

## **Texas Woman's University Financial Conflict of Interest Procedures**

The following procedures for ensuring that proposed, awarded, or ongoing TWU research projects or educational activities shall not be biased by any significant financial interest of any investigator responsible for the design, conduct, or reporting of that research or activity. These procedures apply to proposals made to and sponsored projects supported by the U.S. Public Health Service (PHS), the National Science Foundation (NSF), other agencies as necessary to comply with regulations or as necessary to maintain objectivity in research. These procedures meet the requirements set forth by the PHS regulations on Promoting Objectivity in Research (effective August 25, 2012) codified at 42 Code of Federal Regulations Part 50 (42 CFR 50), Subpart F and the NSF Grant Policy Manual V.510.

The ORSP shall update the TWU Financial Conflict of Interest (FCOI) Policy and Procedures and all associated documents and forms as necessary to comply with applicable regulations. The FCOI Policy and Procedures shall be available on the TWU website.

### **Definitions**

**Designated Official:** The Designated Official, appointed by the Executive Vice President for Academic Affairs and Provost, shall ensure that TWU meets its responsibilities under the TWU FCOI policy. The Designated Official serves as the TWU administrator who oversees the submission and review of disclosures of significant financial interests from each investigator who is planning to participate in, or is participating in, funded research governed by the TWU FCOI policy. The Designated Official shall also oversee the establishment and implementation of procedures related to FCOIs in accordance with the TWU FCOI policy.

**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

**Financial conflict of interest (FCOI):** A significant financial interest that could directly and significantly affect the design, conduct, or reporting of research funded by federal agencies designated in this policy.

**FCOI report:** The University's report of a financial conflict of interest to a PHS funding agency.

**Financial interest:** Anything of monetary value, whether or not the value is readily ascertainable.

**HHS:** The United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

**Institutional responsibilities:** 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.

**Investigator:** The project director (PD) or principal Investigator (PI) and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded or proposed for such funding by PHS or NSF. This may include co-investigators or a subrecipient PD or PI.

**Manage:** 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.

**PD/PI:** 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.

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

**Publicly Traded Entity:** A company issuing stocks, which are traded on the open market, either on a stock exchange or on the over-the-counter market.

**Non-Publicly Traded Entity:** A company owned either by non-governmental organizations or by a relatively small number of shareholders or company members which does not offer or trade its company stock (shares) to the general public on the stock market exchanges.

**Remuneration:** Includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship);

**Research:** A systematic investigation, study, or experiment designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. The term encompasses basic and applied research (e.g., a published article, book, or book chapter) and product development (e.g., a diagnostic test or drug).

**Senior/key personnel:** 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.

**Spouse and dependent children:** For purposes of disclosure, spouse and dependent children includes:

1. a spouse;
2. a dependent child or stepchild or other dependent, for purposes of determining federal income tax liability during the period covered by the disclosure; and
3. an unmarried adult who resides in the same household as the investigator and with whom the investigator is financially interdependent as evidenced, for example, by the maintenance of a joint bank account, mortgage, or investments.

If the investigator is in doubt about whether an individual is a covered family member, the investigator should resolve the doubt in favor of disclosure.

### **Agency Specific Definitions and Exclusions**

**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:

1. 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.
2. With regard to any non-publicly traded entity, a significant financial interest exists if:
  - a. the value of any remuneration received from the entity in the 12 months preceding the disclosure, when aggregated, exceeds \$5,000, **or**
  - b. 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**
3. Income related to Intellectual property rights and interests (e.g., patents, copyrights, royalties)
4. 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.

***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.

***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).

***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.

### **Designated Official**

The Vice Provost for Research and Innovation serves as the **Designated Official** appointed by the Executive Vice President for Academic Affairs and Provost. The Designated Official (or his/her designee) shall solicit and review the completed significant financial interest disclosure form from each investigator who is planning to participate in, or is participating in, PHS or NSF funded research. The Designated Official shall review SFI disclosures to ensure that TWU meets its responsibilities under 42 CFR 50 and the NSF Grant Policy Manual V.510. The Designated Official (or his/her designee) shall also establish and oversee procedures in accordance with this policy.

