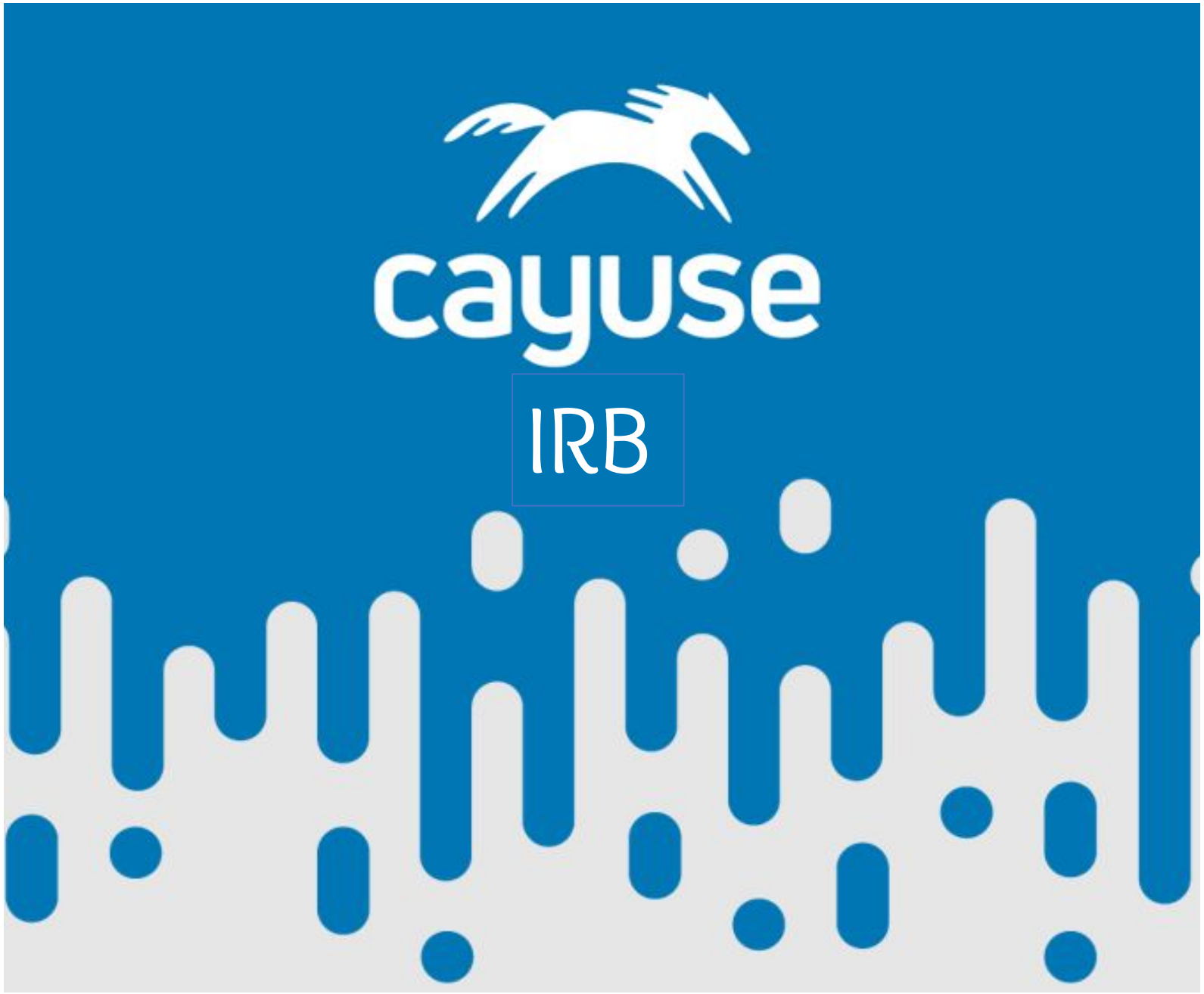


Cal State University East Bay
March 26, 2020

Jeanne Dittman
Director of Compliance and Standards
Academic Resources and Planning
ORSP

BEFORE WE GET STARTED

IRB QUESTIONS
Quick Review

WHAT IS IRB?

- IRB is an acronym for Institutional Review Board
  - The committee or body that is delegated the authority to provide oversight of human subjects research

WHAT IS RESEARCH, AS DEFINED BY IRB REGULATIONS?

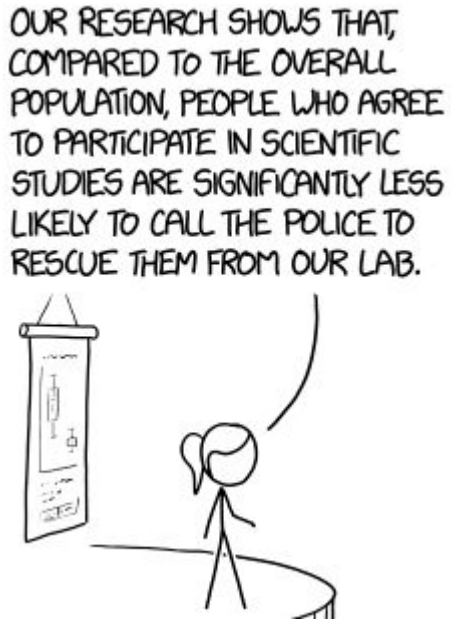
- A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- At CSUEB, the IRB considers any research intended for publication to be research. This includes journal articles, conference presentations or masters theses. In general, class projects are not considered research (unless they may be published).
- Human subject research is research that involves humans as research subjects by collecting data from them, performing experiments on them or with them, and may include observing humans.

BEFORE WE GET STARTED

WHEN DO I NEED TO SUBMIT AN IRB PROTOCOL?

When your research includes the use of Human Subjects.

- Collecting information and biospecimens from humans - surveys, questionnaires, blood samples, hair samples, dna. "obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens (46.102[e][1][ii]"
- Performing experiments on humans or with humans - tests, drugs, observations on identified individuals whether or not influenced/manipulated.
- In a few instances research may be Exempt from full review, **but the IRB Protocol must still be submitted s**o that the designated IRB representative can review the project and make the determination.
- Journalism, certain scholarly activities such as oral history, public health surveillance, criminal justice or criminal investigative activities, and activities in support of intelligence, homeland security, defense, or other national security missionse][1][ii] have been deemed not to be research.
- **Goal is to protect human subjects, their privacy, and confidentiality.**



1999 Explain XKCD

IRB Review Categories - Non-exempt Research (Full Committee Review)
Exempt Research (Administrative Review)
Expedited Review of Non-Exempt Research (without an IRB meeting)
Normal Educational Practices Considered Exempt from Full Committee Review.

USING CAYUSE IRB TO SUBMIT AND MANAGE IRB PROTOCOLS.

What?

- Cayuse IRB for Human Subjects Research **provides** **an online space for IRB protocol submission, IRB review and approval.**

Why?

- Use of Cayuse is **beneficial to all** - **efficient, effective, thorough**.
- Cayuse IRB **expedites** all phases of **protocol creation, submission, review, approval, and renewal, creates an online repository**, and is **integrated with the required CITI training**.

Who?

- **Faculty**, **students**, **staff**, and **administrators** will use **Cayuse**.
- Whose research are we talking about?
  - **Research conducted** by **CSUEB faculty, staff,** or **student investigators**, and also **research by investigators from other institutions or agencies who are working in conjunction with CSUEB in any capacity**. (Only the CSUEB team will use Cayuse IRB.)

When?*

- Effective **3/1/20** Cayuse is **required for use by faculty, staff, and administrators**
- Effective **6/1/20** Cayuse is **required for use by Student PIs**

*Cayuse has been available since January for early adopters.

CAYUSE IRB FOUND IN MANY LOCATIONS

CAYUSE IRB TRAINING SITE LINK (FOR PRACTICE ONLY)
https://csueastbay-t.cayuse424.com/

