



TEXAS WOMAN'S
UNIVERSITY™

Denton & Dallas Institutional Review Boards (IRBs)

Workshop Session I - IRB Process

Rhonda Buckley, Chair – Denton

Brandon (Rhett) Rigby, Co-Chair – Denton

Sharon Wang-Price, Chair – Dallas

Marsha Neville, Co-Chair – Dallas

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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 – December 2014.

Resources on our Website

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

Find Information on the following:

- Basic IRB Process
- IRB Procedures & Policy
- Full Review Meeting Dates
- Cayuse & Submitting New Applications
- Consent Form Guidelines and Samples
- Human Subjects Training Requirements
- Workshop and Training Sessions

Human Subjects Research

Research is a systematic investigation designed to test hypotheses, evaluate programs, draw conclusions, or contribute to generalizable knowledge. Research is usually described in a formal protocol that sets forth objectives and a set of procedures designed to reach those objectives.

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. Identifiable private information includes any acquired information via self-report, behavior, or observation in which the identity of research subjects is or may readily be ascertained by the investigators or be associated with the information.

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.

[TWU Human Subjects Training](#)

Cayuse

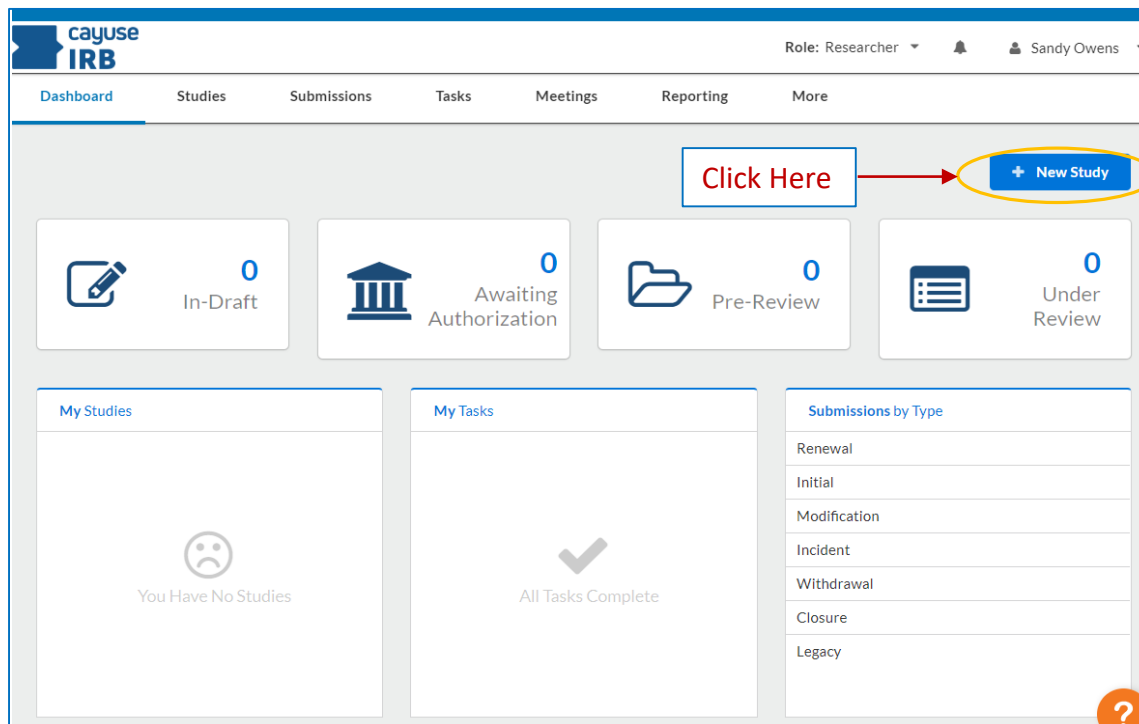
All TWU research team members **MUST** have a Cayuse account. Email irb@twu.edu to have an account created for yourself and for all other research team members. Be sure to include your:

- TWU email address
- Campus
- Department

Login to <https://twu.cayuse424.com/> with your TWU Portal/Password.

Cayuse User Guide

See our step-by-step [User Guide](#) to help you navigate the Initial application process from beginning to completing a submission.



Categories of Review

- [Exempt](#) – little-to-no risks; e.g., online and anonymous surveys, secondary data analysis, normal classroom activity, etc. *(1-2 weeks to review)*
- [Expedited](#) – no more than minimal risks; e.g., some clinical studies, low-risk interventions (See [OHRP](#) for specific categories and information.) *(2-3 weeks to review)*
- [Full Review](#) – more than minimal risks; e.g.: studies involve sensitive topic, vulnerable population, and high-risk interventions. *(up to 1 week after IRB meeting)*

IRB Process

What happens after you submit the application?

- *Certification Required email* – All PIs, Co-PIs, and Faculty Advisors will receive an email notification once an application has been submitted. After all of the above have certified, the department chair/dean will receive an email as the Organizational Approver to certify as well.
- *Receipt notification email* – Your application has been received by the IRB office. The IRB Analyst (Sandy) will pre-review (check that all necessary items are included) and will route your submission for review.

IRB Process

What happens after you submit the application?

- *More Information Requested (if necessary)* – You will receive an email notifying you that we need more information before we can approve it. Comments will be in your application; not in the letter. You will make revisions to your application and resubmit. All PIs, Co-PIs, and Faculty advisors must re-certify.

Click here for specific [[Instructions](#)] on how to locate and address comments.

IRB Process

What happens after you submit the application?

- *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

Other Cayuse Submissions

After your study is approved, you will be able to initiate the following:

- [Incident Report Submission](#)
- [Modification Submission](#)
- [Renewal Submission](#)
- [Closure Submission](#)

The PI, Co-Investigator(s), and/or Faculty Advisor will need to certify Incident, Modification, and Renewal Submissions. The department chair does not certify these submissions.



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