The Designated Official shall ensure that TWU certifies in each application for funding to PHS or NSF as required that the University:

- 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;
- Shall promote and enforce investigator compliance with the requirements of the TWU FCOI policy, including those pertaining to disclosure of significant financial interests;
- Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS funding agency as required by the TWU FCOI policy;
- 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;
- Shall fully comply with the requirements of 42 CFR 50 and the NSF Grant Policy Manual V.510.

The Designated Official is responsible for ensuring that investigators who are planning to participate in PHS or NSF funded research are notified of:

- The TWU FCOI policy and procedures and applicable Federal regulations
- Responsibilities of investigators responsible for the design, conduct, or reporting of research regarding disclosure of significant financial interests (SFIs).
- Required training for investigators with FCOIs prior to engaging in research related to any PHS or NSF funded grant, at least every four (4) years for the duration of the project, and immediately when any of the following circumstances apply:

- TWU revises its financial conflict of interest policies or procedures in any manner that affects the requirements of investigators;
- An Investigator is new to TWU; or
- ORSP finds that an Investigator is not in compliance with the financial conflict of interest policy or management plan.

The TWU Designated Official shall, within sixty days of receiving a 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;
- if necessary, 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
- determine if 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.

The Director of Operations (ORSP) shall receive, review, and manage all Part A Significant Financial Interest (SFI) Disclosure Forms. Disclosed SFIs shall be referred to the Designated Official who will review such disclosures using the following procedure:

The Designated Official shall review all disclosures of significant financial interests using the following procedure:

1. Determine if SFI exists as defined in the 42 CFR 50.603 definitions and the TWU FCOI policy.
2. Determine if any SFI is related to PHS funded research, i.e., the significant financial interest could be affected by the PHS-funded research or is in an entity whose financial interest could be affected by the research. The Designated Official may involve the investigator in the determination of whether a SFI is related to the PHS or NSF funded research
3. Determine if an FCOI exists, i.e., the significant financial interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research
4. If a FCOI exists, develop and implement a management plan in conjunction with the investigator that shall specify the actions that shall be taken to manage such FCOI. This management plan should be documented in writing and signed by the investigator.

### **Investigator Requirements**

- Disclosures must include financial interests of the investigator, the investigator's spouse and dependent children. The Designated Official shall ensure that SFI Disclosure forms are provided to investigators as necessary to comply with the TWU FCOI policy.
- **Proposal Process:** SFI Disclosure forms must be completed by each investigator who plans to participate in PHS or NSF funded research no later than the time of application for funding.
- **Funding Awarded:** Investigators who are participating in PHS or NSF funded research are required to submit an updated disclosure of significant financial interests at the time of the award and at least annually during the period of the award. The Designated Official (or his/her designee) shall notify

investigators of the update requirement and provide investigators with disclosure forms at least 30 days before the annual renewal date. Updated disclosures must include:

- Any information that was not disclosed initially, or in a subsequent disclosure of SFIs (e.g., any financial conflict of interest identified on a funded project that was transferred from another Institution)
- Updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).
- **New SFI:** Each Investigator who is participating in PHS or NSF funded research is required to notify the Designated Official and submit updated disclosure document(s) within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

### ***Review of Disclosure***

If an investigator discloses payments, intellectual property interests, or royalties, the investigator must permit review of any related agreement, contract, offer letter, or other documentation on request of:

1. the Executive Vice President for Academic Affairs and Provost,
2. any other person or entity with administrative responsibility in regard to reviewing financial interest disclosure statements or approving a related management plan.

### ***Management Plan***

If the Designated Official identifies a FCOI, the investigator must work with the Designated Official in the development of a management plan and shall agree, in writing, to comply with the plan.

### ***Required FCOI Training***

Investigators with SFIs must complete training on financial conflicts of interests prior to engaging in research related to any PHS funded grant.

