

**University of North Texas Health Science Center
Office of Research Compliance
Research Conflict of Interest Committee
Standard Operating Procedures
December 2020**

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I. Introduction

These Standard Operating Procedures (“SOPs”) are based on the University’s *Research Conflict of Interest Policy* (“the Policy” 12.101) and are intended to provide effective and transparent processes for the disclosure, review, management, and reporting of potential conflicts of interest with the University community.

The definition of a financial conflict of interest is a Significant Financial Interest that could directly and significantly affect the design, conduct, or reporting of Research.

II. Policy Statement

It is the policy of the University of North Texas Health Science Center at Fort Worth (“UNTHSC”) that no proposed, awarded, or ongoing UNTHSC Research shall be biased by any conflicting interests of UNTHSC Investigator’s responsible for the design, conduct, or reporting of that Research. This policy is applicable to all UNTHSC Investigators and applies to all Research regardless of funding. The purpose of this policy is to assure objectivity in Research.

III. Research Conflict of Interest (RCOI) Committee

A. Membership

The RCOI Committee is appointed by the Vice President for Research. Members will serve three-year terms, which will be staggered. The committee shall elect a chair and vice chair on an annual basis.

The RCOI Committee shall be composed of a minimum of five (5) members appointed by the Vice President for Research. The RCOI Committee composition will include members from UNTHSC colleges and schools; one or more

representatives from UNTHSC's Institutional Review Board; Vice President for Research or designee, who will only vote in the case of a tie; at least one representative from the Office of Research Compliance responsible for expedited reviews and determinations. At least one representative from each of the following: Office of Research Development & Commercialization and the Office of Sponsored Programs (formerly Office of Grant and Contract Management).

The RCOI Committee will meet frequently, preferably once a month, for disclosure reviews, as needed. A quorum of three members is required for the RCOI Committee to perform its functions. Situations and/or document reviews that do not appear to require a physical meeting may be held electronically utilizing UNTHSC email accounts. Items that require extensive discussion (i.e. management plans, disclosures requiring a management plan) will necessitate a physical meeting.

B. Responsibilities

The RCOI Committee provides assistance on matters involving identified or perceived financial conflicts of interest of investigators as defined by this regulation. The RCOI Committee makes recommendations on courses of action designed to manage, reduce, or eliminate the conflict.

The RCOI Committee shall maintain written minutes of meetings and, on request, shall prepare reports as needed.

IV. Process for Disclosure and Amendment Review

All UNTHSC personnel, including, but not limited to, administrators, faculty, staff, post-doctoral fellows, students, interns, or residents, whose institutional responsibilities include the design, conduct, or reporting of research (funded, unfunded or proposed for funding) are required to complete the RCOI Training annually and submit an Annual Disclosure Statement. When UNTHSC students are wholly engaged in an unfunded/non-financial training/practicum at external organizations, the non-UNTHSC individuals at that external organization will not be required to complete our RCOI Training/Disclosure Statement.

RCOI Training

As specified in the Policy, all Individuals engaged in research are required to complete Conflict of Interest training prior to involvement in a research project. The training requirement applies whether the project is funded or unfunded. Administrative offices which support the research project are encouraged to take this training as well.

The training module and information regarding training is available on-line. Except as detailed in the Policy, completion of training is required annually. Individuals will be

notified when it is time to re-take the training. Training status for an individual will be maintained in a database for review as needed.

External individuals will be provided with online access or alternative means to complete the RCOI Training and Disclosure Statement requirements.

Disclosures

The standard Annual Disclosure period is September 1 – October 1 for each Fiscal Year. Disclosures shall be made using a secure, web-based software program, unless otherwise authorized in writing by the Office of Research Compliance or the Office of Sponsored Programs. Access to this site will require the use of a login and password. In addition to the Annual Disclosure, Investigators are required to submit an amended Disclosure Statement within 30 days of discovering or acquiring a new Significant Financial Interest or other potential conflict of interest. RCOI training and a current disclosure must be on file prior to assigning an individual to a sponsored award account number.

Access to view submitted Disclosures is restricted to designated personnel. The Office of Research Compliance will initially review the Disclosure. Individuals that only submit information in the Institutional Conflict of Interest (ICOI) form that is not included in the RCOI SFI form will be contacted for further clarification. After further clarification, if determined that information is not related to the individual's research, then it does not meet the RCOI policy regarding review by the RCOI Committee. If the information is related to the individual's research, an RCOI SFI disclosure will be required. If the Disclosure indicates no conflict of interest, then no further action is required. If the Disclosure indicates a possible conflict of interest, then a sub-committee of the RCOI Committee will review the Disclosure (a so-called "expedited review"). If additional information is needed from the Investigator, a notice will be sent to the Investigator from the RCOI Committee Administrator requesting further clarification regarding the Disclosure. When received, the RCOI Committee Administrator will forward that information to the sub-committee. If the sub-committee determines no conflict of interest exists, the disclosure is approved by this expedited review and will forward the determination to the RCOI Committee for final approval at a future RCOI Committee meeting. Once approved by the RCOI Committee, a notice is generated by the RCOI Committee Administrator and then distributed to the appropriate individuals. Disclosures that cannot be approved by this sub-committee expedited procedure are discussed at a future RCOI Committee meeting for approval.

If the RCOI Committee determines additional information is needed prior to making a decision, a notice is sent to the Investigator from the RCOI Committee Administrator requesting clarification. Once the information is received, the disclosure is placed on the agenda for review at a future RCOI Committee meeting. If additional information is not needed and the RCOI Committee determines that the Disclosure does not constitute a conflict of interest, a notice is generated by the RCOI Committee Administrator and then distributed to the appropriate individuals. If the RCOI Committee determines that a

conflict of interest does exist, the RCOI Committee will recommend that a Management Plan be developed by the Investigator.

