Responsible Conduct of Research

IRB Overview and Responsible Recruitment

February 14, 2023
What are we going to talk about?

IRB Overview
- Human Subjects Research
- What is the Institutional Review Board?
- What regulations guide Human Subjects Research?

Recruitment Best Practices
- Common recruitment methods
- Permissions needed
- Things to be mindful of
- Recruitment Templates/Examples
IRB Overview

- Human Subjects Research
- What is the Institutional Review Board?
- What regulations guide Human Subjects 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 research subjects recruited to participate in research activities conducted under the oversight of the institution with which it is affiliated.
The Institutional Review Board (IRB)

**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).
Staff Supporting IRB Operations

**WHO**
The Research Integrity and Compliance staff support the IRB Operations.

**WHAT**
Responsible for reviewing all IRB initial, modification, renewal and closure submission.
Providing a detailed analysis to assess for completeness and compliance with regulations and IRB policies.

**WHERE**
Research Integrity and Compliance staff available through Microsoft Teams during regular business hours (Monday-Friday from 8am-5pm). Email: untirb@unt.edu

**HOW**
Supports the IRB by performing administrative tasks. Performs activities under the Direction of the Assistant Vice President of Research Integrity and Compliance and the Chair of the IRB.
The Regulations

• 45 CFR 46- Common Rule
  • Federal regulations that govern Human Subjects Research
  • Provides guidance 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 (1964)
  • World Medical Association
  • Ethical principles for medical research involving human subjects

• The Belmont Report (1979)
  • National Commission
  • Three key ethical principals that form the ethical foundation for federal regulations
    1. Respect for persons
    2. Beneficence
    3. Justice
Recruitment Best Practices

• Common recruitment methods
• Things to be mindful of
• Recruitment Templates/Examples
What are some ways that you have (or plan to) recruit participants for your research?
Common Recruitment Methods

- Email
  - Listservs
- Flyer
- Social Media
  - Facebook
  - Twitter
  - Instagram
- Snowball Sampling
- Crowdsourcing Platforms
  - Amazon MTurk
  - Qualtrics Panels
- In Class Announcement/Scripted Presentations
- SONA
- Face-to-face recruitment
Obtaining Permission

Depending on the avenue of the recruitment you may need to get written permission from leadership/admin:

• Admins of Social Media groups
  • Ex: Facebook group; subReddits
• Email Listservs
• Private businesses/organizations
• Other universities or schools including K-12
Obtaining Permission

Permission is generally NOT required for recruitment through:

• Public spaces – e.g. notice boards
• A researcher’s personal social media accounts
• Contacting people who’s information in publicly available
Things to Keep in Mind

Participant demographics:
• In general, care must be taken to not exclude participants unnecessarily
• This ties directly back to the concept of justice in Belmont Report

Are your recruitment methods going to reach a representative sample?

Translated Documents for Non-English-Speaking Participants
• Documents must be made available in the participant’s primary spoken language
• If you are recruiting from an area that has a high number of participants that do not speak English, consider this when creating recruitment materials.

Would translating the recruitment flyers allow you to have a more representative sample?

Don’t rush it!
• Allow sufficient time for prospective participants to consider whether or not they are interested in proceeding to the consent process.
Things to Keep in Mind (Cont.)

Avoiding coercion and undue influence in recruiting:
• Instructors/students; Bosses/employees
• Anywhere there is an imbalance of power, there is the potential for undue influence or coercion

Student emails:
• Not available in general – not considered directory information by registrar's office
• Student emails may only be used from listservs currently available to the researcher

Vulnerable Populations
• There may be additional considerations if you are recruiting children, prisoners, people with intellectual disabilities, and other vulnerable people
Recruitment Flyer Examples & Templates

Recruitment Material should include:

• "University of North Texas"
• Name of Department
• The word "research"
• Official title of study
• Location of research (if online, use, "online")
• Inclusion criteria
• Purpose of study
• Study procedures and time requirement
• Type and amount of compensation (if any)
• PI name and contact information

Current Internal Resources

UNT IRB Forms:
• Recruitment Flyer
• Recruitment Email
Recruitment Materials/Templates

Make it Stand out!

- **Canva (free and pro)**
  - Canva has a variety of premade templates to choose from. Even without the purchase of pro, there are still a lot of options to choose from.

- **Microsoft Office**
  - Like Canva, Office has recruitment templates to choose from as well. However, it is limited in what you can design with it.

- **Design Works**
ResearchMatch

- ResearchMatch is only available to be used for Health-related research studies.
- ResearchMatch is a national registry of patients interested in volunteering for medical research. Anyone can register with ResearchMatch – even healthy volunteers.

This can be a great tool to use if you are looking to recruit participants for a health-related project.

If you are interested in learning about health-related research, YOU can sign up as a volunteer!
Upcoming RCR Workshops
# Responsible Conduct of Research (RCR) Workshops

**Spring 2023**

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<tr>
<th>Date</th>
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| February 14<sup>th</sup> | IRB- Human Subjects Research | Overview of UNT IRB  
Recruitment Best Practices                                                                                                                   |
| February 28<sup>th</sup> | COI- Conflict of Interest | Overview of the UNT COI program.  
Difference between research conflicts of interest (RCOI) and institutional conflicts of interests (ICOI).  
Considerations for competitive small business funding programs such as Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR). |
| March 28<sup>th</sup>   | International Affiliations   | Overview of UNT's biosafety program.  
Lab safety  
Guidance on biological safety and risk assessment for work involving biological agents and genetically modified organisms. |
| April 25<sup>th</sup>   | Animal Research and Biosafety | Overview on how to navigate international affiliations in research.  
International affiliations disclosure process  
Visiting Scholars program  
Compliance requirements related to international affiliations in research. |
Questions?

THANK YOU!

Phone: 940-565-4643
Email: untirb@unt.edu
Messaging on Microsoft Teams

One-on-one meetings by appointment via Microsoft Teams or Zoom