



TEXAS WOMAN'S
UNIVERSITY™

Houston Institutional Review Board

Workshop Session - IRB Process & Cayuse

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Institutional Review Board (IRB)

It is the policy of Texas Woman's University (TWU) that all TWU research conducted by any 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 – August 2020.

Resources on our Website

Find Information on the following:

- Basic Information on Levels of Review
- Cayuse Human Ethics (Cayuse IRB) & How to Submit
- Consent Form Guidelines and Samples
- Full Review Meeting Dates
- Human Subjects Training Requirements
- IRB Committee Members
- IRB Procedures & Policy
- Resources (Guidance & Other Important Information)
- 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).

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

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

Informed Consent

Why is informed consent so important?

- Informed consent is the process of telling potential research participants about the key elements of a research study and what their participation will involve. The informed consent process is one of the central components of the ethical conduct of research with human subjects.
<https://twu.edu/institutional-review-board-irb/informed-consent-guidance/>

When are you required to obtain written informed consent?

- <https://twu.edu/institutional-review-board-irb/informed-consent-guidance/when-must-written-informed-consent-be-obtained/>

Guide to Writing a Consent Form

This [Guide to Writing a Consent Form](#) provides the minimum standards for preparation of the written consent form.

New consent form requirements went into effect on January 21, 2019. Most notable requirements are:

- Key Information Summary
- Identifiable Private Information in future research

[Sample Consent Form – Dallas](#)

[Sample Consent Form – Denton](#)

[Sample Consent Form – Houston](#)

Appropriate Processes for Obtaining Consent

The process for obtaining consent is much more than just having the participant sign a consent form. You must provide sufficient details in the application about how/when/where you will obtain consent.

- **How** – Will you do this face-to-face? Will you mail or email consent forms to potential participants? Will participants be allowed appropriate time to read and make their decision? How will they get the forms back to you? How will they contact you with questions? How will they receive a copy of their consent form?
- **When** – Will they need to decide right then and there? Can they take the consent form home to read over and decide later? Will they have access to the consent form prior to the initial meeting time, and if so, is that when they sign the consent form?
- **Where** – Will consent be obtained online? Will you have participants sign the consent form in person at the site of the initial meeting? Will they scan and email their signed consent forms? Will they return consent forms to a school official?

Consent vs. Assent

CONSENT

- Obtained from *adult* participants
- In the state of Texas, the legal age of consent is 18. You may need to check the laws in other states or countries.
- If the participants are minors, consent must be obtained from a parent or legal guardian of the minor.

ASSENT

- Obtained from minors
- Adequate provisions must be made for attaining the assent of minors when the minors are capable of providing assent
- As with consent, it is good practice to obtain written assent

General guidelines to a successful IRB application

- Visit IRB website – Deadlines, meeting dates, contact info (full only)
- Detail recruitment procedures – location, flyers, scripts, agency approvals
- Detailed study procedures – What, when, where & how...
- Identify all risks & how the risks will be mitigated
- Identify appropriate data handling, storage, and destruction methods
- Provide an appropriate informed consent process

General guidelines to a successful IRB application

- Provide the IRB with all supporting materials – List and attach as they are referred
- Read the consent form guidelines
- Keep information consistent – application ↔ consent ↔ flyer/script.
- Consent form in 2nd person and at an 8th grade reading level

Research and COVID-19 Response

Face to face research – Must add the risk of Covid-19 exposure to the procedures and consent form, included necessary safety measures.

Guidance for minimizing the risk of exposure to COVID-19 in human subjects research can be [found here](#).

Guidance for virtual alternatives to face-to-face interaction can be [found here](#)

Cayuse

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

Once you have an account set up, go to: <https://twu.cayuse424.com/> and login using your TWU Portal/Password.

Logging into Cayuse



Cayuse Research Suite

3.8.0

Research Administration Modules

- [Cayuse 424](#)
- [Cayuse IRB \(Human Studies Compliance\)](#)

Click Here

System Administration Applications

- [Backbone](#)
- [Research Contacts](#)
- [Workflow](#)

Application Help

- [Research Suite Support Center](#)

Cayuse Dashboard

Role: Researcher   Sandy Owens

[Dashboard](#) [Studies](#) [Submissions](#) [Tasks](#) [Meetings](#) [Reporting](#) [More](#)

[+ New Study](#)

