Cayuse IRB Initial Submission Directions

Office of Research

MONTCLAIR STATE UNIVERSITY

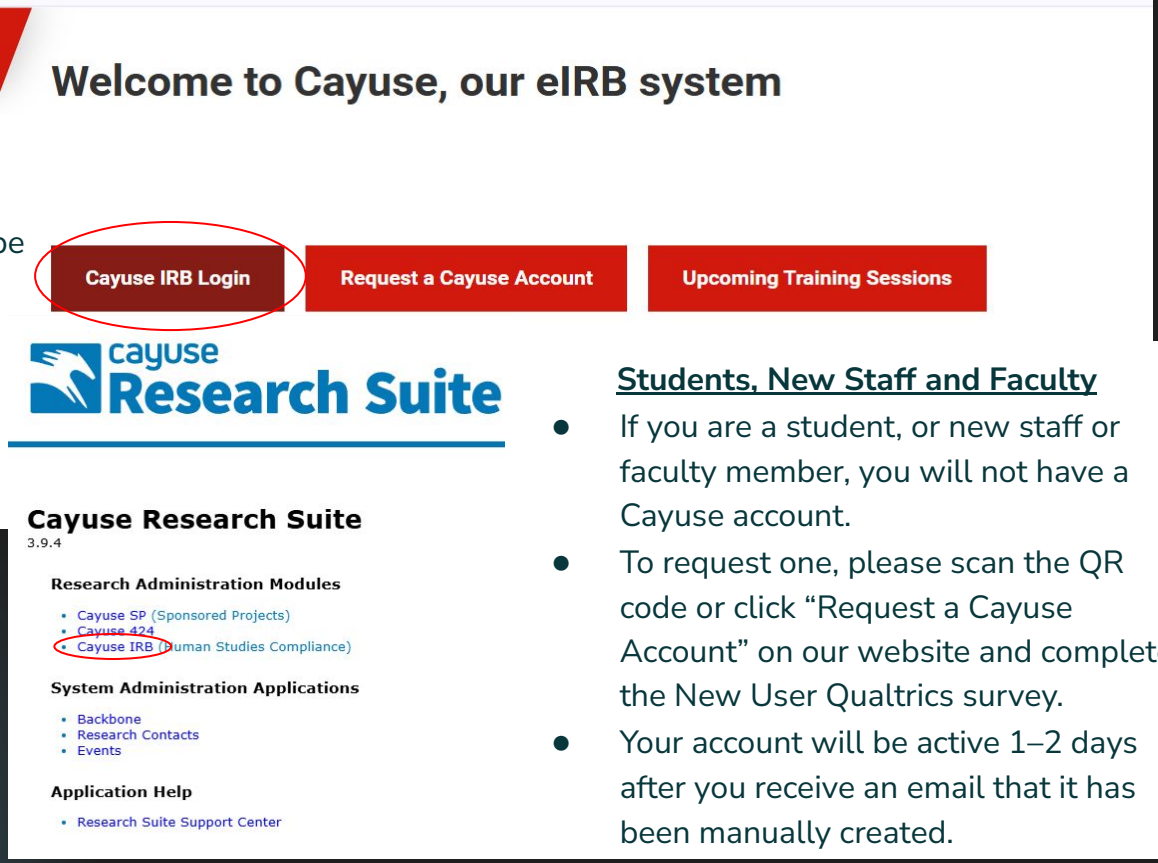
Logging in to Cayuse IRB

MONTCLAIR STATE UNIVERSITY | Institutional Review Board

Active Cayuse Users

- Click “Cayuse IRB Login” on Montclair’s IRB website. You will be directed to sign in with your Montclair netID and password.
- Once successfully logged in, you will click “Cayuse IRB” to access your dashboard.

