UNIVERSITY OF NORTH TEXAS®

Institutional Review Board

Faculty, Staff and Students: Please read the following information regarding important updates to UNT's IRB Program.

Revised Common Rule Information

On January 21st, OHRP released revisions to the Common Rule (45 CFR 46) - the federal regulations that govern human subjects research. Review the following information to determine how this will impact your research.

Studies approved before January 21, 2019
▪ No changes are needed. The "old" regulations apply to all studies approved prior to January 21, 2019 including any future continuing reviews or amendments you submit. ▪ Your protocol number will remain the same and you do not need to make any changes to your protocol or supplemental documents (consent forms, surveys, etc.). ▪ You must still submit continuing reviews on an annual basis for Expedited and Full Board studies as required by the "old" regulations. If your Expedited or Full Board study expires after the three-year timeframe, your new protocol submission will fall under the "new" regulations.
Studies submitted but *not* approved before January 21, 2019
▪ The IRB will work with you to transition your pending study under the new regulations. o The transition will include reclassifying your protocol under the new regulations within Cayuse IRB and updating your consent forms to adhere to the new requirements. The Office of Research Integrity and Compliance will contact you directly to assist you with your consent forms (if applicable to your study.) ▪ With very few exceptions, you will not have to submit Continuing Reviews on an annual basis.
Studies submitted and approved after January 21, 2019
▪ Any protocols submitted and approved after January 21, 2019 must comply with the new regulations. ▪ With very few exceptions, you will not have to submit Continuing Reviews on an annual basis.
CURRENT TURNAROUND TIME FOR INITIAL REVIEW: Due to the changes to the Common Rule, our current turnaround time for initial protocol review is between 15-30 days.

IRB TRAINING OPPORTUNITIES

Please join us to learn more about the revised regulations for human subjects research. Each session will last approximately 60 minutes. The first 30 minutes will focus on the revisions to the Common Rule. Each session will include a special topic (as indicated below) with the last 15 minutes of the session saved for any questions. Sessions are open to all UNT faculty, staff, and students. **RSVP to untirb@unt.edu with your name and session you plan to attend.**

Session 1: Thursday, February 21, 2019, 11:00 AM – 12:00 PM, Union Room 394
Special Topic: Classroom Projects

Session 2: Thursday, February 21, 2019 2:00 PM – 3:00 PM, Union Room 394
Special Topic: Collaborative Research

Session 3: Wednesday, February 27, 2019, 9:30 AM – 10:30 AM, Union 381
Special Topic: Consent Process

Session 4: Wednesday, February 27, 2019, 3:30 PM – 4:30 PM, Union 381
Special Topic: Navigating Cayuse IRB

SUMMARY OF MAJOR CHANGES TO THE COMMON RULE

- **The definition for "research" has changed.**

  Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes.

  Some activities are deemed not to be research:

  - Scholarly and journalistic activities (*e.g.,* oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. **Please consult the Office of Research Integrity and Compliance by sending an e-mail to* untirb@unt.edu *or calling 940-565-4643 for guidance if you believe your projects falls under these activities.*
  - Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
  - Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
  - Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

- **The definition of "Human Subject" has changed to include biospecimens.**

  Human subject is defined as a living individual about whom an investigator conducting research:

  - Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens;
    OR
  - Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
    - ***Identifiable private information*** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
    - *An* ***identifiable biospecimen*** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

- **Exempt Categories**
  - Several changes were made to the Exempt Categories. Please review the updated Exempt Categories on the Common Rule webpage found here.
  - Please note: Two additional exemption categories (Category 7 and 8), both involving broad consent, are included in the revisions to the Common Rule. UNT has chosen **not** to utilize these categories at this time.

- **Clinicaltrials.gov**
  - The updated regulations require that certain clinical trial consent forms be posted on a government website (clinicaltrials.gov). **Please contact* untirb@unt.edu *or 940-565-4643 to determine if this applies to your study or to register for an account on clinicaltrials.gov.*
  - The definition of clinical trial was revised as follows:
    - The definition of ***Clinical Trial*** is: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health related outcomes.

- **Vulnerable Populations Changes**
  - The revisions added "Economically or Educationally Disadvantaged Persons", removed "Pregnant Women" and replaced "Handicapped" with "individuals with Impaired Decision-Making Capacity".

- **Changes to Consent Process and Forms**
  - Consent documents must begin with concise and focused Key Information to assist subjects with making a decision about participation.
    - Key Information must be organized in a way that facilitates a prospective subject's or legally authorized representative's understanding of the reasons why an individual might or might not want to participate in the research.
  - Additional elements of informed consent are included for applicable studies, including items such as whether a study includes whole genome sequencing, or whether clinically relevant results will be returned to subjects.
  - Updated templates can be found on the ORIC webpage here.

CHANGES TO REQUIRED HUMAN SUBJECTS TRAINING

Beginning **May 1, 2019**, human subjects training must be renewed every **3** years.

- Researchers and Key Personnel **with an active protocol** will not have to renew their training until their protocol comes up for annual review or they submit a new protocol.
- Researchers and Key Personnel who submit protocols **on or after May 1, 2019** will be required to update their training certificate if their completion date exceeds three years.

Please note: The NIH no longer offers Protecting Human Research Participants (PHRP) course. However, the IRB will accept NIH/PHRP training certificates if they adhere to the aforementioned requirements.

To complete the required human subjects training, complete the Collaborative Institutional Research Initiative (CITI Program) "Social & Behavioral Research - Basic/Refresher" course or "Biomedical Research - Basic/Refresher" course (depending on which is applicable to your study). Follow instructions found here.

Current IRB Roster:

Charles Blankson, Ph.D., Marketing and Logistics
Case Cagle, Community Member
Daniel Chen, Ph.D., Counseling and Higher Education
Rebecca Glover, Ph.D., Educational Psychology
Lisa Henry, Ph.D., Anthropology
Cynthia Hermann, M.D., Student Health and Wellness Center
Shelley Riggs, Ph.D., IRB Chair, Psychology
Richard Smith, Ph.D., Behavior Analysis
Herschel Voorhees, D.O., IRB Vice Chair, Student Health and Wellness Center
Justin Watts, Ph.D., NCC, Rehabilitation and Health Services
Jennifer Wondracek, J.D., M.L.I.S., UNT Dallas College of Law

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If you have any IRB questions or concerns, please direct them to the Office of Research Integrity and Compliance:

- Jamie Peno, Director, 940-565-3941, jamie.peno@unt.edu
- Janice Magrini, Sr. Research Analyst, 940-565-4643, untirb@unt.edu