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.

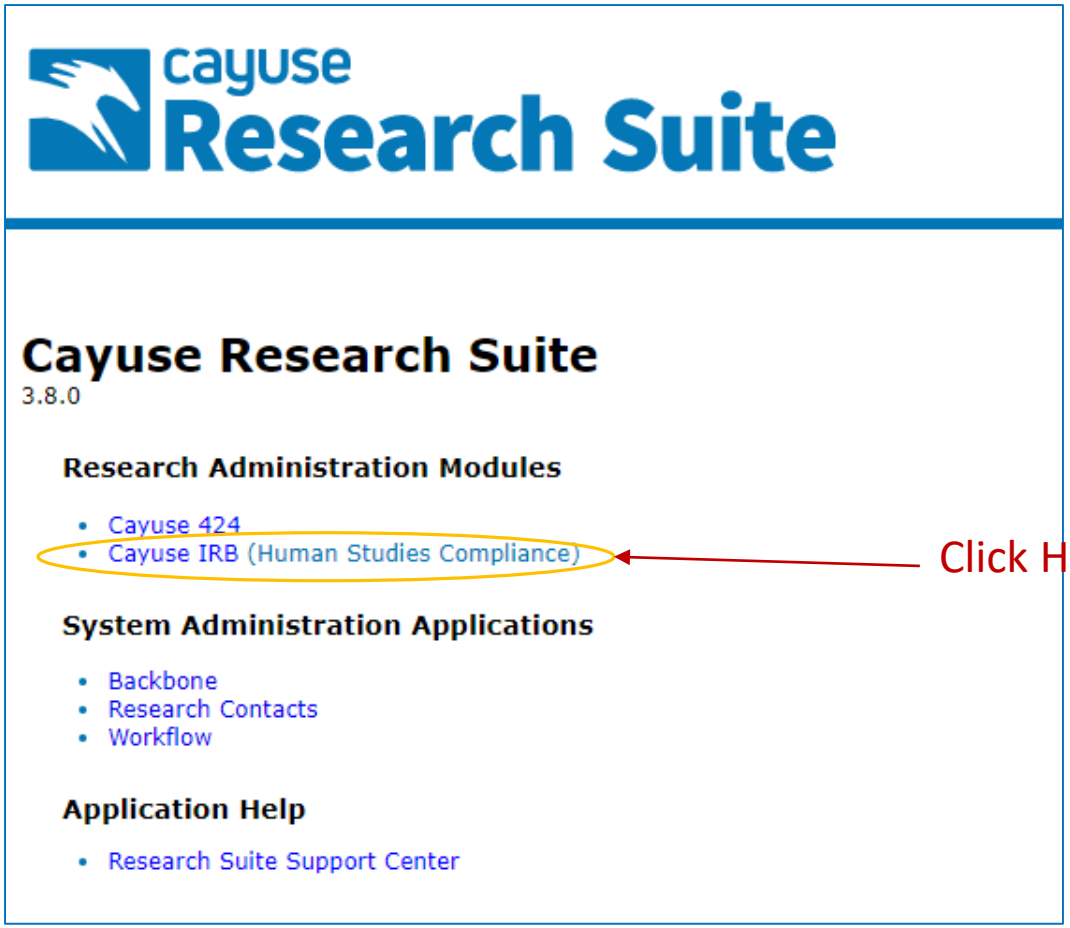
Guidance for virtual alternatives to face-to-face interaction can be found here

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.

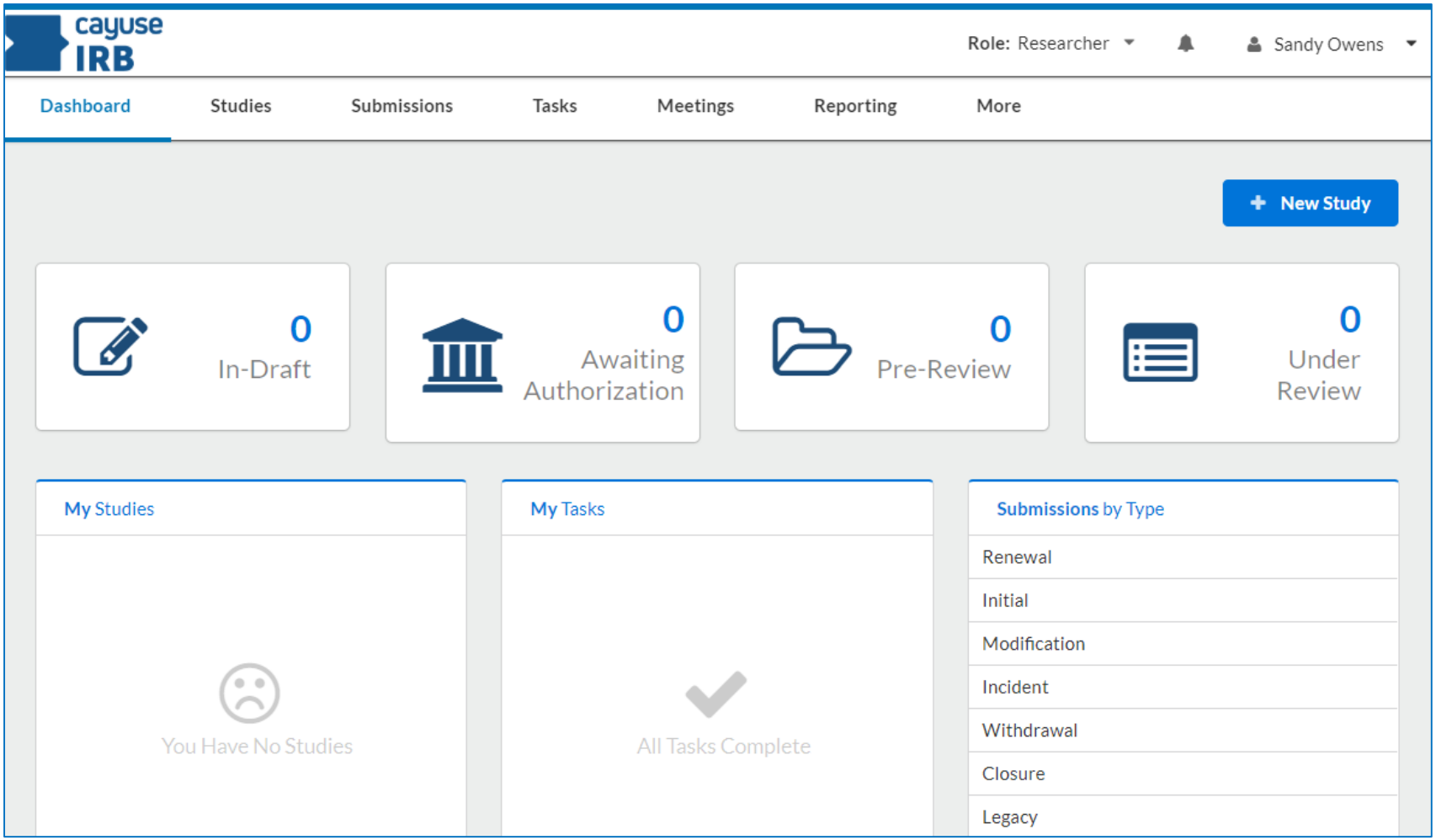
Once you have an account set up, go to: https://twu.cayuse424.com/ and login using your TWU Portal/Password.