- Training must be completed at least every four (4) years for the duration of the project, and immediately when any of the following circumstances apply:
  - TWU revises its financial conflict of interest policies or procedures in any manner that affects the requirements of investigators;
  - An Investigator is new to TWU; or
  - ORSP finds that an Investigator is not in compliance with the financial conflict of interest policy or management plan.
- The training program shall be specified by the Designated Official.
- The Designated Official shall ensure that investigators are notified of the need to complete training per the TWU FCOI policy and Federal regulations.

### **PHS Requirements Regarding Travel Reimbursement**

The Designated Official shall ensure that Investigators 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. 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 as defined at 20 U.S.C. 1001(a), an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. Investigators who have incurred travel expenses that meet the above criteria must include the following details on the SFI disclosure form:

- monetary value of the trip if known
- the purpose of the trip,
- the identity of the sponsor/organizer,
- the destination, and
- the duration of the trip.

The Designated Official will determine if further information is needed to determine if the travel constitutes an FCOI with the PHS funded research.

### **Monitoring and Managing Subrecipient FCOIs**

Pursuant to 42 CFR 50.604(c), TWU shall take reasonable steps to ensure that any subrecipient Investigator that carries out PHS or NSF funded research complies with the FCOI policy by:

- Incorporating as part of a subaward agreement terms that establish whether TWU's FCOI policy or that of the subrecipient will apply to the subrecipient's Investigators.
  - If the subrecipient's Investigators will comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the subaward agreement that its policy complies with 42 CFR 50 Subpart F and NSF Grant Policy Manual V.510.
  - If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to TWU's financial conflicts of interest policy for disclosing SFIs that are directly related to the subrecipient's work for TWU;
  - If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subaward agreement shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to TWU. Such time period(s) shall be sufficient to enable TWU to provide timely FCOI reports, as necessary, to the funding agency as required;
  - If the subrecipient's Investigators must comply with TWU's financial conflicts of interest policy, the subaward agreement shall specify time period(s) for the subrecipient to submit all Investigator disclosures of SFIs to TWU. Such time period(s) shall be sufficient to enable TWU to comply timely with its review, management, and reporting obligations under the FCOI policy.
- Providing FCOI reports to the funding agency regarding all financial conflicts of interest of all subrecipient Investigators prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.
- Development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report pursuant to §50.605(a) and the TWU FCOI policy.

## Management of Financial Conflicts of Interest

### ***Management Plan***

Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
- 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;
- Modification of the research plan;
- Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- Severance of relationships that create financial conflicts.

### ***Noncompliance with FCOI Policy: Retrospective Reviews and Mitigation Reports***

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 sixty 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;

If a financial conflict of interest is not identified or managed in a timely manner including failure by the 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 or NSF 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.

The retrospective review shall include the following elements pursuant to 42.CFR 50.605(a)(3)(ii)(B):

1. Project number;
2. Project title;
3. PD/PI or contact PD/PI if a multiple PD/PI model is used;
4. Name of the Investigator with the FCOI;
5. Name of the entity with which the Investigator has a financial conflict of interest;
6. Reason(s) for the retrospective review;
7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

8. Findings of the review; and
9. Conclusions of the review.

Based on the results of the retrospective review, if appropriate, TWU shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, TWU shall notify the PHS funding agency promptly and submit a *mitigation report* to the PHS funding agency. The *mitigation report* must include, at a minimum:

1. the key elements documented in the retrospective review as listed above;
2. a description of the impact of the bias on the research project; and
3. the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias, including but not limited to:
  - a. impact on the research project
  - b. the extent of harm done, including any qualitative and quantitative data to support any actual or future harm;
  - c. an analysis of whether the research project is salvageable

The Designated Official 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 Institution's retrospective review.

If a management plan is implemented in conjunction with a retrospective review and mitigation report, the Designated Official shall monitor investigator compliance with the management plan on an ongoing basis until the completion of the PHS or NSF funded research project.