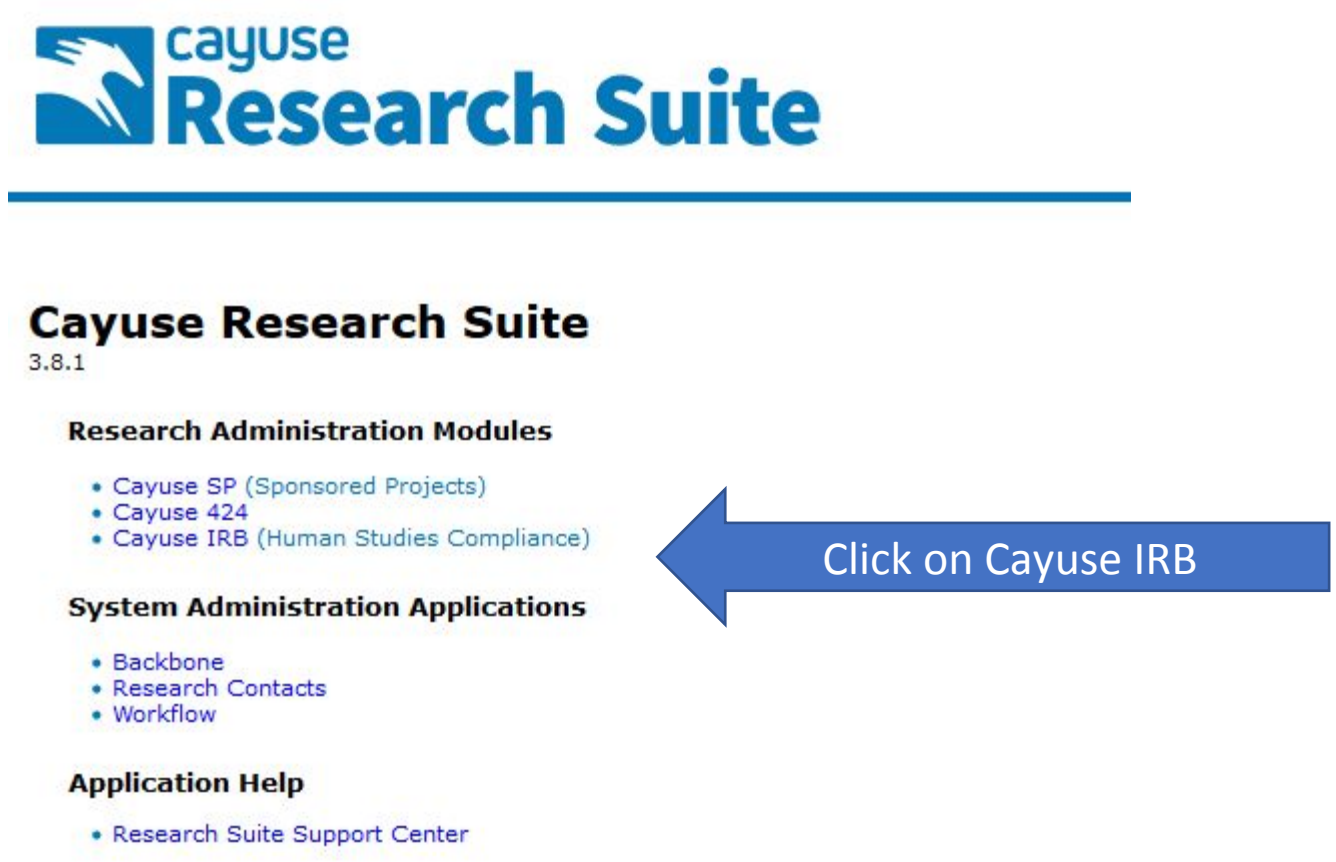
CSU EAST BAY CAYUSE WEB SITE (TO SUBMIT YOUR PROTOCOL)
- https://csueastbay.cayuse424.com/

ORSP CAYUSE WEB PAGE
- https://www.csueastbay.edu/orsp/cayuse/

ORSP COMPLIANCE TOOLS WEB PAGE
- **https://www.csueastbay.edu/orsp/compliance/tools.html**

CAYUSE IRB HOW TO
https://www.csueastbay.edu/orsp/compliance/irb/protocol-submission.html

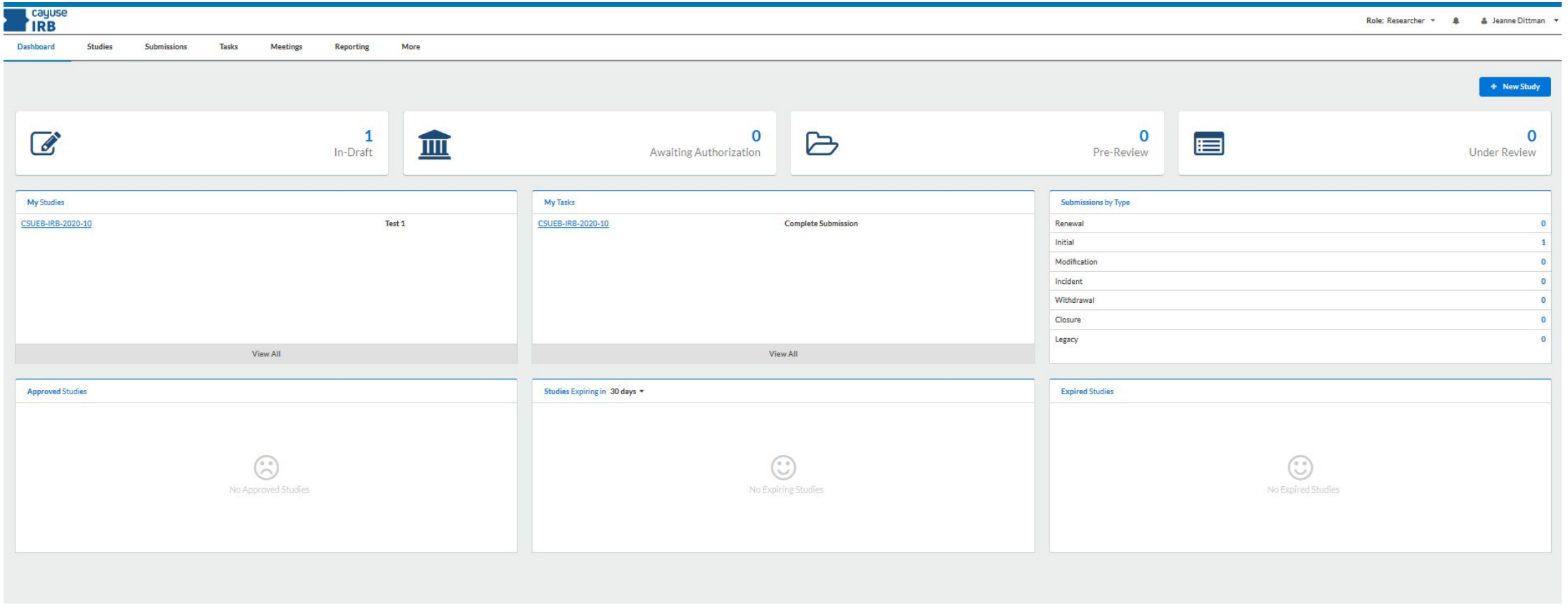
Welcome to Cayuse IRB!



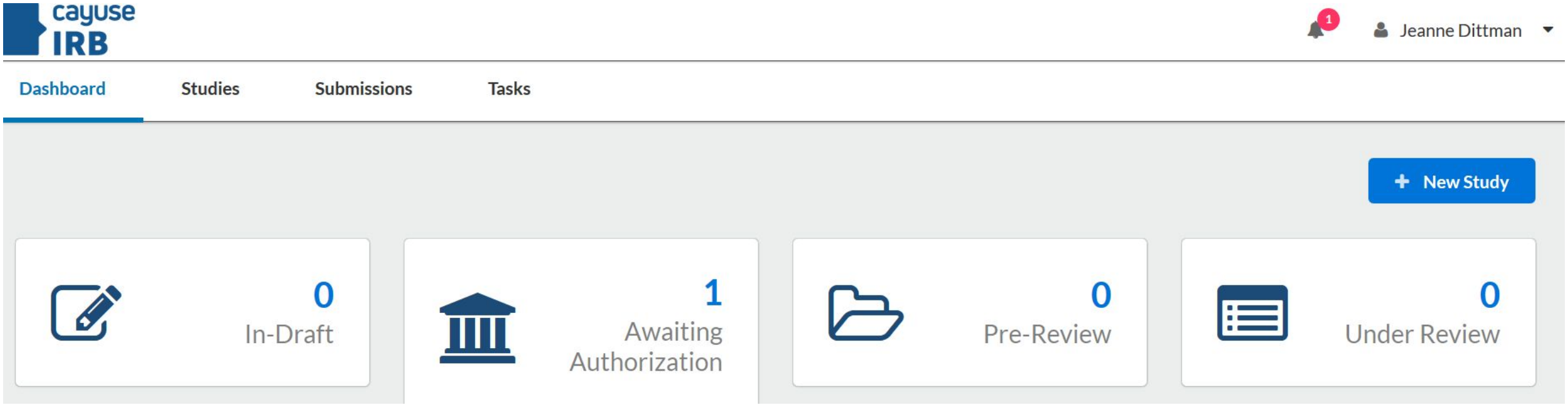
https://csueastbay.cayuse424.com/

Training site password: CSUEBF%

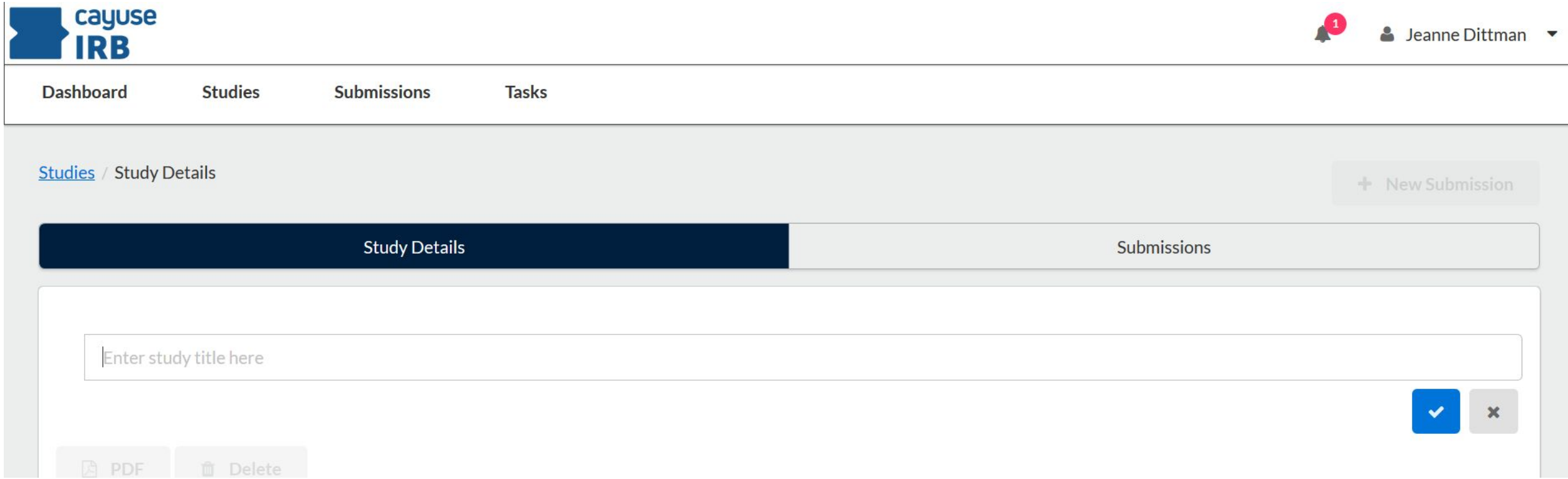
- **Click on Cayuse IRB**
- **Dashboard** – Studies (IRBs), Tasks (Pending), Approved, Expiring, and Expired – and Submittals listed by whether they are Initial, Modifications, Renewals, have Incidents, were withdrawn, or closed.



