

GENERAL RCOI FAQs FOR ALL INDIVIDUALS

Access to the current Research Conflict of Interest UNTHSC Policy is available at the web site:
http://web.unthsc.edu/download/downloads/id/5457/research_conflict_of_interest_policy

Q: What is a Research Conflict of Interest (RCOI)?

A: Conflict of interest relates to situations in which financial or other personal considerations may compromise, may involve the potential for compromising, or may have the appearance of compromising an employee's objectivity in meeting University duties or responsibilities, including research activities.

Q: Where does the UNTHSC RCOI policy come from?

A: The UNTHSC RCOI policy is based on a combination of federal regulations (Code of Federal Regulations, 42 CFR Part 50 and 45 CFR Part 94).

Q: Who is covered by UNTHSC RCOI policy?

A: Anyone engaged in research with UNTHSC. In addition all UNTHSC personnel, including, but not limited to, administrators, faculty, staff, post-doctoral fellows, students, interns, residents, collaborators, subcontractors or consultants whose institutional responsibilities include the design, conduct, or reporting of Research, funded or proposed for funding.

Q: Where can I access the RCOI Training and Annual Disclosure Statement site?

A: The RCOI Training and Annual Disclosure Statement are located at <https://apps.unthsc.edu/rcoi>. You will need to log in with your EUID and password. Once you have completed the training you will need to submit your disclosure.

Q: I am unable to access the disclosure website and I keep getting error messages. What do I do?

A: You can call the Research Conflict of Interest Office at 817-735-2742 or the Helpdesk at 817-735-2192.

Q: I don't know how to answer the questions on the RCOI disclosure forms. Where can I get help?

A: If you or any personnel do not know how to answer a question then please email research.compliance@unthsc.edu or call 817-735-2742.

Q: I made mistakes on my RCOI disclosure. How do I re-open it and make corrections?

A: Please review your disclosure prior to selecting the Complete Disclosure/Certification button. Prior to completing your disclosure, you will have the option to Save and Complete Later or Reset Entire Form. Once you have entered all of your information, select the Complete Disclosure/Certification button. You will still have the opportunity to Edit your form. To submit your Disclosure, select the Submit Entities & Forms button.

Q: What happens if the University determines that I have a Research Conflict of Interest?

A: The Research Conflict of Interest Committee will review your disclosure. If there is a determination that a potential conflict of interest exists, you will need to submit a management

plan to the RCOI Committee for review and approval. A Research Conflict of Interest can exist even if no improper acts have occurred. Having a conflict of interest does not necessarily mean you are guilty of anything. The RCOI Committee will give guidance as to how to manage personal and financial interests and relationships appropriately, pursuant to University Policy.

Q: What is the procedure for handling a Research Conflicts of Interest?

A: If the RCOI Committee determines there is a potential conflict of interest, the individual will submit a signed management plan to the committee for review. If approved by the RCOI Committee, the individual is notified. An annual report is submitted to the RCOI Committee for review as long as the conflict exists.

Q: What will happen if I don't disclose my personal or financial interests related to my institutional responsibilities for the University?

A: The consequences of failing to disclose one's interests, as they relate to one's University duties, can vary depending on the circumstances. Please see the Enforcement Section of 12.101 Research Conflict of Interest - Policies of the University of North Texas Health Science Center.

Q: I am working on my dissertation and I am not receiving funding from anyone. I am using a secondary dataset (no live subjects). Do I need to complete RCOI training?

A: Yes.

RCOI FAQs FOR RESEARCHERS

UNTHSC recognizes that conflicts of interest will arise from the research enterprise, from technology transfer activities, and from the many facets of our investigators' professional activities. We seek to identify and manage these conflicting relationships to preserve transparency, protect research subjects, ensure the integrity of the educational experience, and maintain the credibility of investigators. Research Conflict of Interest administration resides within the Office of Research Compliance.

Q: Who is an "Investigator"?

A: "Investigator" means a UNTHSC principal investigator, faculty member, or any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of Research, funded, or proposed for funding, by an external sponsor. This may include Research assistants, project directors, lab personnel, collaborators or consultants.

Q: What is the RCOI Process?

A: Once a disclosure is submitted online, the form is reviewed by the RCOI staff. Every disclosure starts with an Administrative Review. Depending on the nature of the potential/appearance of a conflict, the disclosure may go through additional reviews. Each disclosure is reviewed on a case-by-case basis.

Q: Will checking "yes" on a research conflict of interest disclosure form put me at risk of losing my funding?

A: No, sometimes it is determined that no conflict exists and other times the conflicts can be managed through a combination of oversight and a management plan.

