Institutional Review Board (IRB) Information Session/Workshop

Institutional Review Board (IRB)

It is the policy of Texas Woman's University (TWU) that all research conducted by any TWU faculty member, staff member, or student using human subjects must have prior approval from a TWU Institutional Review Board (IRB) before the research is initiated.

The purpose of the IRB is to protect the rights and welfare of research subjects and to ensure that such research is conducted in full compliance with both the letter and the spirit of applicable regulations.

The TWU IRB operates under the following governances: Federalwide Project Assurance # FWA00000178, TWU University Policy 1.15 Human Subjects in Research, and TWU IRB Procedures – June 2018.

IRB Review

Only RESEARCH involving HUMAN SUBJECTS must be reviewed by the IRB.

- *Research* is a systematic investigation designed to test hypotheses, evaluate programs, draw conclusions, or contribute to generalizable knowledge.

- *Human subjects* in research are living individuals about whom investigators (professionals or students) conducting research obtain (1) data through intervention or interaction with individuals, or (2) identifiable private information.

Website

Please visit our website: https://twu.edu/institutional-review-board-irb/ where you can find information on:

- Basic IRB Process
- IRB Procedures & Policy
- Levels of Review
- Applications Forms
- Request Forms for Approved Studies
- Consent Form Guidelines and Samples
- Human Subjects Training Requirements

Categories of Review

- *Exempt* – little-to-no risks; ex: online, anonymous surveys
- *Expedited* – minimal risks; ex: interviews
- *Full Review* – more than minimal risks; ex: studies that ask very personal questions or involve physical risks

If you are unsure of the level of review under which your study falls, we will be glad to help you!

Training Requirement

All research team members (including principal investigators, research assistants, major advisors, and staff) are required to successfully complete an IRB (human subjects) training course. A current certification (less than 3 years old) must be submitted with all levels (exempt, expedited, and full reviews) of new IRB applications and with any request for extension.

The TWU IRB accepts human subjects training certificates Collaborative Institutional Training Initiative (CITI).

The human subjects training should not be confused with the Responsible Conduct of Research (RCR) training which is a Graduate School requirement.

https://www.twu.edu/institutional-review-board-irb/training-requirements/

Application Form

Make sure you use the most recent version of the application form from the IRB website.

Make sure you use the application form appropriate to the level of review for the study. (Expedited and Full Review studies use the same application form.)

Make sure all questions are answered. If a question is not applicable to the study, indicate that using an “N/A.”

Make sure application is complete with all signatures and all attachments.

Consent Form

If you have to obtain written consent, please use our sample consent form as a guide (Guide to Writing a Consent Form and Sample Consent Forms: Denton, Dallas, & Houston)

Online survey - include the consent information prior to participants answering survey items.

Written consent form - MUST include multiple pieces of information before they can be approved.

IRB Process

What happens after you submit an application…

- *Receipt notification email* – You receive a protocol number, and your application is sent out for review. We start reviewing it as soon as possible and look to see if everything fits within the Federal & TWU regulations
- *More Information Letter (if necessary)* – we need more information before we can approve it; you'll revise and resubmit
- *Exemption Notification (if appropriate)* – the study involved little-to-no risks and we don't need additional information, so you're good to move forward
- *Approval Letter (when appropriate)* – you provided all of the information we need and/or revised the application packet so that everything fits within the regulations so you're ready to move forward

Who is actually reviewing the applications?

The IRB is made up of volunteer faculty and community members representing various backgrounds.

- We are not here to be a road block (even if it might feel like it)
- We are here to work with you to protect the research participants
- We want to work together to build a community of compliance
- We are here to help you find ways to conduct your research AND stay within the Federal Regulations to protect participants as much as possible from potential harm
- Timing – remember, build into your protocol agenda the time it takes for a proper IRB review (be realistic; give yourself some wiggle room)

Take home points

Complete application

- Signatures in place
- Attachments – referenced, listed, and attached
- Address all required components

Consistency

View guidelines and templates – Application and Consent form

IRB changes

Final rule

IRB platform

Your Questions for Us

We're open to your questions!

Do you have specific questions about any of the information provided?

Do you have specific questions about your current or impending research projects?

You may also call or email us if you think of questions later on.

Contact Us:

Office of Research & Sponsored Programs Institutional Review Board (IRB)

https://twu.edu/institutional-review-board-irb/

Houston IRB Coordinator:

Madhura Maiya, PhD irb-Houston@twu.edu | 713-794-2480

Questions for the Chair or Co-chair:

Chair: Carolyn Da Silva, PT, DSc cdasilva@twu.edu
Co-Chair: Mindy A Patterson, PhD, RDN mpatterson14@twu.edu