

PROCEDURES FOR THE UNT CONFLICT OF INTEREST POLICY FOR SPONSORED PROJECTS

Procedure 1 – For Funded Projects and Applications for Funding from the U.S. Public Health Service (PHS), including the National Institutes of Health (NIH)

Definitions. For the purposes of this procedure, the definitions provided in UNT Policy 13.005, Conflict of Interest Policy for Sponsored Projects, shall apply in addition to the following definitions:

FCOI means a financial conflict of interest as defined in the UNT Conflict of Interest Policy for Sponsored Projects.

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

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.

Institutional responsibilities shall be defined in accordance with the definition provided in the UNT Conflict of Interest Policy for Sponsored Projects.

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

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).

PHS Awarding Component means the organizational unit of the PHS that funds the research.

Senior/key personnel means the Principal Investigator and any other person identified as senior/key personnel by UNT in the grant application, progress report, or any other report submitted to the PHS by UNT.

“SFI” means a Significant Financial Interest as defined in the UNT Conflict of Interest Policy for Sponsored Projects.

“UNT” means the University of North Texas.

Investigator Responsibilities Regarding Financial Conflicts of Interest

1. **Training.** Before engaging in research related to any PHS-funded grant and at least every four years, each Investigator will complete training about Investigator responsibilities under

PHS and UNT requirements relating to disclosure of Financial Conflicts of Interest. This training must also be completed immediately when any of the following circumstances apply:

- when UNT revises its Conflict of Interest Policy for Sponsored Projects or this procedure in any manner that affects the requirements of Investigators;
- when an Investigator is new to UNT; or
- when the UNT Office of Research and Innovation finds that an Investigator is not in compliance with UNT's Conflict of Interest Policy for Sponsored Projects or this procedure or a management plan.

2. Disclosure of Significant Financial Interests. When an Investigator submits a proposal for external funding to a PHS agency (for procedures related to funding entities other than the PHS, see http://research.unt.edu/sites/default/files/COI_Procedure_Non-PHS.pdf) the Investigator will complete and provide to the Research Integrity Officer a "Significant Financial Interest Disclosure" form (the "disclosure") either electronically or in paper form (see <http://research.unt.edu/faculty-resources/research-integrity-and-compliance/financial-conflict-interest>). In the disclosure the Investigator will indicate the general category of any Significant Financial Interests held by the Investigator, the Investigator's spouse, and the Investigator's dependent children that reasonably appears to be related to the Investigator's Institutional Responsibilities.

For any categories of Significant Financial Interests indicated on the disclosure, the Investigator will include supplemental documentation that identifies the entity involved, the nature and the amount of the interest, and how the SFI relates to the PHS funding applied for.

3. Updating Disclosures. The Investigator must update the disclosure on an annual basis while a proposal is pending or during the period of an award, and also within 30 days after the acquisition of any new SFI.

UNT Responsibilities Regarding Investigator Financial Conflicts of Interest

1. Informing Investigators. The Office of Research and Innovation will inform each Investigator of the UNT's Conflict of Interest Policy for Sponsored Projects and related procedures, the Investigator's responsibilities regarding disclosure of SFIs, and of the applicable regulations, and require each Investigator to complete training regarding the same 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:

- when UNT revises its Conflict of Interest Policy for Sponsored Projects or this procedure in any manner that affects the requirements of Investigators;

- when an Investigator is new to UNT; or
- when UNT finds that an Investigator is not in compliance with UNT's Conflict of Interest Policy for Sponsored Projects or this procedure or a management plan.

2. Procedures for Subrecipients. If UNT carries out the PHS-funded research through a subrecipient (e.g., a subcontractor, contractor or collaborator), the Office of Research and Innovation must take reasonable steps to ensure that any subrecipient Investigator complies with this subpart by:

(a) Incorporating as part of a written agreement with the subrecipient terms that establish whether the UNT Conflict of Interest Policy for Sponsored Projects and related procedures or that of the subrecipient will apply to the subrecipient's Investigators.