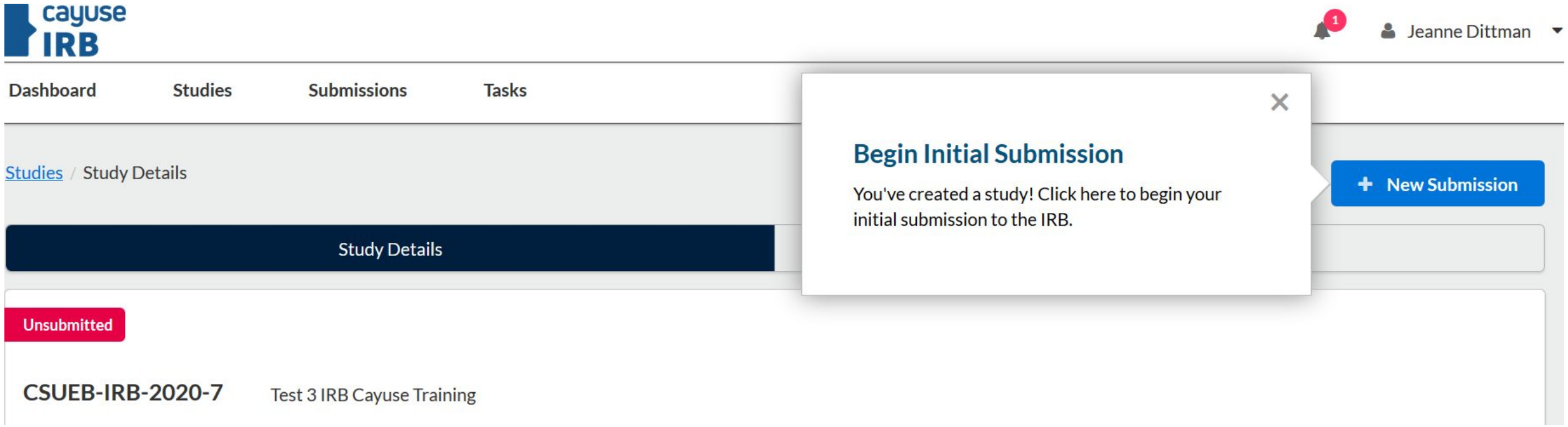
- **Click on New Study button in Upper Right Hand Corner**



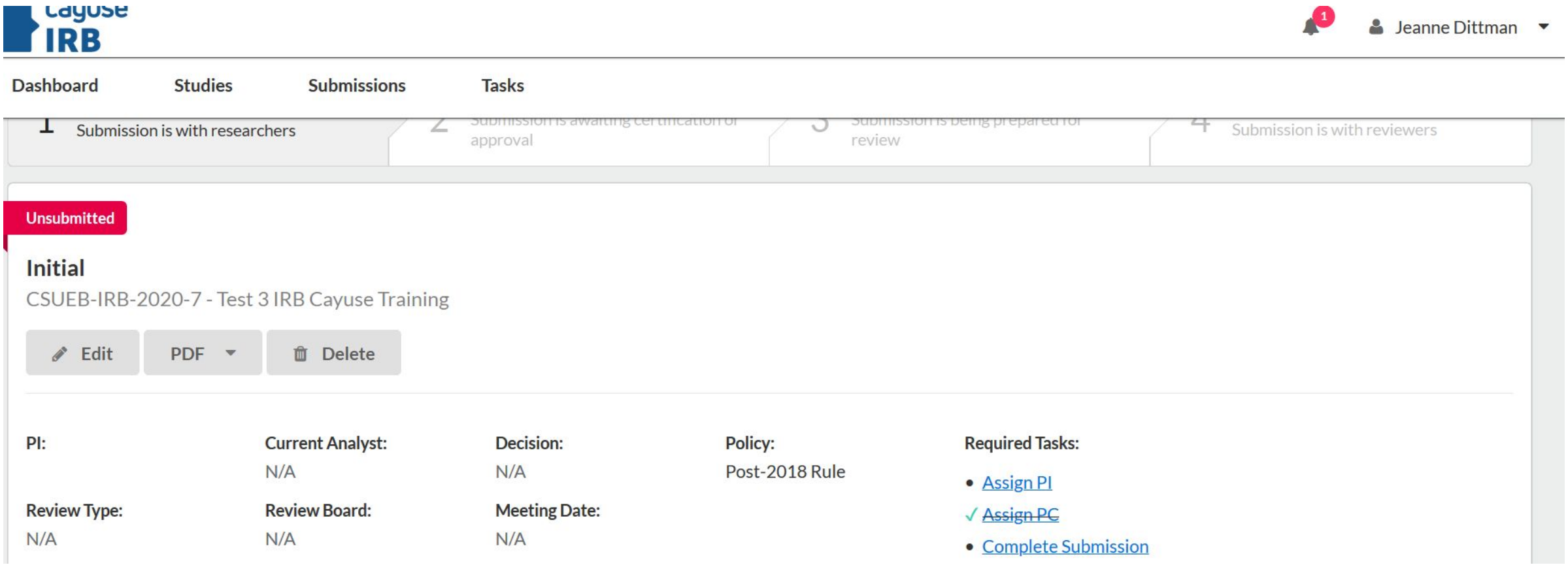
- **Enter Your Protocol Title and Click the blue check mark on the right**



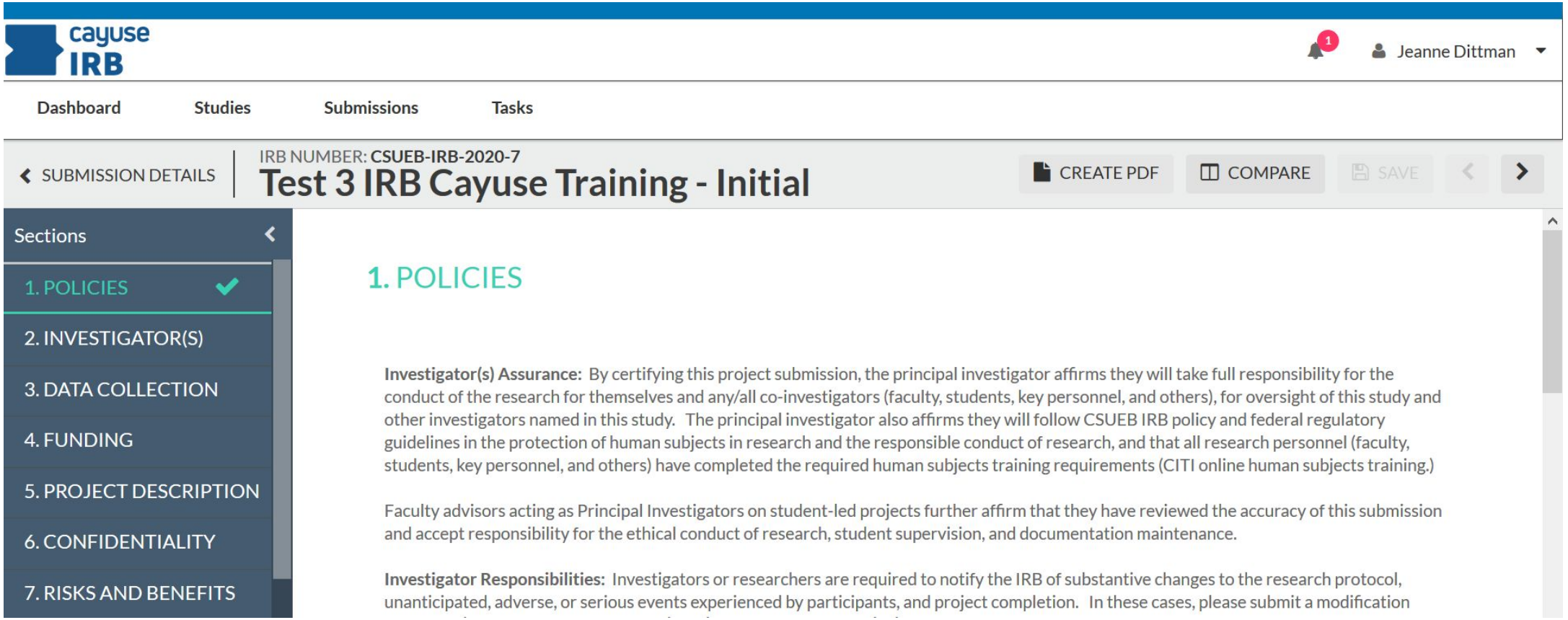
- **Click on the blue button that now says “+ New Submission”**



- **Click “Initial” and on the right it will begin showing you tasks to complete under the Task bar. In this case, it says Assign PI.**



- **Once you click on Assign PI you are taken to a new set of menus, through which you do all the rest of the completion steps.**