Management Plan

If the RCOI Committee determines that the Disclosure does constitute a conflict of interest, then the Investigator is notified by email with an attached Management Plan Template. The Investigator then completes a plan and obtains appropriate signatures of a Research Monitor (to be recommended by the RCOI Committee) and the relevant Department Chair/Supervisor. The Investigator then returns the completed Management Plan (with signatures) to the RCOI Committee Administrator for review at a future RCOI Committee Meeting.

When reviewing the submitted Management Plan, if the RCOI Committee determines additional information is needed prior to approving the Management Plan, an email will be sent from the RCOI Committee Administrator to the Investigator to request the required information. Once the additional information is received by the RCOI Committee Administrator, the revised Management Plan is reviewed at a future RCOI Committee Meeting. If the Management Plan is approved, the RCOI Committee Chair will sign off and the RCOI Committee Administrator will forward the Management Plan to the Vice President for Research (or designee) for a confirming signature as the Institutional Official. If the Department Chair is engaged in the managed project, then an alternate signature will be required (i.e. Vice Chair). Similarly, if the Vice President for Research is engaged in the project, the Provost or President will sign as the confirming authority. Once all appropriate signatures are obtained, the Management Plan is returned to the RCOI Committee Administrator.

If there are any substantive changes made to the Management Plan after the initial review and approval by the RCOI Committee, then the revised Management Plan is again reviewed by the RCOI Committee at a future meeting for final approval. If there are no substantive changes, a letter indicating the decision of the RCOI Committee is sent to the Investigator. Copies of the approved Management Plan are then sent to all relevant signatory parties.

Review of the Management Plan will occur annually typically during the anniversary month of the original review/approval by the RCOI Committee. (For example, a Management Plan that was approved in January 2014 would be due in January 2015 for annual review by the RCOI Committee.) In special cases where changes are required, such as a new Department Chair/Supervisor, the original approval date would be retained for future review.

The RCOI Committee Administrator will notify the Investigator prior to the anniversary date requesting the Investigator submit their annual status report for review by the RCOI Committee. The submitted report will be reviewed at a future RCOI Committee Meeting. If the report is approved by the RCOI Committee as submitted, a notice indicating the decision of the RCOI Committee is sent to the Investigator and copies of the notice are sent

to all relevant signatory parties. If there is a change in Research Monitor and/or Department Chair/Supervisor, a Signature Page Addendum is submitted for approval. If the RCOI Committee approves the change(s), the RCOI Committee Chair will sign off and the RCOI Committee Administrator will forward a copy of the current Management Plan with the new Signature Page Addendum to the Vice President for Research (or designee) for a confirming signature as the Institutional Official. [If the Vice President for Research is engaged in the project, the Provost or President will sign as the confirming authority.] Once acknowledged, the RCOI Committee Administrator will forward copies of the current Management Plan and Signature Page Addendum to all relevant signatory parties.

V. Enforcement

The Office of Research Compliance shall conduct audits of Investigators and Annual Disclosure Statements to determine compliance with the approved Management Plan on file and with the RCOI Policy. In general, if an issue or concern is identified by the Office of Research Compliance staff, the matter will be presented to the RCOI Committee Chair, who will then present the matter to the RCOI Committee. If the RCOI Committee determines that a breach of the RCOI Policy, or serious non-compliance with an RCOI Committee directive has occurred, it will notify the appropriate Investigator in writing and the Investigator will be given the opportunity to respond in writing or in person to the RCOI Committee and take corrective action within 15 calendar days. If such corrective action is not taken within the specified time period, the RCOI Committee may recommend sanctions for the Investigator to the Vice President for Research.

Retrospective Review

In the event a research conflict of interest is not identified or managed in a timely manner (which may include: failure by the Investigator to disclose a significant financial interest that is determined by the University to constitute a research conflict of interest; failure by the University to review or manage such a research conflict of interest; or failure by the Investigator to comply with a research conflict of interest management plan) the Office of Research Compliance, RCOI Committee, and Office of Sponsored Programs, within 120 days of the University's determination of noncompliance, will work in concert to 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 retrospective review shall include, but not necessarily be limited to, all of the following key elements (in accordance with 45 CFR 94.5 and 42 CFR 50.605):

- 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 bias is found, the appropriate University official will notify the PHS funding agency promptly and submit a mitigation report to the PHS funding agency. 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 the University'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 University will submit FCOI reports annually, as specified in the federal regulations. Depending on the nature of the research conflict of interest, 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 research conflict of interest or the Investigator's noncompliance is determined and the completion of the University's retrospective review.

VI. Sanctions

The Vice President for Research, in consultation with the RCOI Committee, may apply sanctions and disciplinary actions when an Investigator fails to disclose Significant Financial Interests or other potential conflicts of interest or otherwise fails to comply with the RCOI Policy. Sanctions may include a letter in a personnel file, restrictions on future submission of Research proposals, and other disciplinary actions in accordance with other UNTHSC policies. Recommendations of the Vice President for Research shall be made to the appropriate UNTHSC official in accordance with the employment status of the Investigator.

If a determination is made by a federal funding agency 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 Financial Conflict of Interest that was not managed or reported by UNTHSC as required by federal regulation, then in addition to other actions required by UNTHSC policies and procedures, UNTHSC shall require the Investigator 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 that address the Financial Conflict of Interest.

In addition, Investigators may also be subject to criminal sanctions or civil liability under federal or state law. Violations of full and prompt disclosure may result in the loss of grant funding and sanctions regarding future funding from federal agencies.