Responsible Conduct of Research

Let’s Start From the Very Beginning….

Research
The systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human Subject
A living individual about whom an investigator conducting research obtains data through the intervention, or interaction with the individual or identifiable private information.

IRB
An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated.
The Institutional Review Board:

**Who**
The IRB must have at least five members of varying backgrounds in order to provide complete and adequate review of human research and its institutional, legal, scientific, and social implications. The Board will also include at least one member who is not affiliated with the institution and one member who is not a scientist.

**What**
Responsible for reviewing all research (whether funded or not) involving human participants prior to its initiation. The IRB is concerned with protecting the welfare, rights, and privacy of human subjects and to ensure research activities are being conducted per institutional policies and federal guidelines.

**Where**
The UNT Institutional Review Board (IRB) reviews all proposed research projects involving human subjects to be conducted at UNT or to be conducted at any location by UNT faculty, staff, and students in connection with their institutional responsibilities.

**How**
Operating under a Federal-wide Assurance (FWA) issued by the Office for Human Research Protections (part of the U.S. Department of Health and Human Services).
<table>
<thead>
<tr>
<th>Who</th>
<th>The Research Integrity and Compliance staff support the IRB Operations.</th>
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<tr>
<td>What</td>
<td>Responsible for reviewing all IRB new study, modification, renewal and close out applications and providing a detailed analysis to assess for completeness and compliance with regulations and IRB policies.</td>
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<tr>
<td>Where</td>
<td>Research Integrity and Compliance staff may be contacted through TEAMS and at <a href="mailto:untirb@unt.edu">untirb@unt.edu</a>.</td>
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<tr>
<td>How</td>
<td>Supports the IRB by performing administrative tasks. Performs activities under the Direction of the Director of Research Integrity and Compliance and the Chair of the IRB.</td>
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The Regulations

• 45 CFR 46- Common Rule
  • Federal regulations that govern Human Subjects Research
  • provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS)

• Department of Health and Human Services
  • Office for Human Research Protections (OHRP)

• The Declaration of Helsinki
  • World Medical Association
  • Ethical principles for medical research involving human subjects

• The Belmont Report
  • National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
  • Leading work concerning ethics in human subjects research.
  • 3 principles: beneficence, justice, respect for persons.

• Texas Health and Human Services
My Study Needs IRB Approval...

1. Can I be a Principal Investigator?
2. How can I prepare my study for IRB submission?
3. What type of training do I need to complete?
4. How do I submit my study for review?
5. What does the IRB review process entail?
6. I now have approval. What else do I need to worry about?
7. Other considerations and special circumstances
Can I be a Principal Investigator?

• Principal Investigator must be:
  • Full-time UNT faculty member
  • Full-time staff employee whose job responsibilities include conducting human subject research

• Cannot be:
  • Student
  • Lecturer*
  • Adjunct instructor*

*May provide a letter or email from your Department Chair that acknowledges your research endeavors. If you are unsure, please contact us at untirb@unt.edu.
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How can I prepare my study for IRB submission?

- Plan ahead to allow a sufficient amount of time for submission, review and approval of your study.
- The current review timeline is posted in a message in the Cayuse system
  - Timeline will depend on the volume of submissions received by the IRB office.
  - Timeline is impacted by many variables and will vary throughout the year.
  - Please reach out to the office at untirb@unt.edu if you have questions regarding the posted review timeline.
- Protocols that are incomplete or lack details will be returned to the team
- Please review all of your study documents to assess the readiness for review.
How can I prepare my study for IRB submission?

• Gather your attachments
• Attachments include, but are not limited to:
  • Informed consent forms/notices (unsigned)
    • Waiver or Alteration of Informed consent if using an informed consent notice
  • Surveys/Questionnaires
  • Training completion certificates
  • Scope of work for any proposal for internal or external funding for the study
  • Recruitment materials (flyers, e-mail scripts, classroom announcements, advertisements, etc.)
  • Approval letter on letterhead for each data collection site (other than UNT); example: ISD approval
  • A copy of all data collection instruments, interview scripts, and intervention protocols.
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What type of training do I need to complete?

- Researchers and all research team members must complete required training before receiving IRB approval
- Complete the Collaborative Institutional Research Initiative (CITI Program) course:
  - [https://about.citiprogram.org/en/homepage/](https://about.citiprogram.org/en/homepage/)
  - “Social & Behavioral Research - Basic/Refresher”
  - “Biomedical Research - Basic/Refresher”
- Training must be renewed every 3 years
- Additional Trainings:
  - Responsible Conduct of Research (RCR)
    - CITI program course for studies funded by the NSF, NIH, USDA
    - In-person training workshops monthly
  - Good Clinical Practice
    - Personnel working on clinical studies
  - Custom upon request at untirb@unt.edu
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How do I submit my study for review?