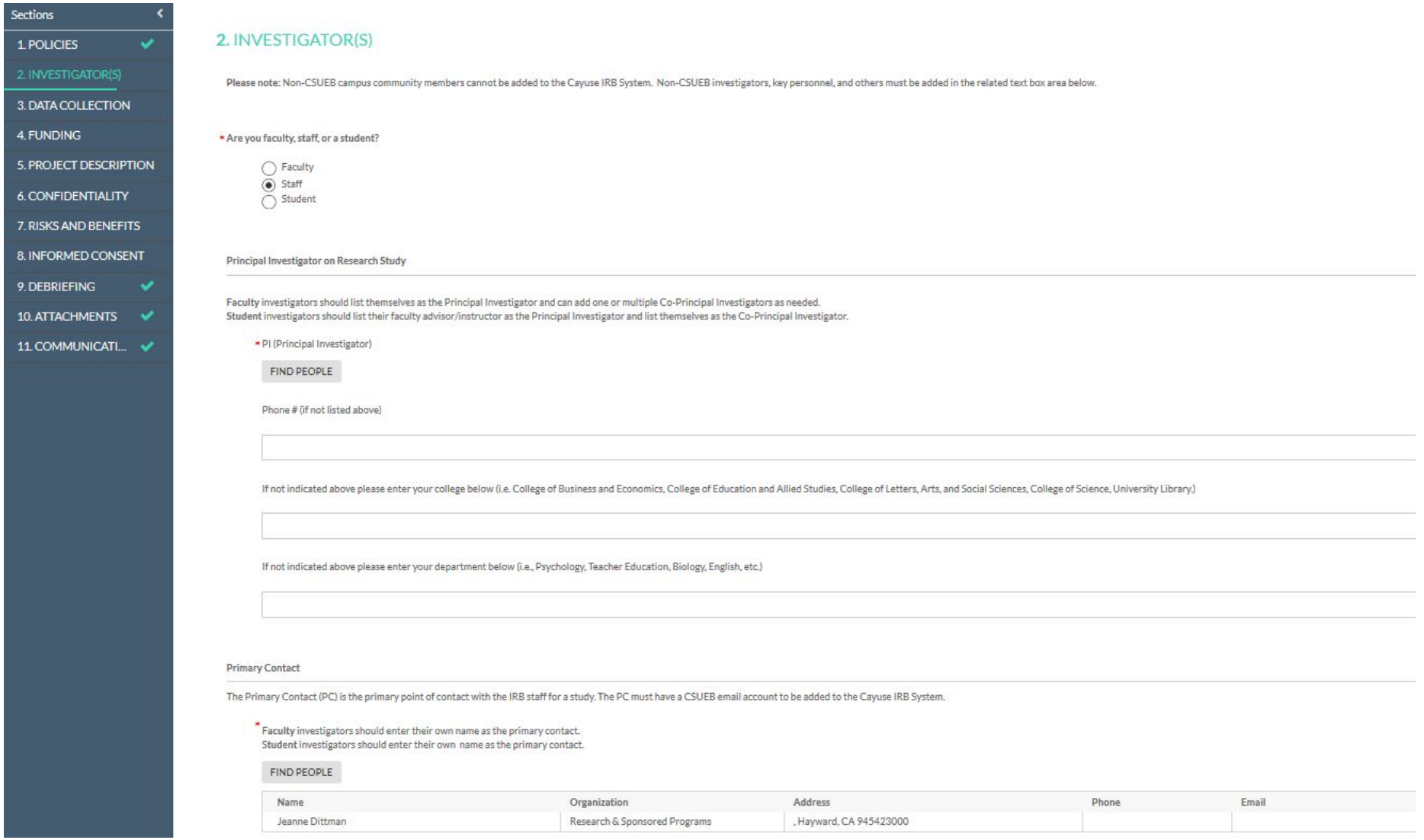
- **Click on New Study in the upper right hand corner.**
- The system is user friendly and will walk you through the steps.
- Enter your Study Title, then Click New Submission in the upper right hand corner.
- The remaining sections to complete are shown below.
- Click Edit

Policies: Example-

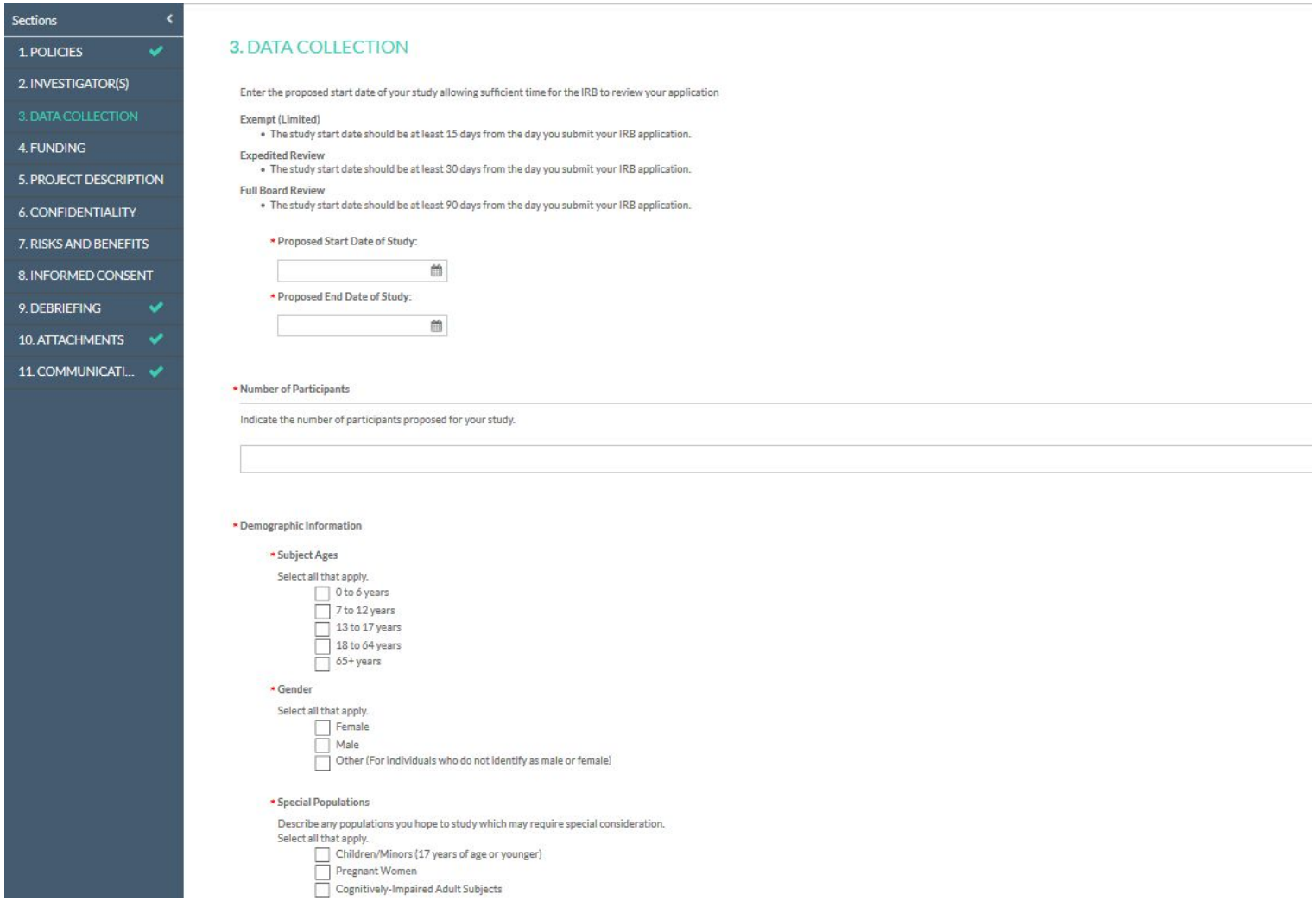
"Investigator(s) Assurance: By certifying this project submission, the principal investigator affirms they will take full responsibility for the conduct of the research for themselves and any/all co-investigators (faculty, students, key personnel, and others), for oversight of this study and other investigators named in this study. The principal investigator also affirms they will follow CSUEB IRB policy and federal regulatory guidelines in the protection of human subjects in research and the responsible conduct of research, and that all research personnel (faculty, students, key personnel, and others) have completed the required human subjects training requirements (CITI online human subjects training.)

Faculty advisors acting as Principal Investigators on student-led projects further affirm that they have reviewed the accuracy of this submission and accept responsibility for the ethical conduct of research, student supervision, and documentation maintenance."