 0
In-Draft

 0
Awaiting Authorization

 0
Pre-Review

 0
Under Review

My Studies



You Have No Studies

My Tasks



All Tasks Complete

Submissions by Type

Renewal
Initial
Modification
Incident
Withdrawal
Closure
Legacy

Creating a New Study

The screenshot displays the cayuse IRB dashboard interface. At the top left is the logo for 'cayuse IRB'. On the top right, the user's role is 'Researcher' and the name is 'Sandy Owens'. A navigation bar below the header contains links for 'Dashboard', 'Studies', 'Submissions', 'Tasks', 'Meetings', 'Reporting', and 'More'. The 'Dashboard' link is currently selected. The main content area features four summary cards: 'In-Draft' (0), 'Awaiting Authorization' (0), 'Pre-Review' (0), and 'Under Review' (0). Below these are three panels: 'My Studies' (empty, with a sad face icon and the text 'You Have No Studies'), 'My Tasks' (empty, with a checkmark icon and the text 'All Tasks Complete'), and 'Submissions by Type' (a list including Renewal, Initial, Modification, Incident, Withdrawal, Closure, and Legacy). A blue button labeled '+ New Study' is highlighted with a yellow circle, and a red box with the text 'Click Here.' and an arrow points to it. A small orange question mark icon is located in the bottom right corner.

Role: Researcher **Sandy Owens**

Navigation: Dashboard | Studies | Submissions | Tasks | Meetings | Reporting | More

Summary Cards:

- In-Draft: 0
- Awaiting Authorization: 0
- Pre-Review: 0
- Under Review: 0

My Studies: You Have No Studies

My Tasks: All Tasks Complete

Submissions by Type: Renewal, Initial, Modification, Incident, Withdrawal, Closure, Legacy

Action: [+ New Study](#)

Adding a Title

cayuse IRB Role: Researcher Sandy Owens

Dashboard Studies Submissions Tasks Meetings Reporting More

Studies / Study Details [+ New Submission](#)

Study Details Submissions

Sandy's Amazing Super Study, Yeah! (SASSY!)

PDF Delete

Enter your title here.

Click on the check mark when you are satisfied with your title.

Approval Date:	Expiration Date:	Organization:	Active Submissions:	Population Flags:	Additional Flags:
N/A	N/A	N/A			
Admin Check-In Date:	Closed Date:	Current Policy	Sponsors:		
N/A	N/A		N/A		

Editing your Title

The screenshot shows the 'cayuse IRB' interface. The navigation menu includes Dashboard, Studies, Submissions, Tasks, Meetings, and Reporting. The current page is 'Study Details' for 'IRB-FY2020-3'. A red 'Unsubmitted' badge is present. The title 'Sandy's Amazing Super Study, Yeah! (SASSY!)' is displayed in a text box with a pencil icon to its right, which is circled in yellow. Below the title are 'PDF' and 'Delete' buttons. A table of study details is shown at the bottom.

Approval Date:	Expiration Date:	Organization:	Active Submissions:	Population Flags:
N/A	N/A	N/A	N/A	
Admin Check-In Date:	Closed Date:	Current Policy	Sponsors:	
N/A	N/A	Post-2018 Rule	N/A	

Hover your cursor to the side of your title, and click on the pencil to edit. Once you are finished editing, click on the check mark to save.

Creating a New Submission

The screenshot shows the Cayuse IRB web application interface. At the top left is the logo for Cayuse IRB. The top right shows the user's role as 'Researcher' and their name 'Sandy Owens'. Below the header is a navigation menu with 'Dashboard', 'Studies', 'Submissions', and 'Tasks'. The main content area is titled 'Study Details' and shows an 'Unsubmitted' status for a study named 'IRB-FY2020-3 Sandy's Amazing Super Study, Yeah! (SASSY!)'. There are buttons for 'PDF' and 'Delete'. A dialog box titled 'Begin Initial Submission' is overlaid on the screen, with the text: 'You've created a study! Click here to begin your initial submission to the IRB.' A blue button with a plus sign and the text '+ New Submission' is highlighted with a yellow circle. A red arrow points from this button to a callout box containing the text: 'Click here, then click on "Initial."'

Role: Researcher | Sandy Owens

Dashboard | Studies | Submissions | Tasks

Studies / Study Details

Study Details

Unsubmitted

IRB-FY2020-3 Sandy's Amazing Super Study, Yeah! (SASSY!)

PDF | Delete

Approval Date: N/A | Expiration Date: N/A | Organization: N/A | Active Submissions: N/A | Population Flags: | Additional Flags:

Admin Check-In Date: N/A | Closed Date: N/A | Current Policy: Post-2018 Rule | Sponsors: N/A

Begin Initial Submission

You've created a study! Click here to begin your initial submission to the IRB.

+ New Submission

Click here, then click on "Initial."