Logging into Cayuse

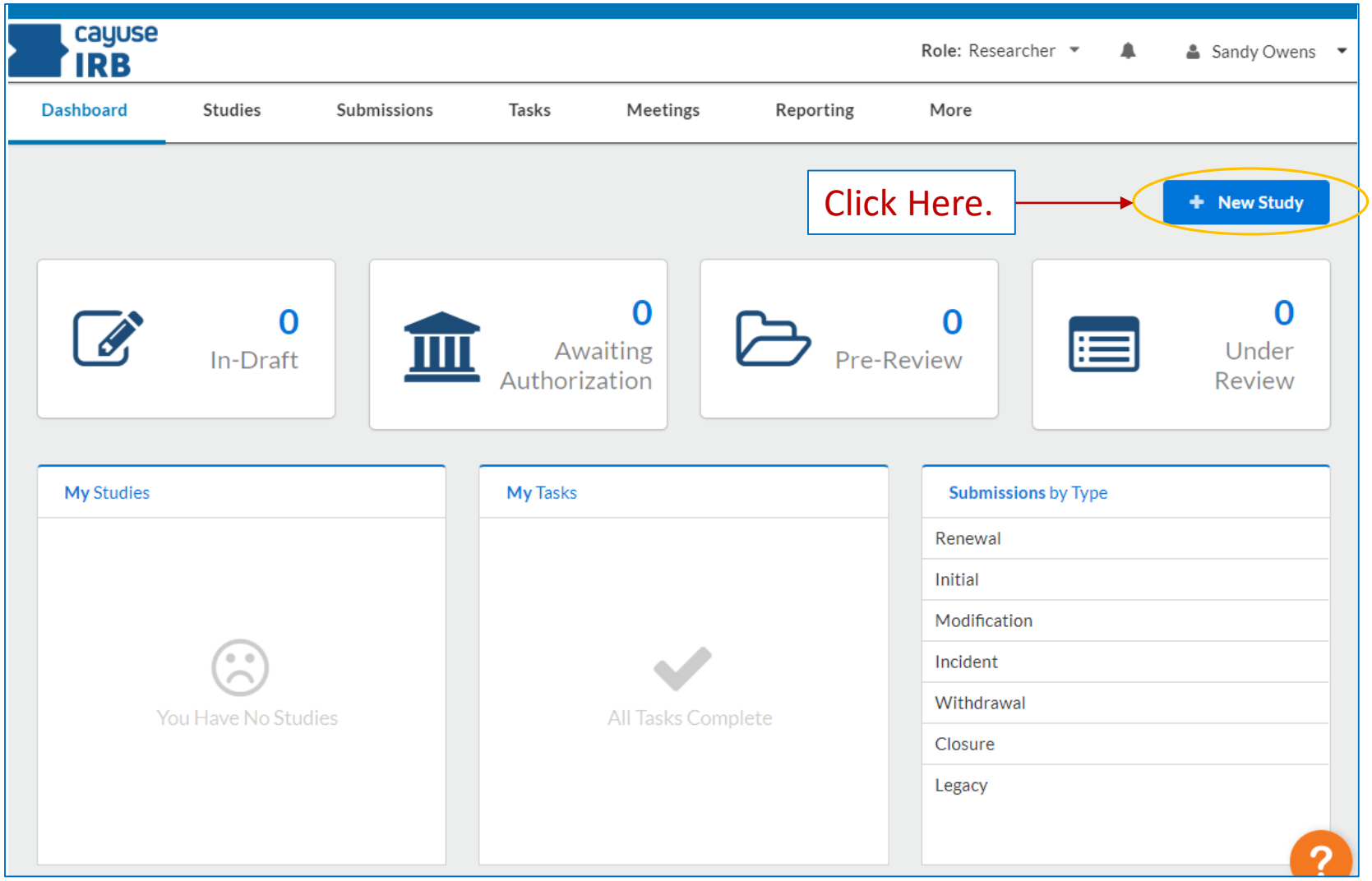


Click Here

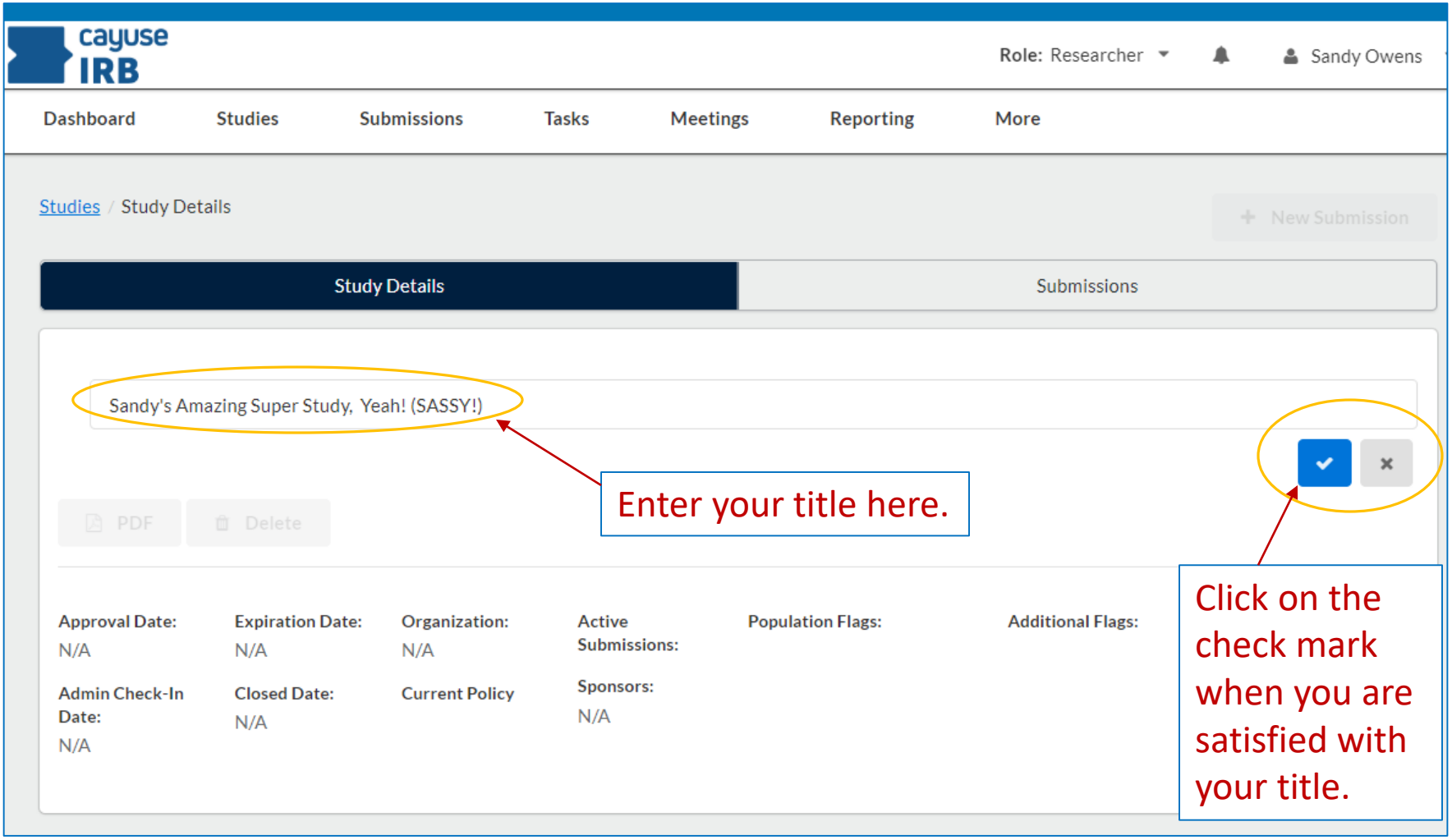