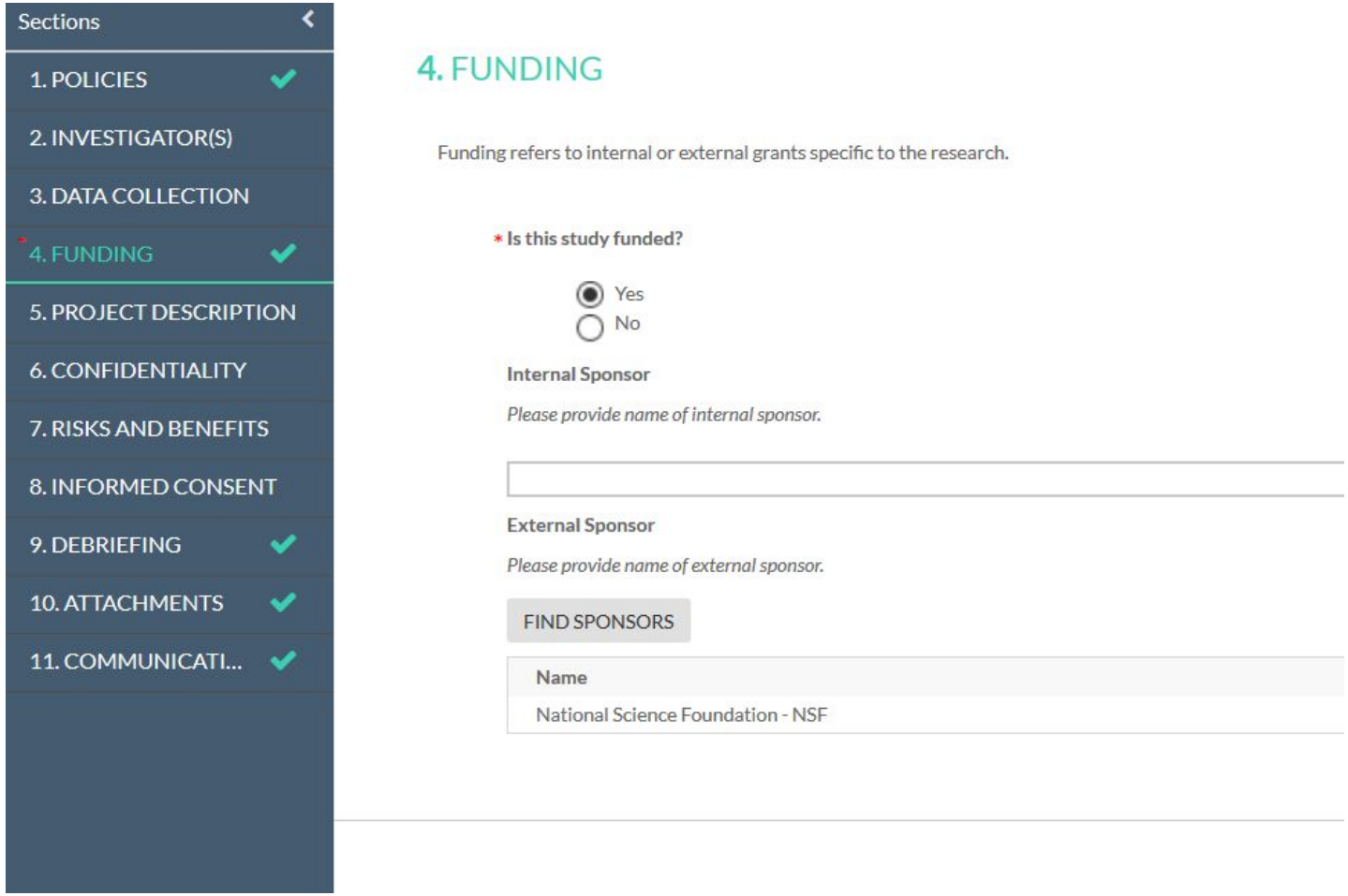
- **After reading the Policy content carefully, Click on Investigators**
- Identify yourself, your collaborators, other personnel, and other institutions involved.



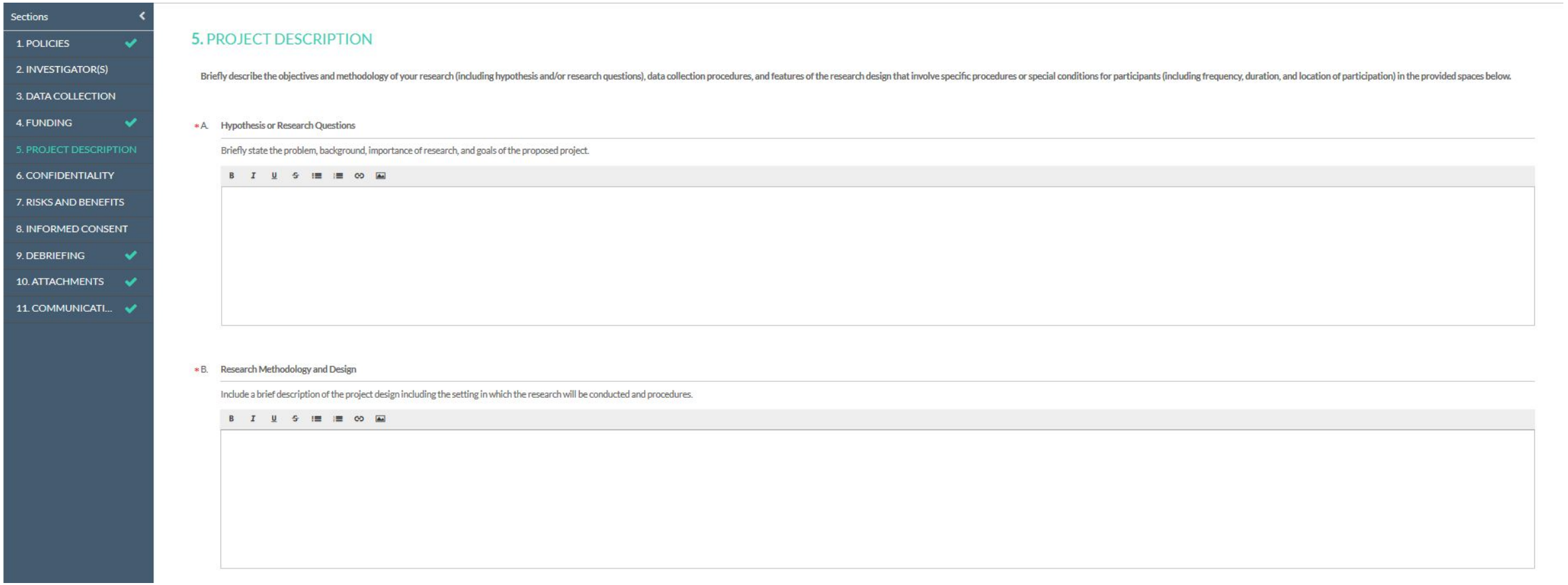
- **Next Click on Data Collection**
- Complete the section by identifying your study start and end dates, number of participants, and demographic information about the study population.



- **Next Click on Funding**
- If your project is funded by Internal or External Funding check, Yes.
- If you check yes, also complete the applicable sponsor information.

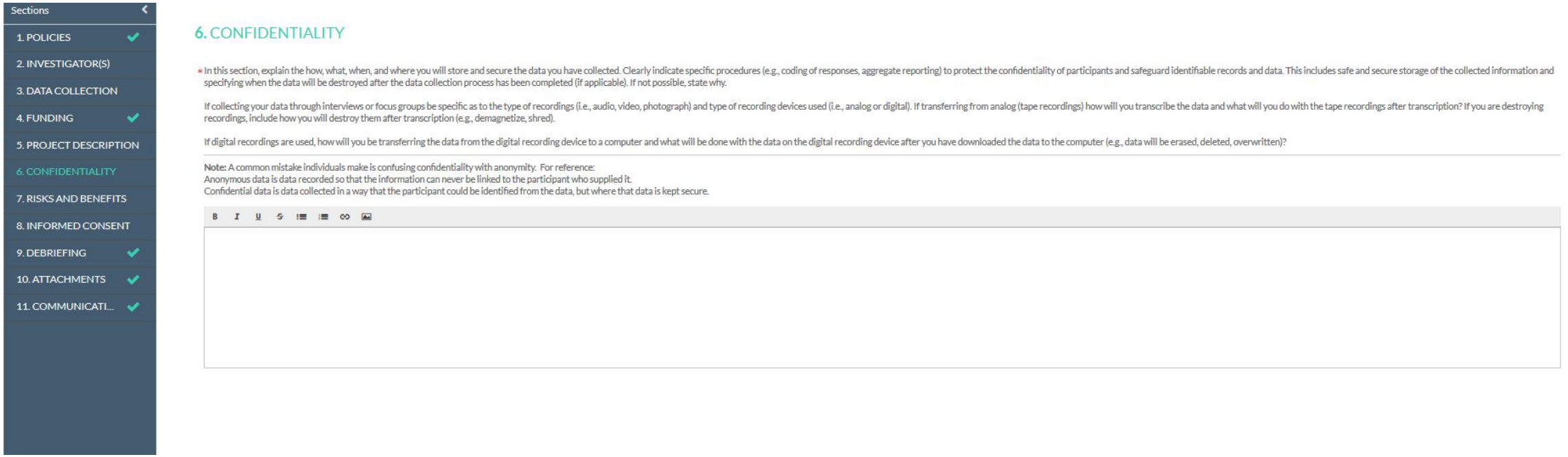


- **Next Click on Project Description**
- This is where you will put important details for the basis of your protocol

