

TO: All Faculty Members

FROM: Dr. David Schultz, Associate Vice President for Research and Innovation

DATE: February 22, 2017

Re: Research Compliance Reminders and Updates

This memo is an annual reminder and update regarding some of the more significant federal, state, and UNT requirements that apply to the conduct of research projects. Please share this information with all of your research team members and contact the Office of Research Integrity and Compliance or the Office of Grants and Contracts Administration if you have any questions about any of the requirements described below.

SPONSORED PROJECTS AND GIFTS

The University and its principal investigators have fiduciary responsibility to properly classify external funding because of federal tax consequences, federal and state regulations regarding gifts and sponsored projects, and state, federal, and university accounting and work policies. Sponsored projects generally include commitments of personnel effort, a statement of work with deliverables, and have requirements for detailed financial or technical reporting. Gifts do not contain any contractual requirements, personnel effort commitments or deliverables, are irrevocable, and have no requirements for fiscal accountability beyond a demonstration of good stewardship. The Office of Grants and Contracts Administration can help clarify this distinction and requirements for sponsored projects' proposal submissions and awards. More information can be found in the PI Handbook: <https://research.unt.edu/faculty-resources/ogca/pi-handbook>

Effort Certification: The federal and state government requires an effort certification when an individual is compensated by or has agreed to contribute time to a federally sponsored project. All faculty who serve as investigators on sponsored agreements are personally responsible to certify the amount of effort that they and their employees spent on sponsored activities. More information about effort certification can be found on the OGCA website: <https://research.unt.edu/faculty-resources/ogca/effort-reporting>.

HUMAN SUBJECTS RESEARCH

Prior approval of a study by the UNT Institutional Review Board (IRB) is required if both of the following definitions apply:

Research: a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge; and

Human Subject: a living individual about whom an investigator (whether professional or student) conducting research obtains: (a) data through intervention or interaction with the individual; or (b) identifiable private information.

Institutional Review Board website, including IRB application forms and links to required online training: <http://research.unt.edu/faculty-resources/integrity-compliance/irb>

NIH Revised Policy on Good Clinical Practice: The National Institutes of Health (NIH) recently issued a new policy on Good Clinical Practice (GCP) training requirement for NIH-funded investigators who are responsible for the conduct, management, and oversight of NIH-funded clinical trials. Please read the NIH notice to determine applicability:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html>

International Research: The Office of Human Research Protections (OHRP) has updated the International Compilation of Human Research Standards guidelines. OHRP has classified the laws, regulations, and guidelines into eight categories. If you plan to conduct research with human subjects internationally, please review the most current regulations that apply:

<https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html>

BIOSAFETY

All research uses of human materials, biohazardous agents, and recombinant DNA at UNT must be approved in advance by the UNT Institutional Biosafety Committee (IBC). Institutional Biosafety Committee website and forms: <https://riskmanagement.unt.edu/>. (To access the Risk Management Services website, copy and paste this link into your web browser. Your system login will be required to access forms.)

RADIATION AND LASER SAFETY

The UNT Radiation Safety Committee has responsibility for receipt, use, monitoring, and disposal of radioactive material, radiation producing devices, and lasers at UNT and must approve in advance any ordering or use of such items. Radiation Safety Committee website and forms:

<https://riskmanagement.unt.edu/>. (To access the Risk Management Services website, copy and paste this link into your web browser. Your system login will be required to access forms.)

VERTEBRATE ANIMALS RESEARCH

All UNT personnel using live vertebrate animals for research or educational purposes must obtain approval from the UNT Institutional Animal Care and Use Committee (IACUC) prior to ordering or beginning work with such animals. Institutional Animal Care and Use Committee website, including protocol application form and link to the required online training:

<https://research.unt.edu/faculty-resources/integrity-compliance/iacuc>

FINANCIAL CONFLICT OF INTEREST

All "Investigators" (defined to include Principal Investigators, Co-Investigators, and any others with responsibility for the design, conduct, or reporting of a research study) with currently proposed or awarded external funding for research must annually disclose certain "Significant Financial Interests." Potential financial conflict of interest (FCOI) situations are reviewed by the Conflict of Interest Review Committee to determine if the conflict necessitates a management plan.

Financial Conflict of Interest website and link to online disclosure:

<https://research.unt.edu/faculty-resources/research-integrity/financial-conflict-interest>

Required Collaborative Institutional Training Initiative (CITI) COI Training for Public Health Service (PHS)/National Institutes of Health (NIH) Awards: When a PHS/NIH award is set up by the UNT Office of Grants and Contracts Administration, all Investigators on the project must have completed the online "UNT Conflict of Interest Course for Public Health Service/NIH Funding" within the last 4 years. Link to CITI training for UNT learners: <http://www.citiprogram.org> (Click "Register" on the right side of the webpage.)**EXPORT CONTROLS**

U.S. statutes and regulations restrict the exporting or sharing within the U.S. of certain "controlled" equipment and technology with foreign nationals (in the absence of an applicable exemption), and limit or prohibit activities (including travel and collaborations) involving sanctioned countries, entities, and persons. Click on this link for more information or to access a helpful checklist for researchers to determine if export controls are applicable to your project:

<https://research.unt.edu/faculty-resources/policies-compliance/export-controls>

RESPONSIBLE CONDUCT OF RESEARCH

National Science Foundation (NSF) and National Institutes of Health proposals for funding must describe the plan for training involved undergraduate students, graduate students, and postdoctoral researchers in the responsible conduct of research (RCR). RCR topics include: Research Misconduct; Data Acquisition, Management, Sharing and Ownership; Conflict of Interest and Commitment; Collaborative Research; Publication Practices and Responsible Authorship; Mentoring; Peer Review; Animal Research; and Human Subjects Research.

Responsible Conduct of Research website, including UNT RCR Plan and links to online training: <http://research.unt.edu/faculty-resources/policies-compliance/research-integrity>

Links to the NSF and NIH RCR requirements:

NSF: <http://www.nsf.gov/bfa/dias/policy/rcr.jsp>

NIH: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html>

NIH Annual Progress Reports for Individual Development Plans (IDPs): This is a reminder regarding graduate students and postdoctoral researchers supported by NIH awards. NIH annual progress reports are required to include a description of whether the institution uses IDPs or not and how they are employed to help manage the training and career development of those individuals. Link to the NIH announcement:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-113.html>

RESEARCH MISCONDUCT

Allegations of "Research Misconduct" (defined by the UNT Research Misconduct Policy to include plagiarism, fabrication, or falsification) by UNT employees while engaged in the conduct of research must be reported to the UNT Research Integrity Officer (the Associate Vice President for Research). The Research Integrity Officer (RIO) will conduct an initial assessment to determine if an Inquiry Committee needs to be appointed to review the allegations. If an investigation is recommended by the Inquiry Committee, an Investigation Committee will determine if Research Misconduct occurred, and if so, will recommend administrative action to the Deciding Official. Link to the Research Misconduct website:

<https://research.unt.edu/faculty-resources/policies-compliance/research-misconduct>