### **Public Access**

The ORSP shall maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with applicable regulations, and shall make such policy available on the TWU website.

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 five (5) business days of a request, of information concerning any FCOIs of senior/key grant personnel identified by TWU that meets the following three criteria:

1. The significant financial interest was disclosed and is still held by the senior/key personnel as defined by this subpart;
2. The University determines that the significant financial interest is related to the PHS-funded research; and
3. The University determines that the significant financial interest is a financial conflict of interest.

The information that the University makes available via a written response to any requestor within five 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; and
4. the nature of the significant financial interest; and 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.

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 Institution's identification of a new FCOI, which should be requested subsequently by the requestor. Information concerning the FCOIs of an individual shall remain available for responses to written requests for at least three years from the date that the information was most recently updated.

### **FCOI Reporting**

As required by 42 CFR 50.605(b)(3), FCOI reports required under the TWU FCOI Policy shall include sufficient information to enable the funding agency to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. Elements of FCOI reports shall include, but are not necessarily limited to the following:

1. Project number;
2. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
3. Name of the Investigator with the financial conflict of interest;
4. Name of the entity with which the Investigator has a financial conflict of interest;
5. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
6. Value of the 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;
7. A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
8. A description of the key elements of the Institution's management plan, including:
  - a. Role and principal duties of the conflicted Investigator in the research project;
  - b. Conditions of the management plan;
  - c. How the management plan is designed to safeguard objectivity in the research project;
  - d. Confirmation of the Investigator's agreement to the xxx plan;
  - e. How the management plan will be monitored to ensure Investigator compliance; and
  - f. Other information as needed.

### ***Initial FCOI Reports to PHS – prior to expenditure of funds***

Prior to the expenditure of any funds under a PHS funded research project, TWU shall provide to the funding agency an FCOI report, in a manner specified by the agency, regarding any investigator's significant financial interest (including subrecipients) found to be conflicting and ensure that a management plan has

been implemented 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.

#### ***Subsequent FCOI Reports to PHS - new investigator or newly identified SFI***

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 funding agency, within sixty days, an FCOI report, in a manner specified by the agency, regarding the financial conflict of interest and ensure that the University has implemented a management plan.

#### ***Mitigation Report 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 funding agency in a manner specified by the agency.

#### ***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 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 funding agency for the duration of the project period (including extensions with or without funds) at the same time the annual progress report is due or in the time and manner specified by the PHS funding agency.

#### ***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.

### **Studies involving drugs, medical devices, or treatments**

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 policy, 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.

## **Administrative Actions to Ensure Investigator Compliance**

The Designated Official shall notify the Executive Vice President for Academic Affairs and Provost, investigator's Department Chair, Director, or Dean in the event that the investigator fails to comply with any of the requirement set forth in the TWU FCOI policy and procedures. TWU employs the following enforcement mechanisms / sanctions to ensure compliance with FCOI regulations:

- All required financial disclosure forms must be on file with ORSP prior to proposal submission. If requirements have not been met, proposal will not be submitted.
- All required information regarding financial disclosures and the review for financial conflict of interests must be completed prior to the expenditure of PHS funds. Investigators will not have access to grant funds until all requirement documentation is completed.
- If an investigator fails to disclose a significant financial interest in a timely manner, misrepresents any interests which may require disclosure under the TWU FCOI policy, or fails to follow a management plan for FCOI, the Designated Official, in conjunction with the Executive Vice President for Academic Affairs and Provost, Dean, Department Chair, and/or any other appropriate administrative office, will determine corrective action(s).

## **Remedies**

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

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. To the extent permitted by law, HHS will maintain the confidentiality of all records of financial interests.

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 policy.

## **Record Retention**

The TWU Designated Official shall oversee the maintenance of 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 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. All SFI Disclosure Forms that disclose significant financial interests will be kept in a locked file cabinet in the ORSP Director of Operation's office. All records pertaining to an identified FCOI will be stored in a separate locked file cabinet in the Designated Official's office.