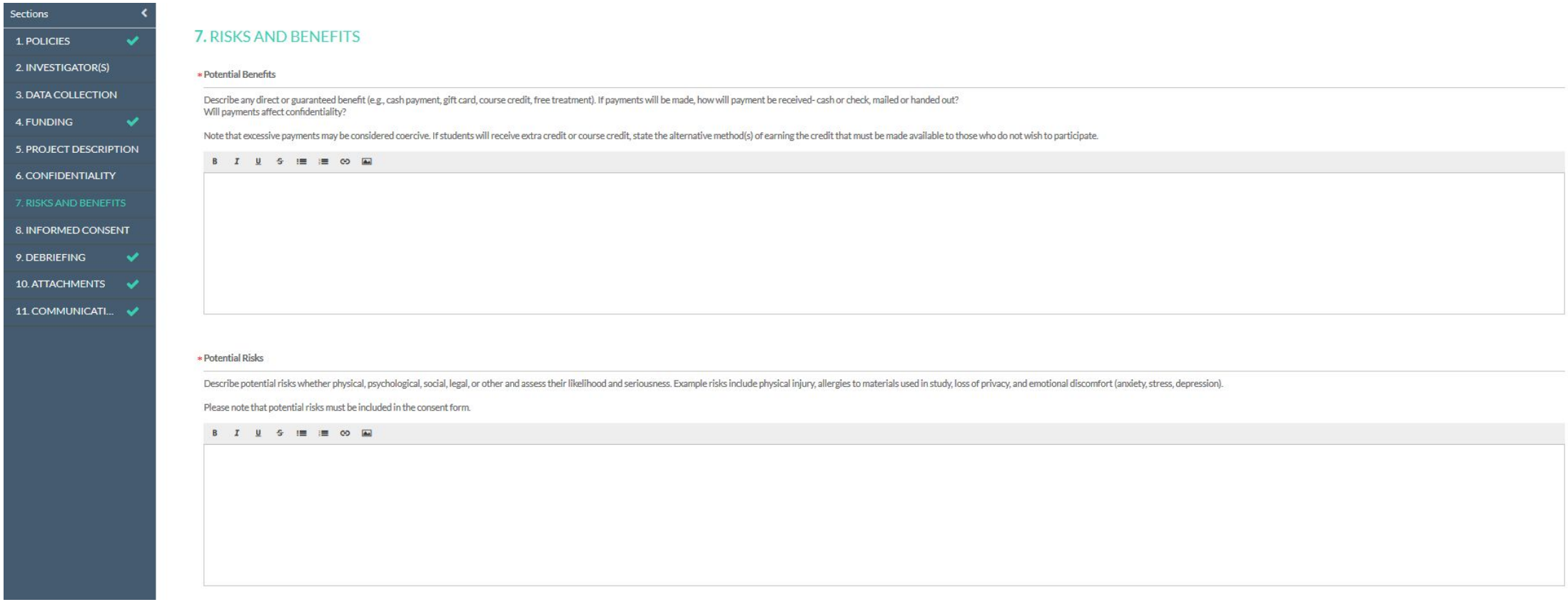


- **Project Description**
- ***Protocol Details:***
  - A. Your Hypothesis or Research Questions
  - B. Methodology and Design
  - C. Human Subjects Involvement – what procedures, where will they be performed, and for how long.
  - D. Subject Population – number and categories, access or recruitment, inclusions/exclusions, rationale
  - E. Recruitment Plan
  - F. Research Material – How will information be obtained from the subjects – attach surveys or other collection or tracking documents
  - G. Data Analysis – How will you analyze the data (qualitative, quantative, methods)
  - H. Dissemination – How do you plan to present and publish your research

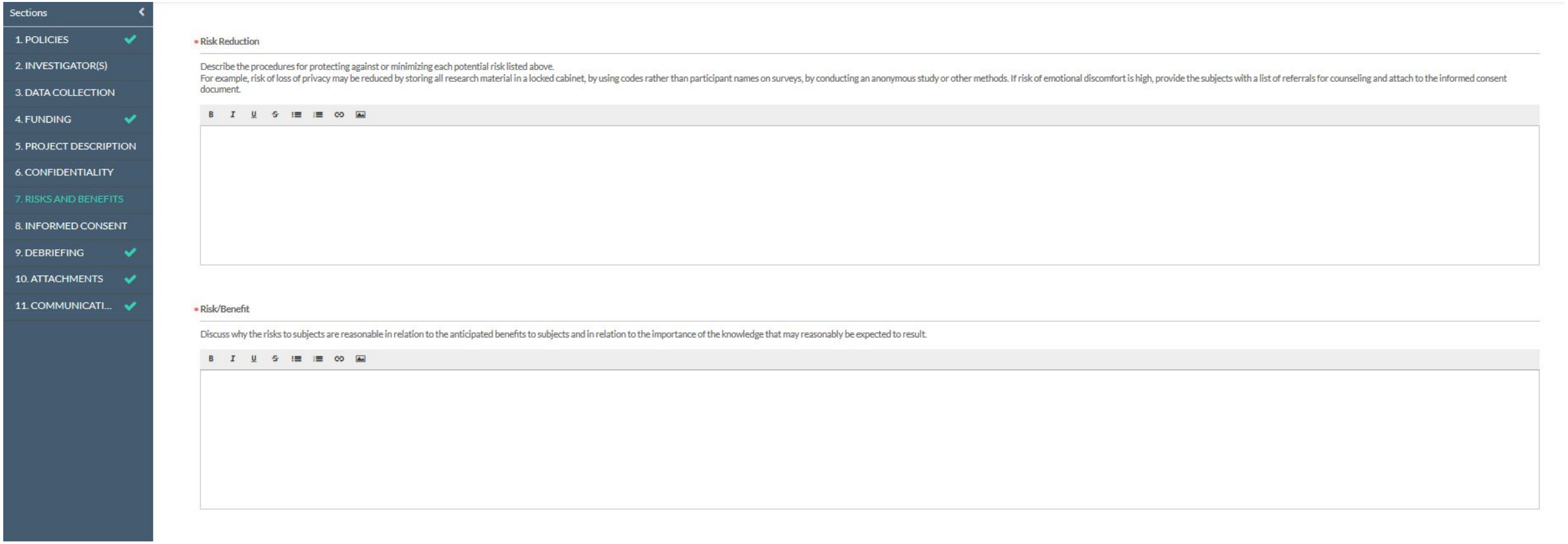
- **Next Click on Confidentiality**
- Describe how, what, when, and where you will store and secure data you have collected.



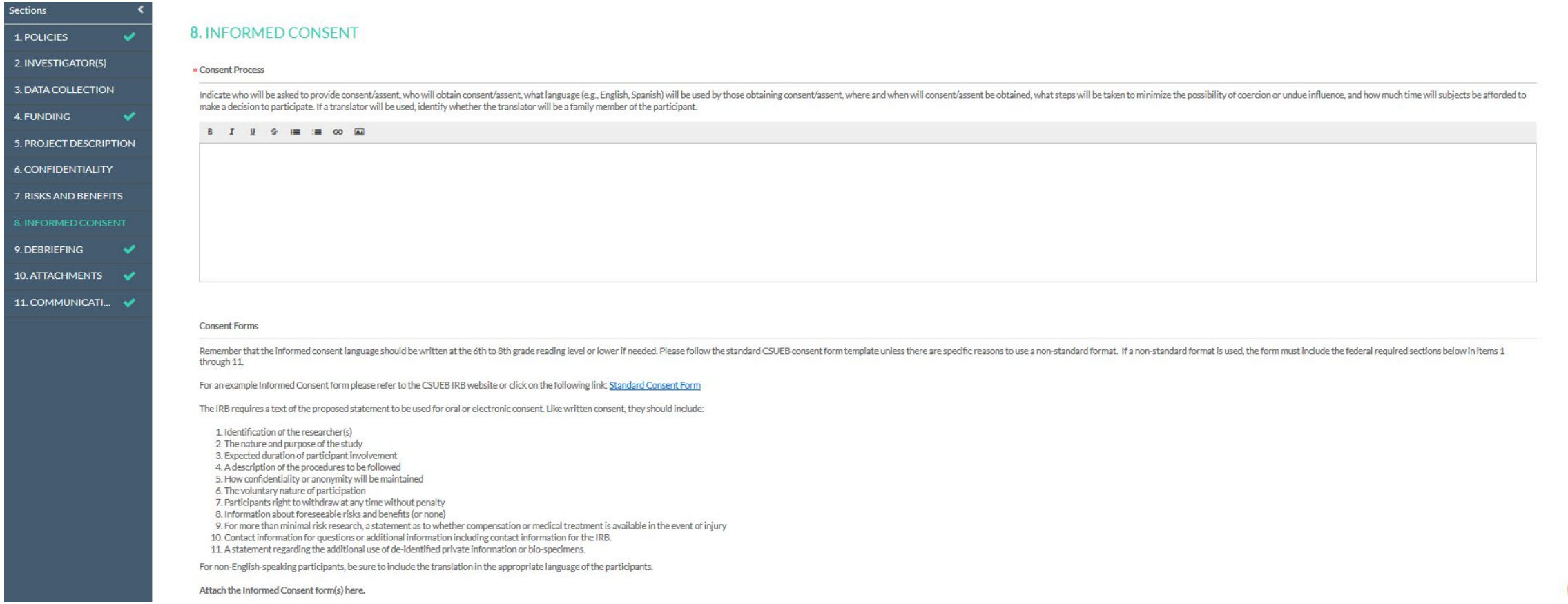
- **Next Click on Risks and Benefits**
- Describe the
  - Potential Benefits
  - Potential Risks
  - Risk Reduction techniques
  - Risk/Benefits summary



- **Risks and Benefits**
- Describe the
  - Potential Benefits
  - Potential Risks
  - Risk Reduction techniques
  - Risk/Benefits summary



- **Informed Consent**
- Describe the who, what, how, where, and when
  - Who will provide consent, who will obtain consent
  - How, Where, and When will the consent be obtained? Translation? Interpreters?
  - Consent Forms – Attach copies of the Consent forms and waivers you will use. Follow the CSUEB Standard Consent Form.



- **Informed Consent**
  - Regulations regarding consent forms are stringent and require specific information.

The IRB requires a text of the proposed statement to be used for oral or electronic consent. Like written consent, they should include:

1. Identification of the researcher(s)
2. The nature and purpose of the study
3. Expected duration of participant involvement
4. A description of the procedures to be followed
5. How confidentiality or anonymity will be maintained
6. The voluntary nature of participation
7. Participants right to withdraw at any time without penalty
8. Information about foreseeable risks and benefits (or none)
9. For more than minimal risk research, a statement as to whether compensation or medical treatment is available in the event of injury
10. Contact information for questions or additional information including contact information for the IRB.
11. A statement regarding the additional use of de-identified private information or bio-specimens.