• To get access to Cayuse IRB submission portal, submit access request form: https://research.unt.edu/cayuse-access-access-change-request

• Submission Steps:
  1. Log in to Cayuse IRB portal
  2. Use EUID and EUID password to log in.
  3. Upper right hand corner → blue button “+ New Study”
  4. Enter title of study and click save.
  5. blue button → “+ New Submission” → Select Edit.
  6. Add personnel (Remember rules about being a Principal Investigator)
  7. Complete submission and mark “complete”
  8. Principal Investigator mark “certify”
  9. Once the principal investigator certifies, the submission will be received by the UNT IRB.

• For technical issues, contact cayusetechsupport@unt.edu. For study content or IRB process questions, contact untirb@unt.edu.

Cayuse IRB
https://unt.cayuse424.com/rs/irb/
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What does the IRB review process entail?

- IRB submissions are reviewed in the order that they are received.
- Check the status of your protocol in the Cayuse IRB System from your Cayuse Dashboard.
- Research Compliance Analyst will conduct an initial review of your study.
  - If revisions are needed, we will return the study to you in the Cayuse IRB System for edits.
  - You will receive an email from the Cayuse IRB System, which will let you know your protocol has been returned.
  - Please complete the revisions in their entirety ASAP and resubmit the revised documents within the Cayuse IRB System.
What does the IRB review process entail?

• Based on the risk of your study, you will be assigned a review category by the Research Compliance Analyst or Board Member:
  • Exempt
    • Typically reviewed and approved within the Compliance Office.
  • Expedited
    • Typically sent to a secondary reviewer (IRB Board Member) for sign off.
  • Full Board
    • Reviewed by all IRB Board Members at Monthly meetings. Deadlines and meeting dates can be found on our website.

• Approval Documentation- Once you have satisfied all necessary requirements, and approval is issued, we will:
  • Email the approval letter
  • Attach your stamped informed consent document to your Cayuse IRB study
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I now have approval. What else do I need to worry about?

• Modifications:
  • Any changes to your final approved study must be approved by the IRB
  • Submit a modification form before you implement any changes (i.e. adding key personnel, increasing recruitment, changes in study procedures, etc.)

• Continuing Reviews:
  • Expedited and Full Board studies, you MUST renew your study each year on the date before it is set to expire.
  • We send 90 day, 60 day, 30 day, and day of expiration reminders to you via e-mail.
  • If you do not renew your protocol by the expiration date, your protocol will be administratively closed, and you will not be able to use the data you collect after the expiration date.

• Reportable Events:
  • Any adverse effects, unanticipated problems, and protocol deviations or errors must be reported to our office.
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Other considerations and special circumstances

**• International Research:**

- IRB will evaluate the research in light of the local research context (international site)
- PIs are responsible for compliance with all applicable laws, regulations, guide-lines for human subject research in each country where research will be conducted.
- International studies typically take longer to review. Plan ahead!
- Pertinent information to include in Cayuse:
  
  o Research location(s)
  o Local research rules and requirements pertinent
  o Community and cultural knowledge
  o Political climate, societal norms, etc.
  o Collaborator(s)
  o Language and literacy level of population
  o Status of women and children
  o Detailed explanation of consent process
Other considerations and special circumstances

• Multi-institutional or Collaborative Research:
  • Researchers from two or more institutions collaborating on a research project
  • These studies typically take longer to review. Plan ahead!
  • “IRB Authorization Agreement”
    • An agreement between two institution IRBs where one site’s IRB will be relying on the other site’s IRB for approval and oversight of the research activities.
    • This process requires:
      • Direct conversations between UNT IRB staff and the collaborating site’s IRB
      • Special signed documents between the institutions.

• Other Important Considerations:
  o Research location(s)  o Collaborator(s)
  o IRB of Record  o Local research rules and requirements pertinent
  o Training  o Data storage and transfer

• Please reach out to the IRB at untirb@unt.edu if your research qualifies as a collaborative or multi-institutional study to discuss your options.
Need help?

- **One-on-one meetings**
  - By appointment via TEAMS or Zoom
- **Call**
  - 940-565-4643
- **Email**
  - untirb@unt.edu
Questions?

THANK YOU!

Phone: 940-565-4643
Email: untirb@unt.edu