- If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient will certify as part of the agreement referenced above that its policy complies with the PHS requirements. If the subrecipient cannot provide such certification, the agreement will state that subrecipient Investigators are subject to the UNT Conflict of Interest Policy for Sponsored Projects and related procedures for disclosing significant financial interests that are directly related to the subrecipient's work for UNT;
- Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above will specify time period(s) for the subrecipient to report all identified financial conflicts of interest to UNT. Such time period(s) will be sufficient to enable UNT to provide timely FCOI reports, as necessary, to the PHS.
- Alternatively, if the subrecipient's Investigators must comply with the UNT Conflict of Interest Policy for Sponsored Projects and related procedures, the agreement referenced above will specify time period(s) for the subrecipient to submit all Investigator disclosures of SFIs to UNT. Such time period(s) will be sufficient to enable UNT to comply timely with its review, management, and reporting obligations under this sub-section of the procedures.

(b) Providing FCOI reports to the PHS Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with applicable regulations, *i.e.*, prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

3. Disclosure Process for Investigators. The Vice President for Research and Innovation will designate a Research Integrity Officer to solicit and review disclosures of SFIs

from each Investigator who is planning to participate in, or is participating in, the PHS-funded research.

The Research Integrity Officer will require that each Investigator who is planning to participate in the PHS-funded research disclose to the Research Integrity Officer the Investigator's SFIs (and those of the Investigator's spouse and dependent children) no later than the time of application for PHS-funded research.

Each Investigator who is participating in the PHS-funded research will submit an updated disclosure of SFIs to the Research Integrity Officer at least annually during the period of the award. Such disclosure will include any information that was not disclosed initially to the UNT Office of Research and Innovation or in a subsequent disclosure of SFIs (e.g., any FCOI identified on a PHS-funded project that was transferred from another Institution), and will include updated information regarding any previously disclosed SFI (e.g., the updated value of a previously disclosed equity interest).

Each Investigator who is participating in the PHS-funded research will submit an updated disclosure of SFIs to the Research Integrity Officer within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new SFI.

An Investigator's SFI is related to PHS-funded research when the UNT Office of Research and Innovation, through its Research Integrity Officer, reasonably determines that the SFI:

- could be affected by the PHS-funded research; or
- is in an entity whose financial interest could be affected by the research.

A FCOI exists when the UNT Office of Research and Innovation, through its Research Integrity Officer or its Conflict of Interest Review Committee (see Policy Number 16.12.3.3), reasonably determines that the SFI could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.

4. Management of Financial Conflicts of Interest. The Research Integrity Officer will take such actions as necessary to manage Financial Conflicts of Interest, including any financial conflicts of a subrecipient Investigator. Management of an identified FCOI requires development and implementation of a management plan and, if necessary, a retrospective review and a mitigation report as required by applicable federal regulations and UNT's Conflict of Interest Policy for Sponsored Projects.

5. Reporting to PHS. The Research Integrity Officer will provide initial and ongoing FCOI reports to the PHS as required by applicable regulations.

8. Certification in Funding Applications. The UNT Office for Research and Innovation will certify, in each application for PHS funding to which this procedure applies, that UNT:

- 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 from the PHS;
- Will promote and enforce Investigator compliance with this procedure's requirements, including those pertaining to disclosure of SFIs;
- Will manage financial conflicts of interest and provide initial and ongoing FCOI reports to the PHS Awarding Component consistent with PHS requirements;
- Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and UNT's review of, and response to, such disclosure, whether or not the disclosure resulted in the UNT's determination of a FCOI; and
- Will fully comply with the requirements of UNT's Conflict of Interest Policy for Sponsored Projects and this procedure and any PHS requirements related to SFIs and FCOIs.