For non-English-speaking participants, be sure to include the translation in the appropriate language of the participants.

Attach the Informed Consent form(s) here.

ATTACH

Consent/Assent waivers

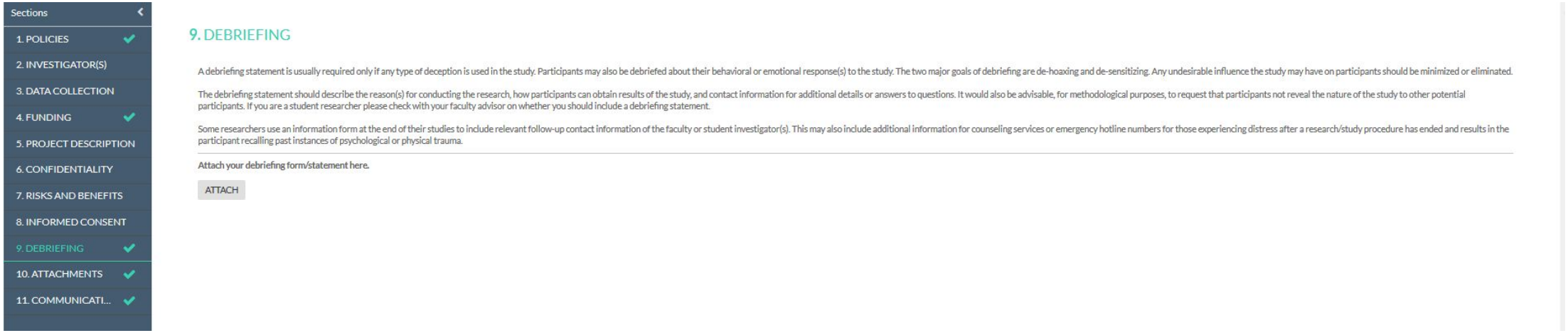
☐ Documentation of consent
Documentation of consent is often provided via a signature on a consent form. For studies completed online or over the phone, or where anonymity is desired, a waiver of the requirement to document consent in writing may be granted. Please check this box if you would like to request a waiver of the requirement to document consent in writing.

☐ Additional consent provisions
Waivers of additional informed consent provisions may be granted under certain limited conditions. Any request for such should include an explicit justification.

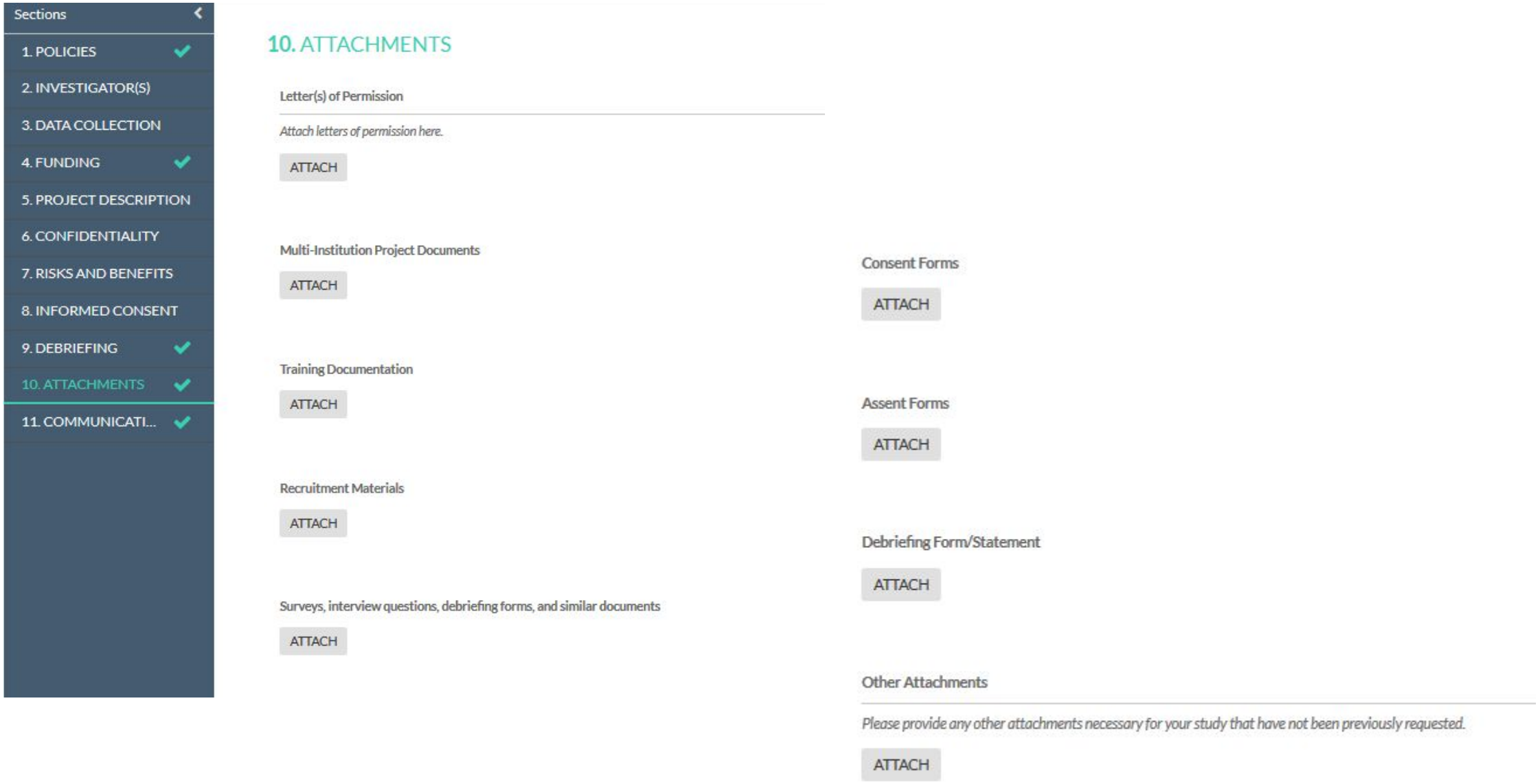
☐ Assent waiver
Waivers of the assent requirement may be granted under certain limited conditions. Any request for such should include an explicit justification.

☐ [illegible]
Waivers of the assent requirement may be granted under certain limited conditions. Any request for such should include an explicit justification.

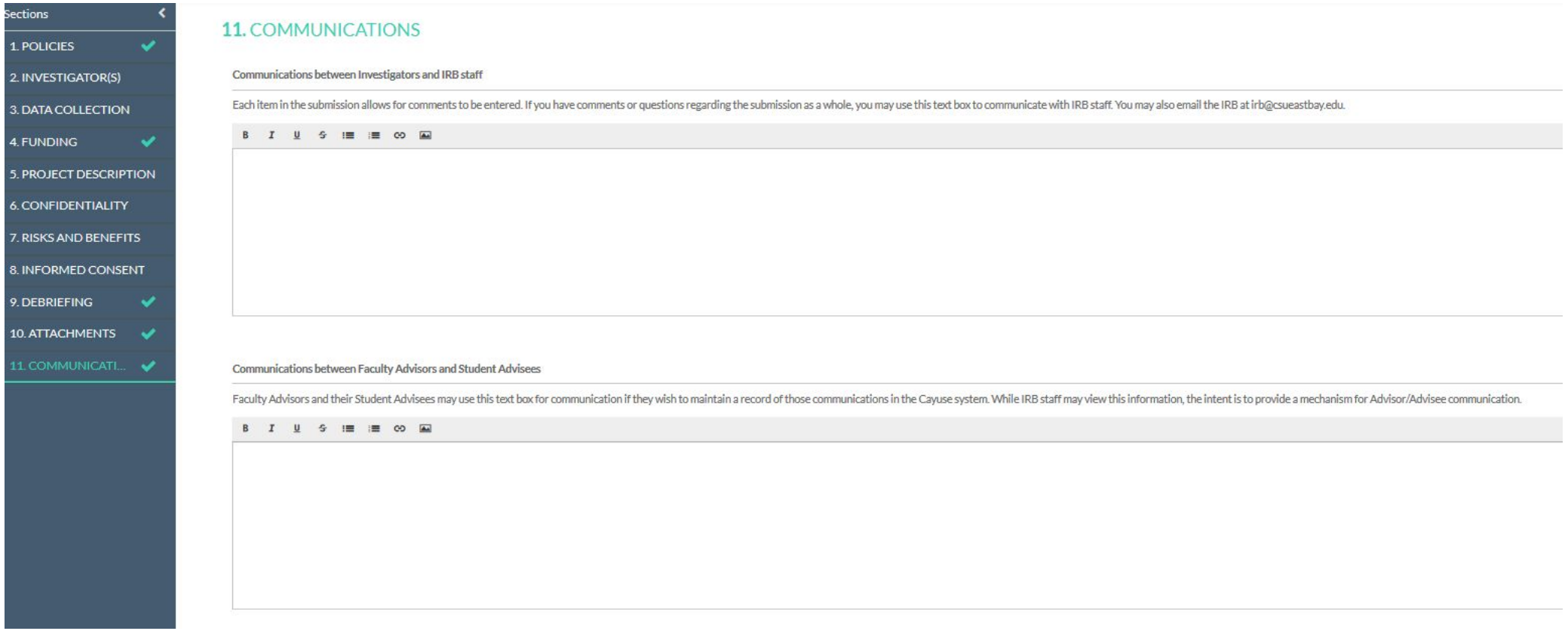
- **Debriefing**
- Attach a copy of your Debriefing Statement
  - When deception has been used in the study
  - When your design debriefs participants about their behavioral or emotional responses
  - When your design provides additional information, such as future contact info or emergency hotlines



- **Attachments**



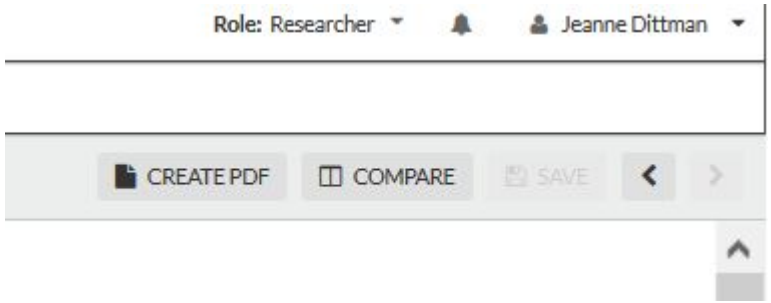
- **Communications**
- You can use the Communications link at the bottom of the menu
  - Communicate with the IRB Staff (or email them at irb@csueastbay.edu)
  - Communications between Faculty Advisors and Student Advisees



BEFORE YOU HIT SUBMIT

YOU CAN CREATE A PDF OF YOUR ENTIRE PACKAGE TO REVIEW WHAT YOU HAVE DONE.