Cayuse Dashboard



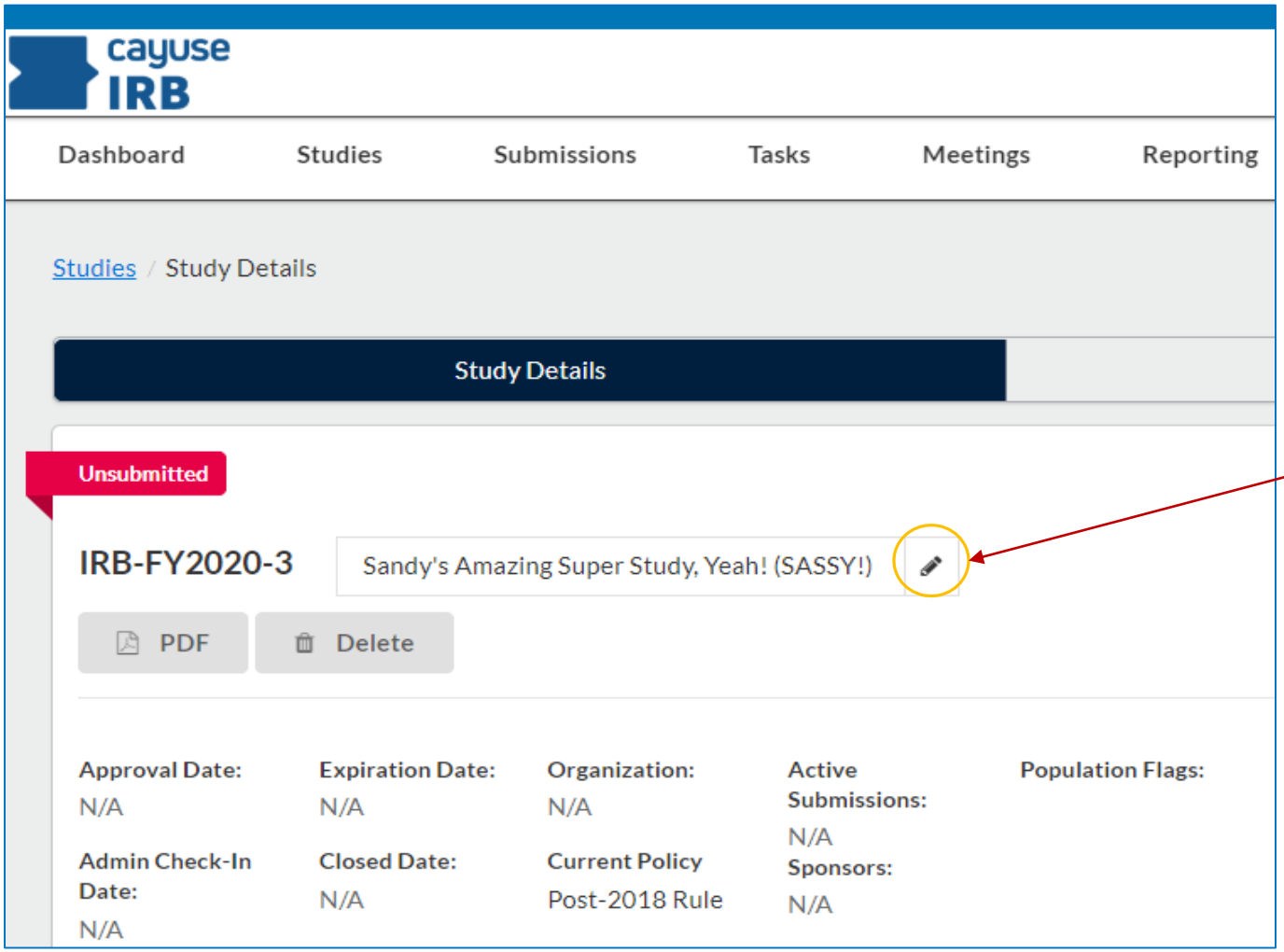
Creating a New Study



Adding a Title

