response to any requestor within ten business days of a request shall 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 (dollar ranges are permissible: \$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.

D. TWU will note in its written response 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 University's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

E. Information concerning the significant financial interests of an individual subject to this URP shall remain available for responses to written requests for at least three years from the date that the information was most recently updated.

VI. Reporting of Financial Conflicts of Interest

As required by 42 CFR 50.605(b)(3) and as listed in the TWU Financial Conflict of Interest Procedures, FCOI reports required under this URP shall include elements containing sufficient information to enable the funding agency to understand the nature and extent of the financial conflict, and to assess the appropriateness of the University's management plan.

VII. Initial FCOI Reports to PHS - Report before funds expended

Prior to the expenditure of any funds under a PHS or NSF-funded research project, TWU shall provide to the funding agency an FCOI report regarding any investigator's significant financial interest found to be conflicting and ensure that the University has implemented a management plan in accordance with 42 CFR 50.605(b)(1). TWU shall not submit an FCOI report to the funding agency in cases in which a financial conflict of interest is eliminated prior to the expenditure of PHS awarded funds.

VIII. Subsequent FCOI Reports to PHS- subsequent to initial report (new investigator)

If TWU identifies a significant financial interest as conflicting subsequent to the initial FCOI report during an ongoing PHS-funded research project (e.g., upon the participation of an investigator who is new to the research project), TWU shall provide to the PHS funding agency, within 60 days, an FCOI report regarding the financial conflict of interest and ensure that the University has implemented a management plan in accordance with this URP.

IX. Mitigation Reports to PHS

If TWU has conducted a retrospective review due to a significant financial interest that was not disclosed timely by an investigator or, for whatever reason, was not previously reviewed or managed by TWU (e.g., was not timely reviewed or reported by a subrecipient), and has determined that PHS-funded research, or portions thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research, TWU shall submit a mitigation report to the PHS funding agency.

X. Annual Reports to PHS

TWU shall provide an annual FCOI report to PHS funding agencies for any financial conflict of interest previously reported by the University with regard to an ongoing PHS-funded research project. The report shall address the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. TWU shall provide annual FCOI reports to the PHS funding agency for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS funding agency.

XI. Reports to NSF

Per the NSF Grant Policy Manual V.510, TWU shall notify NSF's Office of the General Counsel if TWU finds that it is unable to satisfactorily manage a conflict of interest on an NSF-funded research project.

XII. Enforcement Mechanisms and Sanctions

TWU shall establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance with this URP as appropriate.

XIII. Studies Involving Drugs, Medical Devices, or Treatments

A. In any case in which the HHS determines that a PHS-funded project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment has been designed, conducted, or reported by a TWU investigator with a financial conflict of interest that was not managed or reported by the University as required by this URP, the University shall require the investigator involved:

1. To disclose the financial conflict of interest in each public presentation of the results of the research, and
2. To request an addendum to previously published presentations.

XIV. Remedies

A. TWU shall promptly notify the PHS funding agency of any corrective action taken or to be taken if the failure of an investigator to comply with this URP or if a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the PHS-funded research. Actions taken by the PHS funding agency may include directions to TWU on how to maintain appropriate objectivity in the funded research project. PHS may require TWU to enforce any applicable corrective actions prior to a PHS award or when the transfer of a PHS grant involves such an investigator.

B. Upon receipt of an inquiry from a PHS or NSF funding agency at any time during or after an award, TWU shall submit, or permit on site review of, all records pertinent to any investigator disclosure of financial interests and the University's review (including any retrospective review) of, and response to, such disclosure, regardless of whether the disclosure resulted in the determination of a financial conflict of interest.

C. TWU will comply with the imposition of special award conditions, suspension of funding, or other enforcement actions should the funding agency decide that a particular financial conflict of interest will bias the objectivity of the funded research to such an extent that further corrective action is needed or that TWU has not managed the financial conflict of interest in accordance with this URP.

XV. PHS/NSF Exclusions

A. Exclusions to significant financial interest as defined by 42 CFR 50 (PHS): 50.603 (3)

1. Salary royalties, or other remuneration paid by TWU to the investigator if the investigator is currently employed or otherwise appointed by TWU;
2. Intellectual Property Rights assigned to TWU and agreements to share in royalties related to such rights;
3. 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;
4. Income from seminars, lectures, or teaching engagements sponsored by a federal, state or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education; or
5. Income from service on advisory committees or review panels for a federal, state, or local government agency, Institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an Institution of higher education.

B. Significant financial interest as defined by NSF Grant Policy Manual V.510:

Anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interest (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

C. Exclusions to significant financial interest as defined by NSF Grant Policy Manual V.510:

1. Salary, royalties, or other remuneration from the University;
2. Any ownership interests in the University, if TWU is an applicant under the Small Business Innovation Research Program or Small Business Technology Transfer Program;
3. Income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities;
4. Income from service on advisory committees or review panels for public or nonprofit entities;
5. An equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, meets both of the following tests: does not exceed \$10,000 in value as determined

through reference to public prices or other reasonable measures of fair market value, and does not represent more than a 5% ownership interest in any single entity; or

6. Salary, royalties, or other payments that, when aggregated for the investigator and the investigator's spouse and dependent children, are not expected to exceed \$10,000 during the 12 month period.

REVIEW

This policy will remain in effect and published until it is reviewed, updated, or archived. This policy is to be reviewed once every six years. Interim review may be required as a result of updates to federal and state law or regulations, Board of Regents policies, or internal processes or procedures.

REFERENCES

None

FORMS AND TOOLS

None

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