Starting your Application

The screenshot displays the Cayuse IRB application interface. At the top, the logo for 'cayuse IRB' is on the left, and the user's role 'Role: Researcher' is on the right. A navigation bar includes 'Dashboard', 'Studies', 'Submissions', 'Tasks', 'Meetings', 'Reporting', and 'More'. The main content area shows a breadcrumb trail 'Studies / Study Details / Submission Details' and a four-step process flow: 1. In-Draft (Submission is with researchers), 2. Awaiting Authorization (Submission is awaiting certification or approval), 3. Pre-Review (Submission is being prepared for review), and 4. Under-Review (Submission is being prepared for review). Below this, a submission titled 'Initial' (IRB-FY2020-3 - Sandy's Amazing Super Study, Yeah! (SASSY!)) is shown with an 'Unsubmitted' status. Action buttons for 'Edit', 'PDF', and 'Delete' are visible, with 'Edit' circled in yellow. A red box with the text 'Click on any of these to start your application.' has arrows pointing to the 'Edit' button and the 'Required Tasks' list. The 'Required Tasks' list includes 'Assign PI', 'Assign PC', and 'Complete Submission', with the first and last items circled in yellow.

Unsubmitted

Initial
IRB-FY2020-3 - Sandy's Amazing Super Study, Yeah! (SASSY!)

[Edit](#) [PDF](#) [Delete](#)

Required Tasks:

- [Assign PI](#)
- ✓ [Assign PC](#)
- [Complete Submission](#)

Application Form

The screenshot shows the Cayuse IRB application interface. At the top, the logo for 'cayuse IRB' is on the left, and the user's role 'Role: Researcher' and name 'Sandy Owens' are on the right. Below the header is a navigation menu with options: Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, and More. The main content area is titled 'STUDY' and 'IRB NUMBER: IRB-FY2020-3' with the study name 'Sandy's Amazing Super Study, Yeah!...'. There are buttons for 'CREATE PDF', 'COMPARE', and 'SAVE'. A sidebar on the left lists sections 1 through 10, with green checkmarks next to '1- Basic Information' and '2- Research & Review...'. The main form area shows 'Study Dates' with a prompt: 'Provide an estimated start and end date for this study.' There are two date input fields: 'Start Date' (10/01/2019) and 'End Date' (10/01/2020). Below these is a question: '* Does this study require IRB review by more than one institution?' with radio buttons for 'Yes' and 'No'. Annotations include a yellow oval around the sidebar sections, a red asterisk around the 'Start Date' and 'End Date' labels, and a red asterisk around the question text. Red arrows point from the asterisks to a text box on the right and from the sidebar sections to a text box at the bottom.

Role: Researcher | Sandy Owens

Dashboard | Studies | Submissions | Tasks | Meetings | Reporting | More

STUDY | IRB NUMBER: IRB-FY2020-3 | CREATE PDF | COMPARE | SAVE

Sandy's Amazing Super Study, Yeah!...

Sections

- 1- Basic Information ✓
- 2- Research & Review... ✓
- 3- Study Personnel Inform...
- 4- Study Design & Method...
- 5- Subject Information
- 6- Subject Recruitment
- 7- Study Procedures
- 8- Informed Consent Proc...
- 9- Study Instruments
- 10- Risks & Benefits

Study Dates

Provide an estimated start and end date for this study.

* Start Date
This is an estimated start date. You may NOT start your study until you receive IRB approval.
10/01/2019

* End Date
We will use the estimated end date you provide here as a basis for your expiration date.
10/01/2020

* Does this study require IRB review by more than one institution?
 Yes
 No

The red * means you must answer the question. You cannot submit until it is answered.

Each section will be marked with a green check mark once it is complete. You cannot submit until each section has a green check mark beside it.

Completing Your Submission

The screenshot displays the Cayuse IRB submission interface. At the top, the logo for Cayuse IRB is visible, along with the user's role (Researcher) and name (Sandy Ow). The navigation bar includes options for Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, and More. The current study is identified as "Sandy's Amazing Super Study, Yeah! (SA...)" with IRB number IRB-FY2020-3. A sidebar on the left lists ten sections, each with a green checkmark indicating completion. A yellow oval highlights the "COMPLETE SUBMISSION" button at the bottom of the sidebar. A red box highlights the "10- Risks & Benefits" section, with a red arrow pointing to it from a text box. The main content area shows the "Potential Risks and the Steps to Minimize the Risks" section, with a text editor containing the text "Loss of Confidentiality".

Role: Researcher | Sandy Ow

Dashboard Studies Submissions Tasks Meetings Reporting More

IRB NUMBER: IRB-FY2020-3

STUDY Sandy's Amazing Super Study, Yeah! (SA...)