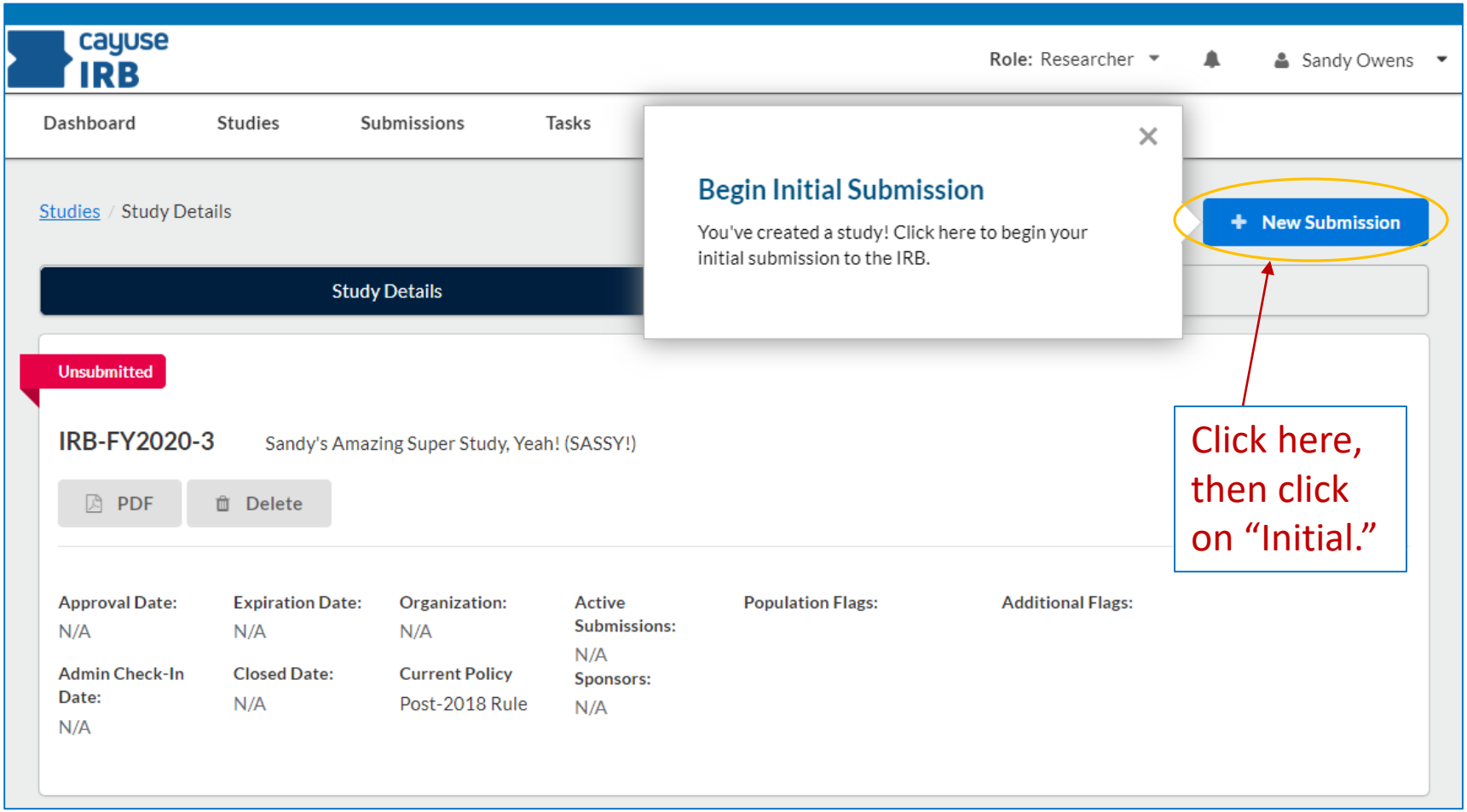


Editing your Title

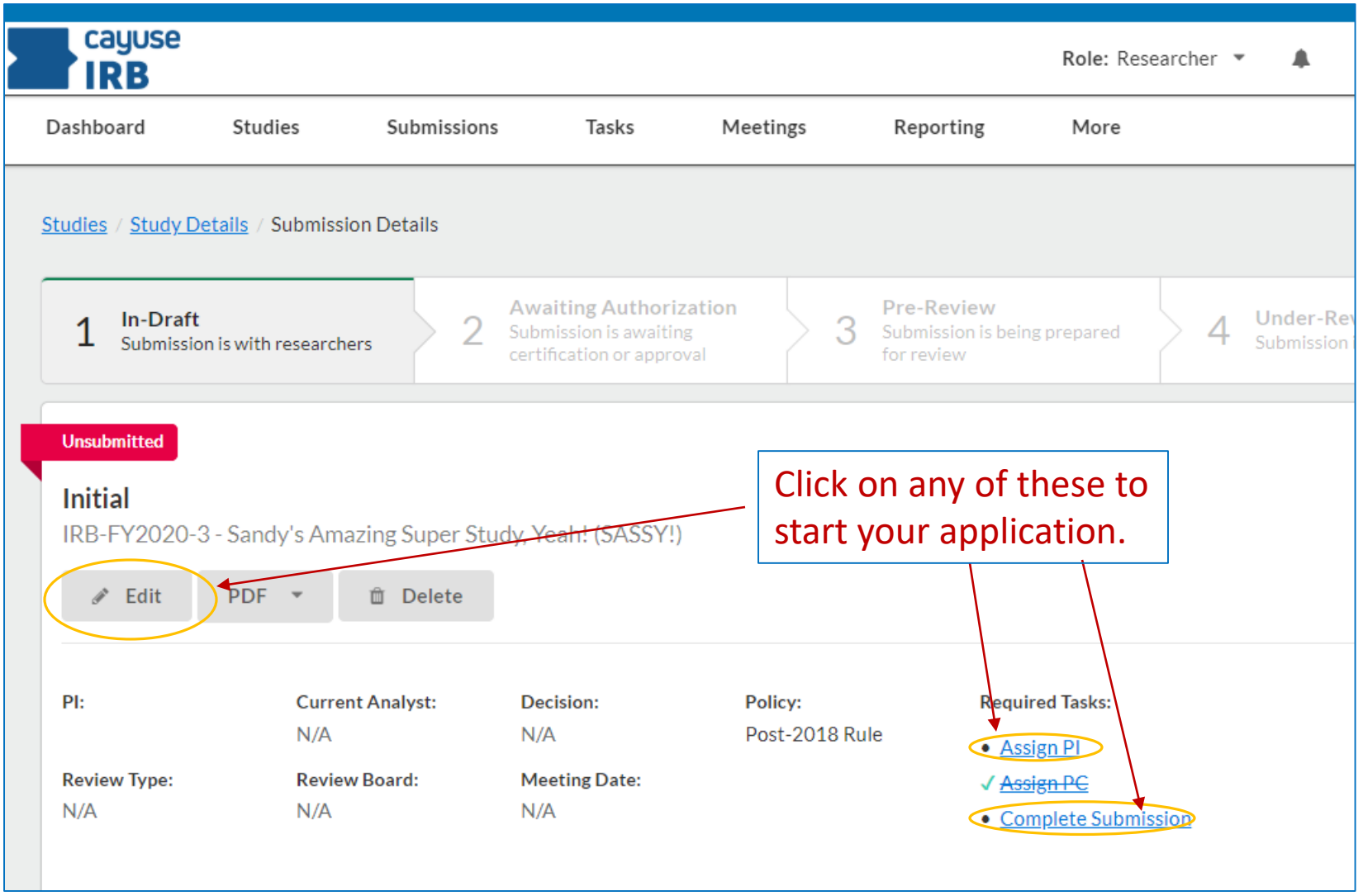


Hover your cursor to the side of your title, and click on the pencil to edit. Once you are finished editing, click on the check mark to save.