Q: What Agencies are part of the Public Health Services (PHS)?

A: The Department of Health and Human Services (HHS) has designated eight of its 11 operating divisions (agencies) as components of the U.S. Public Health Service.

- (1) Agency for Healthcare Research and Quality (AHRQ)
- (2) Agency for Toxic Substances and Disease Registry (ATSDR)
- (3) Centers for Disease Control and Prevention (CDC)
- (4) Food and Drug Administration (FDA)
- (5) Health Resources and Services Administration (HRSA)
- (6) Indian Health Service (IHS)
- (7) National Institutes of Health (NIH)
- (8) Substance Abuse and Mental Health Services Administration (SAMHSA)

Q. I am submitting a grant proposal to a PHS funding agency. Do I need to complete the RCOI Training and submit a Disclosure Statement?

A. *Yes. All investigators (persons engaged in research as stated in the “Definitions” section of the policy), listed on the grant proposal to a PHS funding agency are required to have completed the RCOI Training and have a current Disclosure Statement on file prior to submission of a proposal to a PHS funding agency. Disclosures are submitted by the researcher using the on-line submission form. If the Investigator's RCOI Training and Disclosure Statement are not on file, this will result in a delay of submitting the grant proposal.*

Q. I am submitting a grant proposal to a NON-PHS funding agency. Do I still need to complete the RCOI Training and submit a Disclosure Statement before I can submit the proposal?

A. *Under the current policy, a proposal for non-PHS funding can be submitted without prior RCOI disclosures for investigators. However, this is not a recommended strategy. Before any grant award account (projID) can be set-up, all personnel engaged in research that will be paid on that account are required to have completed the RCOI Training and have a current Disclosure Statement on file. The better (and less potentially delay causing) approach is to have all RCOI Disclosures submitted, current and on file before submitting any proposal.*

Q. I received a grant award from an organization that is not PHS funded. Do I need to complete the RCOI Training and submit a Disclosure Statement?

A. *Yes. Before any grant award account (projID) can be set-up, all personnel engaged in research that will be paid on that account are required to have completed the RCOI Training and have a current Disclosure Statement on file.*

Q. I completed the RCOI Training and submitted a Disclosure Statement when my grant award was originally set up. If I do not have a current Disclosure Statement on file, can subsequent year budget funds be held?

A. *Yes. RCOI Training is valid for four (4) years, but your Disclosure Statement is only valid for up to one year+, or whenever a change in status occurs. You must be current on both your training and your Disclosure Statement in order for the next year of budget dollars to be loaded into your projID.*

Q: As part of this policy, what am I being asked to do?

A: You are being asked to do two things: complete the RCOI Training and submit a disclosure statement. This is a global disclosure statement and should not be confused with the IRB Conflict of Interest Disclosure Statement, which is project specific. The RCOI Training must be completed prior to submitting a disclosure statement.

Q: Are disclosure forms kept confidential?

A: Yes. Disclosure forms are kept confidential except as required for internal administrative purposes and except when disclosure is required by law.

Q: I am paid to edit a textbook for Organization X, which is CME supported. I don't conduct any research with them so is this something I need to report? If so—how do I report it?

A: Yes. You should disclose this instance paid authorship to the University because it is paid authorship related to your institutional responsibilities.

FAQS FOR RCOI TRAVEL

Q: Where can I go to submit a RCOI Travel Disclosure?

A: Go to <http://www.unthsc.edu/rcoi> and log in with your EUID and password. If your RCOI Training is current, you will be able to submit your RCOI Travel disclosure. If your RCOI Training is not current, you will be prompted to complete the training prior to submitting your RCOI Travel disclosure.

Q: If my travel related to my institutional responsibilities is sponsored or reimbursed by universities outside of the US, a government of another country, or a non-governmental organization (NGO), do I still need to disclose it to the University?

A: Yes. All exclusions listed in the federal regulations only apply to United States (U.S.) Institution of higher education or a federal, state or local government agency within the U.S.

Q: When do I have to submit my RCOI Travel disclosures for reimbursed or sponsored travel related to my institutional responsibilities?

A: RCOI Travel disclosures can be submitted before the travel occurs. An individual can disclosure up to 30 days after the travel.

Q: I am traveling to World Health Organization (WHO) in Switzerland this year and they are reimbursing me for travel. I am not doing any research with WHO and I have no contract or grants with them. Is this travel something I need to report? If so—how do I report it?

A: You should disclose this travel to the University because it is travel related to your institutional responsibilities.

Revised 9/17/2014