- Click on “Create PDF” found at the top righthand of your screen.




Submission Type: Initial Date: 2-17-2020

IRB #: CSUEB-IRB-2020-10
Title: Test 1
Creation Date: 2-7-2020
Status: Unsubmitted
Principal Investigator:

1. POLICIES

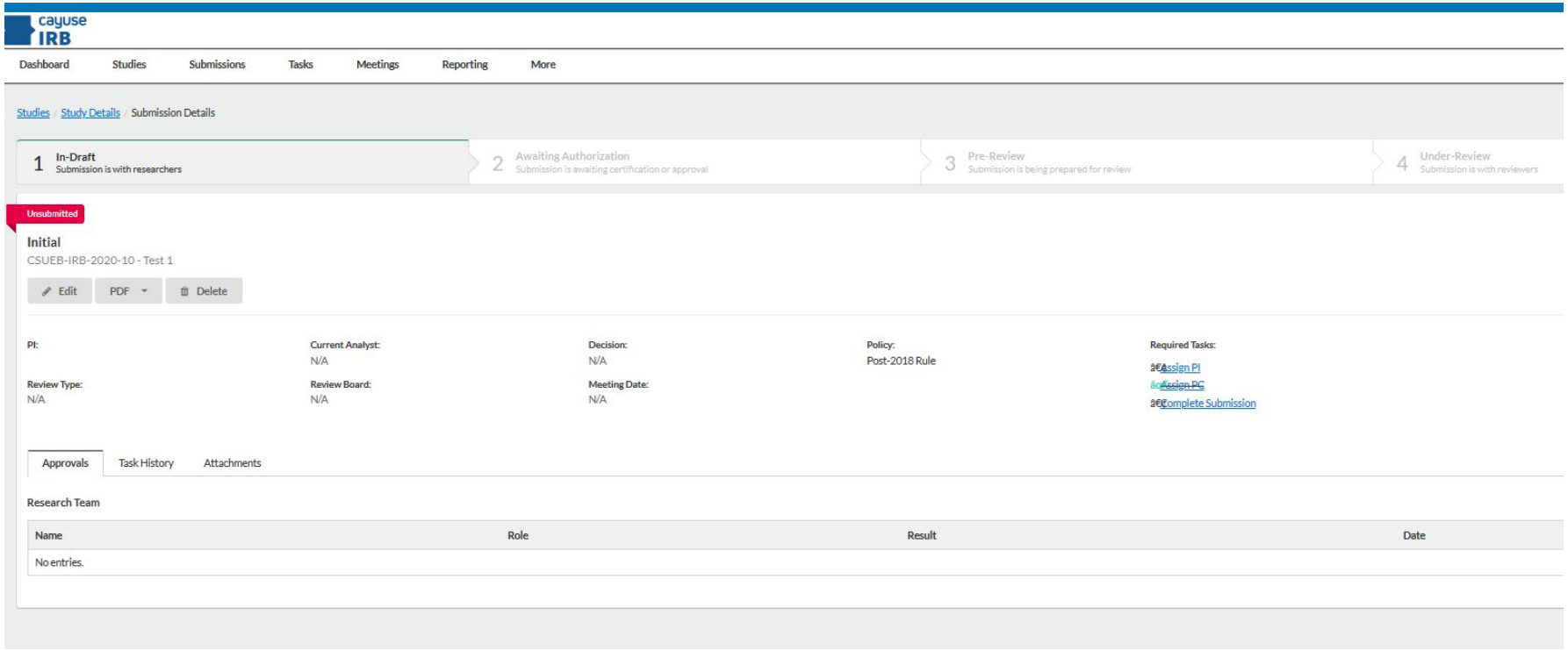
Investigator(s) Assurance: By certifying this project submission, the principal investigator affirms they will take full responsibility for the conduct of the research for themselves and any/all co-investigators (faculty, students, key personnel, and others), for oversight of this

Quick Meme

EDIT

YOU CAN STOP WHERE YOU ARE AT ANY TIME AND RETURN LATER TO EDIT YOUR PROTOCOL BEFORE SUBMITTAL.

- Go to the Dashboard
- Click on the Protocol Number or Title
- Click on the type listed in the Active column
- Click on Edit



SUBMIT

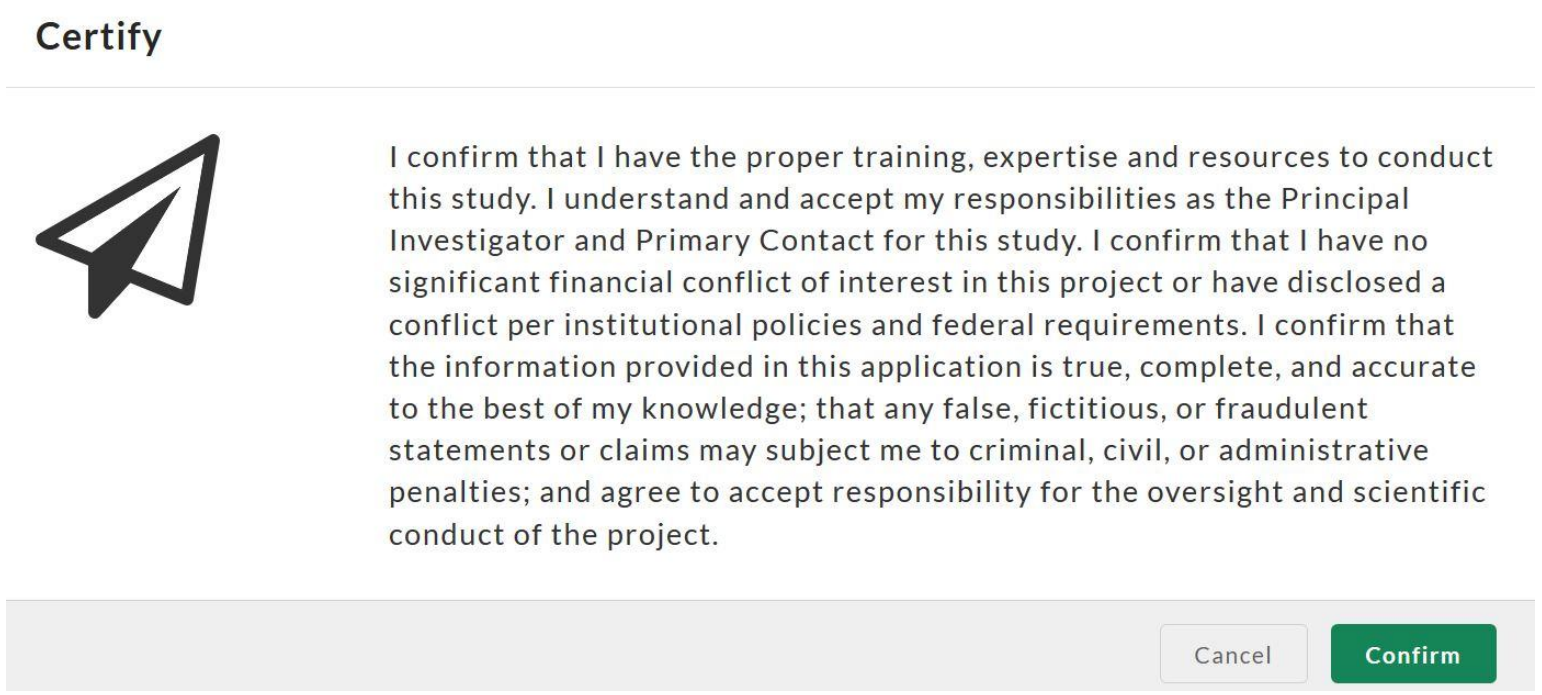
ONCE YOU HAVE COMPLETED ALL OF THE SECTIONS AND THEY ALL SHOW A GREEN CHECK YOU CAN SUBMIT YOUR PROTOCOL

Certify

After Submittal Certify.

Go to the Dashboard

- See Tasks
- Click on Certify to Certify



Voila!

- You submitted an IRB protocol.
- The IRB will review the submittal.
- The initial reviewers may ask for additional information or move the submittal to the committee.
- You will receive notification of whether your project is approved.
- During the project as your protocol or project changes, you can use Cayuse IRB to modify your request.
- Renew your IRB every year using Cayuse IRB.

Questions?

Click here for Answers