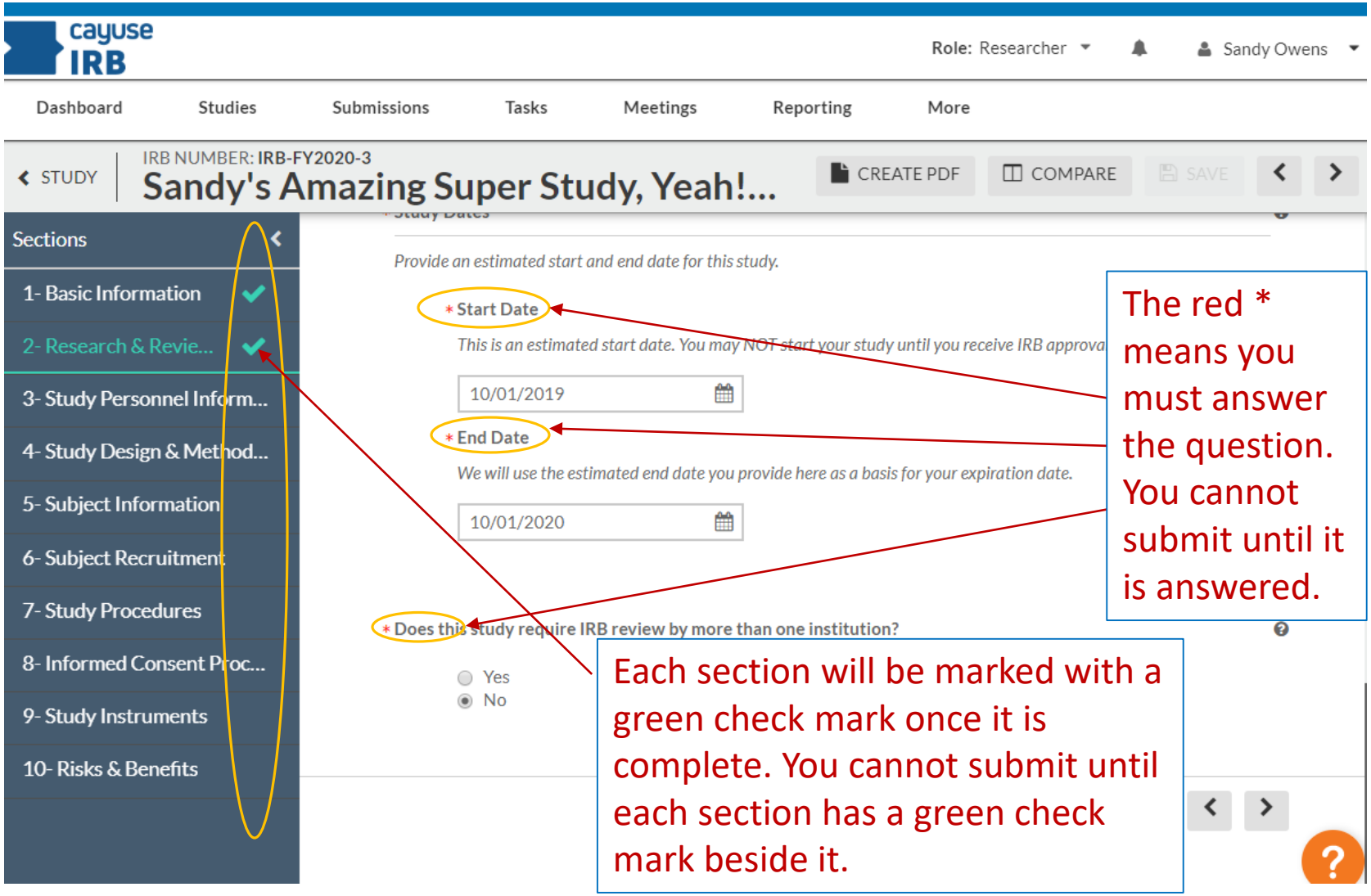
Creating a New Submission



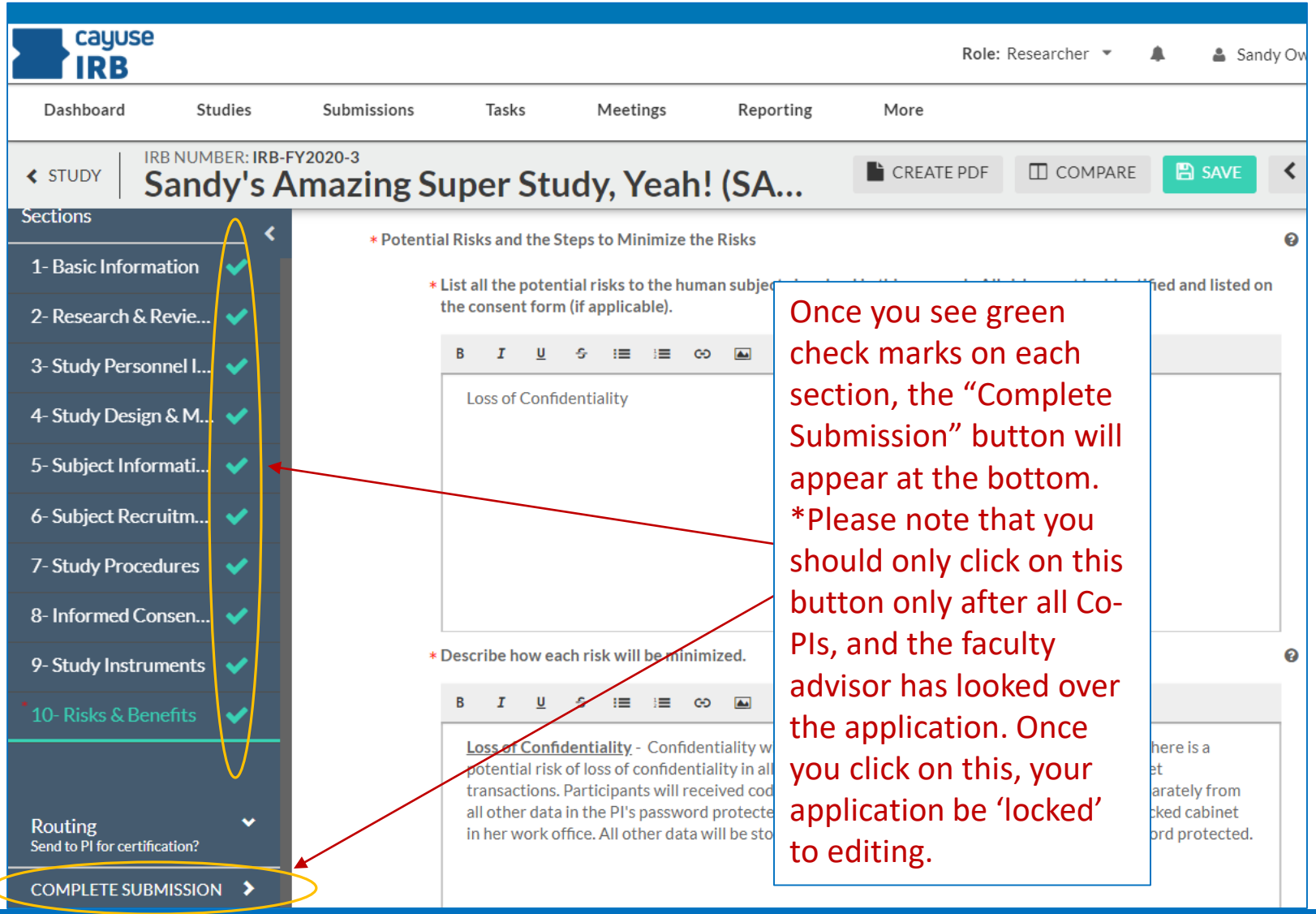
Starting your Application



Application Form

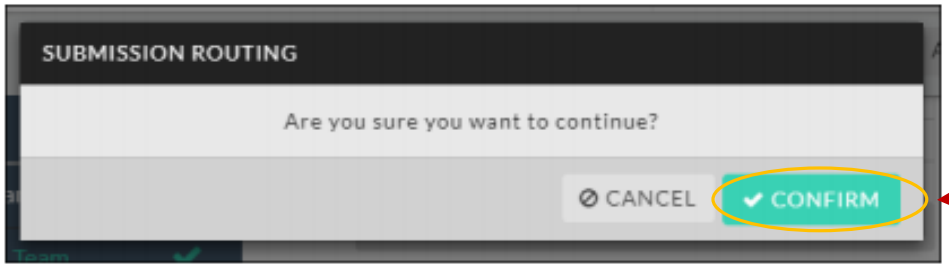


Completing Your Submission

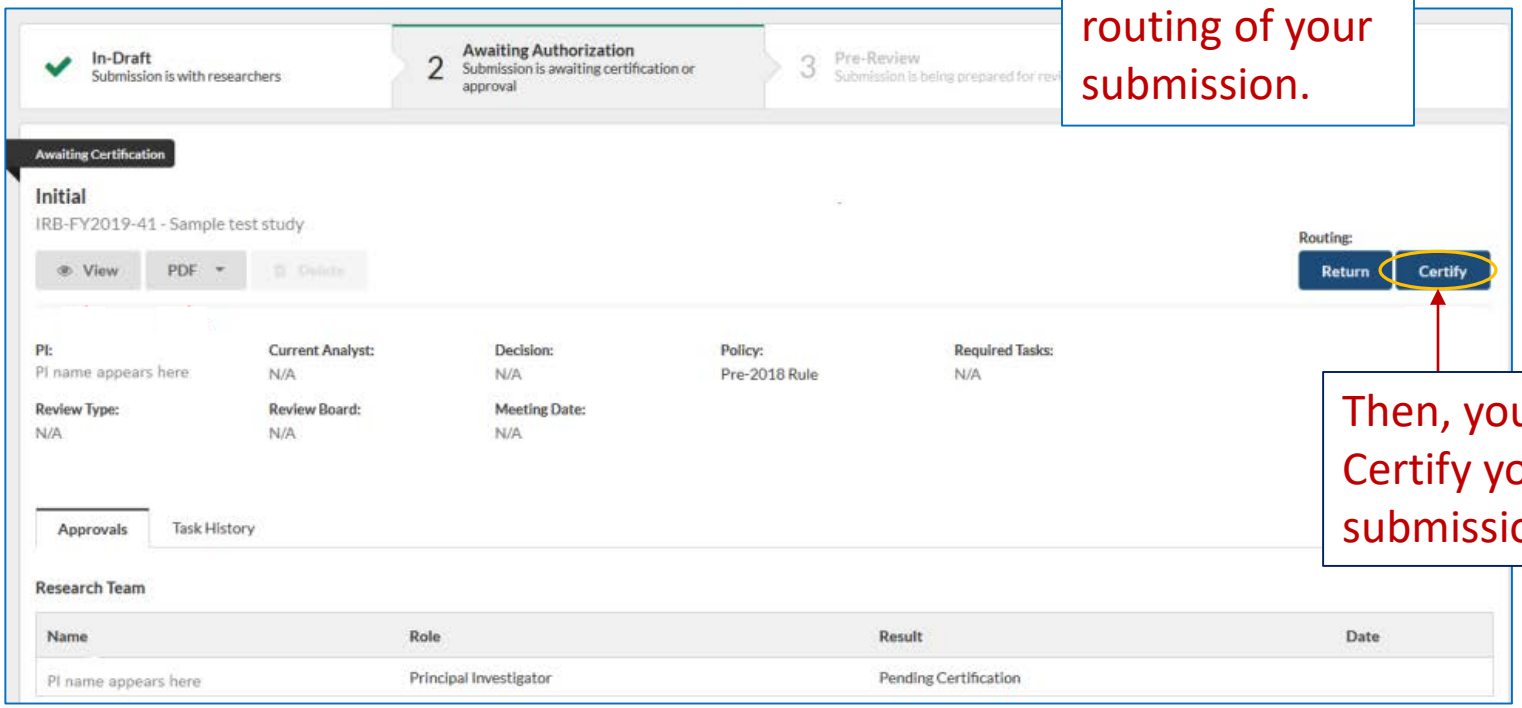


Once you see green check marks on each section, the “Complete Submission” button will appear at the bottom. *Please note that you should only click on this button only after all Co-PIs, and the faculty advisor has looked over the application. Once you click on this, your application be ‘locked’ to editing.

Confirm & Certify

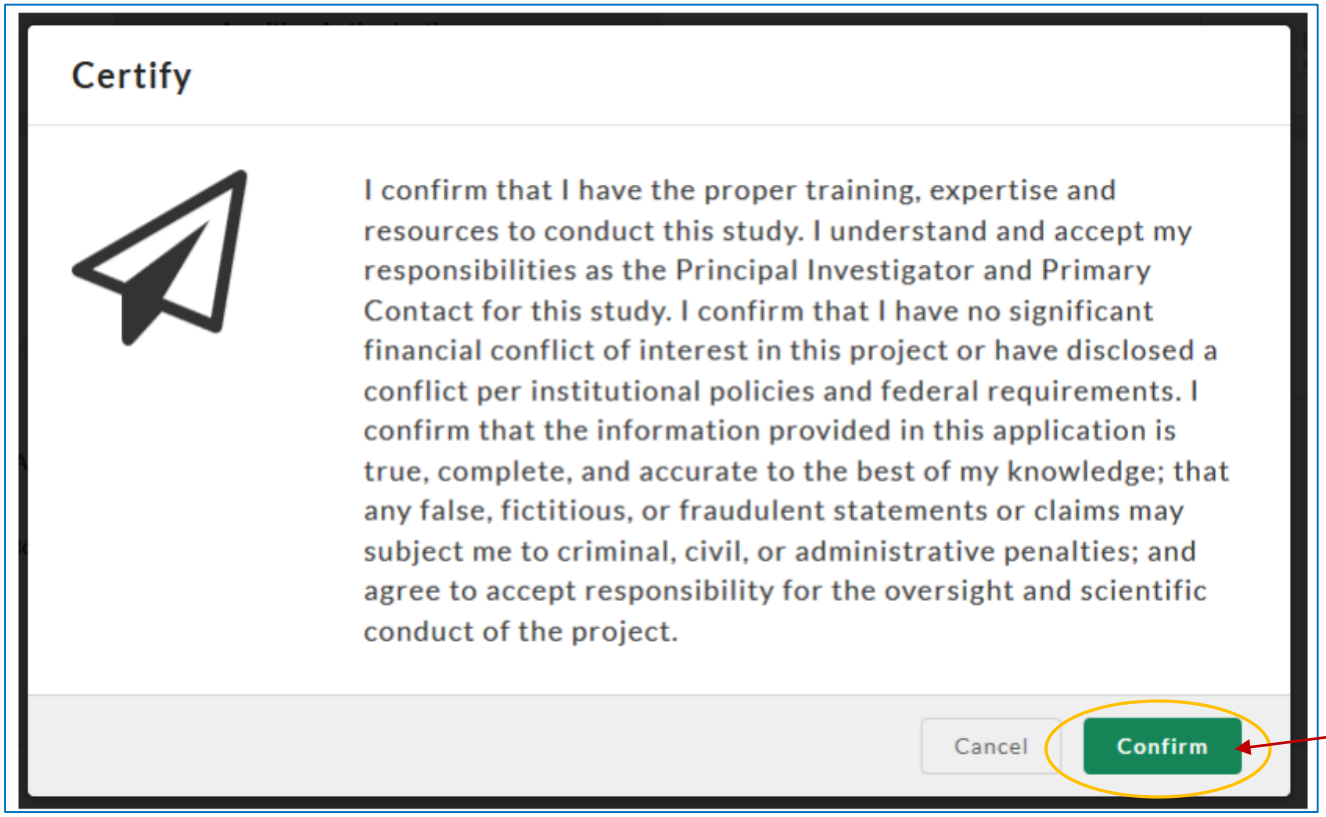


Once you click on “Complete Submission,” you will have to confirm the routing of your submission.



Then, you must Certify your submission.

Confirm Again



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 the 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 UNIVERSITY

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