CREATE PDF COMPARE SAVE

Sections

- 1- Basic Information ✓
- 2- Research & Review ✓
- 3- Study Personnel Information ✓
- 4- Study Design & Methods ✓
- 5- Subject Information ✓
- 6- Subject Recruitment ✓
- 7- Study Procedures ✓
- 8- Informed Consent ✓
- 9- Study Instruments ✓
- 10- Risks & Benefits ✓

Routing
Send to PI for certification?

COMPLETE SUBMISSION >

* Potential Risks and the Steps to Minimize the Risks

* List all the potential risks to the human subject and listed on the consent form (if applicable).

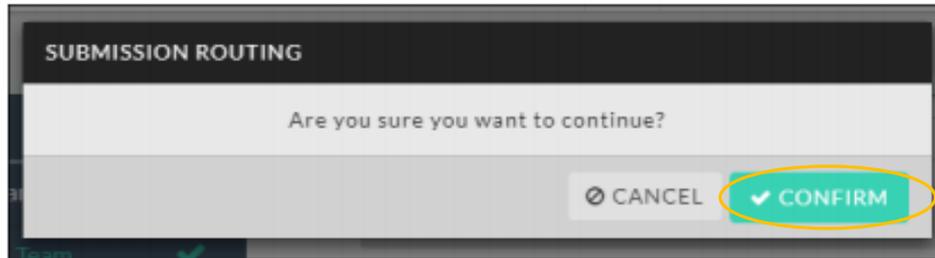
Loss of Confidentiality

* Describe how each risk will be minimized.

Loss of Confidentiality - Confidentiality will be a potential risk of loss of confidentiality in all transactions. Participants will receive coded data and all other data in the PI's password protected work office. All other data will be stored in her work office. All other data will be stored in her work office.

Once you see green check marks on each section, the "Complete Submission" button will appear at the bottom. *Please note that you should only click on this button only after all Co-PIs, and the faculty advisor has looked over the application. Once you click on this, your application be 'locked' to editing.

Confirm & Certify



Once you click on "Complete Submission," you will have to confirm the routing of your submission.

A screenshot of a submission page. At the top, there is a progress bar with three stages: 1. In-Draft (Submission is with researchers), 2. Awaiting Authorization (Submission is awaiting certification or approval), and 3. Pre-Review (Submission is being prepared for review). The 'Awaiting Authorization' stage is currently active. Below the progress bar, the submission is titled 'Initial' with the ID 'IRB-FY2019-41 - Sample test study'. There are buttons for 'View', 'PDF', and 'Delete'. On the right, there is a 'Routing:' section with 'Return' and 'Certify' buttons. The 'Certify' button is highlighted with a yellow oval. Below this, there is a table of metadata:

PI:	Current Analyst:	Decision:	Policy:	Required Tasks:
PI name appears here	N/A	N/A	Pre-2018 Rule	N/A
Review Type:	Review Board:	Meeting Date:		
N/A	N/A	N/A		

Below the metadata table, there are tabs for 'Approvals' and 'Task History'. At the bottom, there is a 'Research Team' section with a table:

Name	Role	Result	Date
PI name appears here	Principal Investigator	Pending Certification	

Then, you must Certify your submission.

Confirm Again

Certify



I confirm that I have the proper training, expertise and resources to conduct this study. I understand and accept my responsibilities as the Principal Investigator and Primary Contact for this study. I confirm that I have no significant financial conflict of interest in this project or have disclosed a conflict per institutional policies and federal requirements. I confirm that the information provided in this application is true, complete, and accurate to the best of my knowledge; that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties; and agree to accept responsibility for the oversight and scientific conduct of the project.

Confirm one last time. Each PI, Co-PI, and Department Chair/Dean must also certify and confirm.

Cayuse Help

Remember, you can always call the Houston -IRB office at 713-794-2480 or email irb@twu.edu and we can help you with Cayuse issues.

For detailed instructions on how to start and submit a new study, here is a [Guide to Creating and Submitting a New Study in Cayuse](#).

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 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 make revisions in Cayuse](#).

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.

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
- 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)

Your Questions for Us

We are 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.



TEXAS WOMAN'S
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Contact Us:

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

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

Houston Research Coordinator:

Madhura Maiya, PhD: mmaiya@twu.edu | 713-794-2480

Questions for the Chair or Co-chair:

Chair: Mindy A Patterson, PhD, RDN mpatterson14@twu.edu

Co-Chair: Wayne Brewer PT, PhD, MPH wbrewer@twu.edu