9. Management of Financial Conflicts of Interest. Prior to UNT's expenditure of any funds under a PHS-funded research project, the Research Integrity Officer will review all Investigator disclosures of SFIs; determine whether any SFIs relate to PHS-funded research; determine whether a FCOI exists; and, if so, develop and implement a management plan that will specify the actions that have been, and will be, taken to manage such FCOI. The Research Integrity Officer at his or her discretion may refer an Investigator disclosure to the Conflict of Interest Review Committee (see Policy Number 16.12.3.3) to determine whether a FCOI exists. Examples of conditions or restrictions that might be imposed to manage a FCOI include, but are not limited to:

- (i) Public disclosure of FCOIs (e.g., when presenting or publishing the research);
- (ii) For research projects involving human subjects research, disclosure of Financial Conflicts of Interest directly to participants;
- (iii) 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;
- (iv) Modification of the research plan;
- (v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

- (vi) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- (vii) Severance of relationships that create financial conflicts.

10. New Investigator or New SFI. Whenever in the course of an ongoing PHS-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 to the UNT Office of Research and Innovation, the Research Integrity Officer will, within 60 days: review the disclosure of the SFI; determine whether it is related to PHS-funded research; determine whether a FCOI exists or refer the disclosure to Conflict of Interest Review Committee for such a determination; and, if a FCOI exists, implement, on at least an interim basis, a management plan that will specify the actions that have been, and will be, taken to manage such FCOI. Depending on the nature of the SFI, the Research Integrity Officer may determine that additional interim measures are necessary with regard to the Investigator's participation in the PHS-funded research project between the date of disclosure and the completion of review by the UNT Office of Research and Innovation.

11. SFI Not Disclosed or Reviewed. Whenever UNT identifies a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by UNT during an ongoing PHS-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the Research Integrity Officer will, within sixty days: review the SFI; determine whether it is related to PHS-funded research; determine whether a FCOI exists or refer the disclosure to the Conflict of Interest Review Committee for such a determination; and, if so:

(i) 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;

(ii)(A) In addition, whenever a FCOI is not identified or managed in a timely manner including failure by the Investigator to disclose a SFI that is determined by UNT to constitute a FCOI; failure by UNT to review or manage such a FCOI; or failure by the Investigator to comply with a FCOI Management plan, the Research Integrity Officer will, within 120 days of UNT's determination of noncompliance, complete a retrospective review of the Investigator's activities and the PHS-funded research project to determine whether any PHS-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 Research Integrity Officer is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

- (1) Project number;

- (2) Project title;
- (3) Principal Investigator;
- (4) Name of the Investigator with the FCOI;
- (5) Name of the entity with which the Investigator has a FCOI;
- (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.

(iii) Based on the results of the retrospective review, if appropriate, the Research Integrity Officer will update the previously submitted FCOI report, specifying the actions that will be taken to manage the FCOI going forward. If bias is found, the Research Integrity Officer will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and UNT's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Research Integrity Officer will submit FCOI reports annually, as specified elsewhere in this procedure. Depending on the nature of the FCOI, the Research Integrity Officer 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 FCOI or the Investigator's noncompliance is determined and the completion of the Research Integrity Officer's retrospective review.

Whenever the Conflict of Interest Review Committee implements a management plan pursuant to this subsection, the UNT Office of Research and Innovation will monitor Investigator compliance with the management plan on an ongoing basis until the completion of the PHS-funded research project.

12. Public Accessibility. Prior to UNT's expenditure of any funds under a PHS-funded research project, the UNT Office of Research and Innovation will ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days

of a request, of information concerning any SFI disclosed to UNT that meets the following three criteria:

- The SFI was disclosed and is still held by the senior/key personnel as defined by this procedure;
- UNT has determined that the SFI is related to the PHS-funded research; and
- UNT has determined that the SFI is a FCOI.

The information that the UNT Office of Research and Innovation makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, will include, at a minimum, the following: the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the SFI is held; the nature of the SFI; and the approximate dollar value of the SFI (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.

If UNT uses a publicly accessible Web site for the purposes of this requirement, the information that UNT posts will be updated at least annually. In addition, the UNT Office of Research and Innovation will update the Web site within sixty days of UNT's receipt or identification of information concerning any additional SFI of the senior/key personnel for the PHS-funded research project that was not previously disclosed, or upon the disclosure of a SFI of senior/key personnel new to the PHS-funded research project, if UNT determines that the SFI is related to the PHS-funded research and is a FCOI. The Web site will note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of UNT's identification of a new FCOI. If UNT responds to written requests for the purposes of this subsection, UNT 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 UNT's identification of a new FCOI, which should be requested subsequently by the requestor.

Information concerning the SFIs of an individual subject to this subsection will remain available, for responses to written requests or for posting via UNT's publicly accessible Web site for at least three years from the date that the information was most recently updated.

13. Reporting of Financial Conflicts of Interest to PHS. Prior to UNT's expenditure of any funds under a PHS-funded research project, the Research Integrity Officer will provide to the PHS Awarding Component an FCOI report regarding any Investigator's SFI found by UNT to be conflicting and ensure that UNT has implemented a conflict management plan. In cases in which the Research Integrity Officer

or the Conflict of Interest Review Committee identifies a FCOI and eliminates it prior to the expenditure of PHS-awarded funds, the Research Integrity Officer will not submit an FCOI report to the PHS Awarding Component.

For any Significant Financial Interest that UNT identifies as conflicting subsequent to the Research Integrity Officer's 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), the Research Integrity Officer will provide to the PHS Awarding Component, within 60 days, an FCOI report regarding the FCOI and ensure that UNT has implemented a conflict management plan. Where such FCOI report involves a SFI that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by UNT (e.g., was not timely reviewed or reported by a subrecipient), the Research Integrity Officer will complete a retrospective review to determine whether any PHS-funded research, or portion thereof, conducted prior to the identification and management of the FCOI was biased in the design, conduct, or reporting of such research. If bias is found, the Research Integrity Officer will notify the PHS Awarding Component promptly and submit a mitigation report to the PHS Awarding Component.

Any FCOI report required in either of the above situations will include sufficient information to enable the PHS Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of UNT's management plan. At a minimum, elements of the FCOI report shall include:

- (i) Project number;
- (ii) Principal Investigator;
- (iii) Name of the Investigator with the FCOI;
- (iv) Name of the entity with which the Investigator has a FCOI;
- (v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
- (vi) 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;

(vii) A description of how the financial interest relates to the PHS-funded research and the basis for UNT's determination that the financial interest conflicts with such research; and

(viii) A description of the key elements of UNT'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 management plan;

(E) How the management plan will be monitored to ensure Investigator compliance; and

(F) Other information as needed.

For any FCOI previously reported by UNT with regard to an ongoing PHS-funded research project, the Research Integrity Officer will provide to the PHS Awarding Component an annual FCOI report that addresses the status of the FCOI and any changes to the management plan for the duration of the PHS-funded research project. The annual FCOI report will specify whether the financial conflict is still being managed or explain why the FCOI no longer exists. The Research Integrity Officer will provide annual FCOI reports to the PHS Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the PHS Awarding Component.

14. Remedies. If the failure of an Investigator to comply with UNT's Conflict of Interest Policy for Sponsored Projects and related policies or a FCOI management plan appears to have biased the design, conduct, or reporting of the PHS-funded research, the Research Integrity Officer will promptly notify the PHS Awarding Component of the corrective action taken or to be taken and will work with the PHS Awarding Component to resolve the failure to comply in a mutually agreeable manner.

If a determination is made by a PHS Awarding Component that clinical research funded by PHS to evaluate the safety or effectiveness of a drug, medical device or treatment has been designed, conducted, or reported by an Investigator with a FCOI that was not managed or reported by UNT as required by federal regulation, then UNT shall require the Investigator to disclose the FCOI in each public presentation of the results of the research and to request an addendum to previously published presentations that address the FCOI.