Scan here to request a Cayuse account:



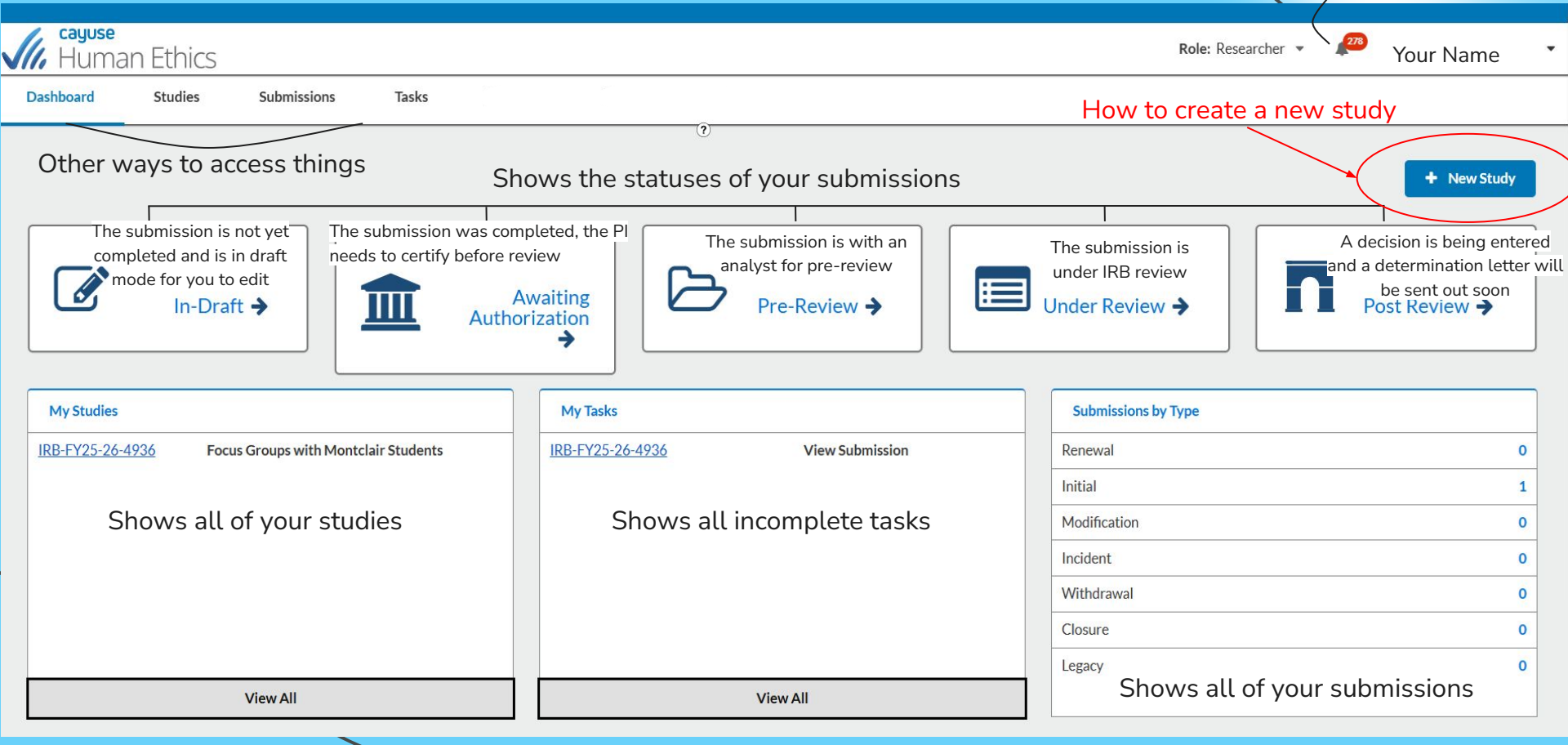
Students, New Staff and Faculty

- If you are a student, or new staff or faculty member, you will not have a Cayuse account.
- To request one, please scan the QR code or click “Request a Cayuse Account” on our website and complete the New User Qualtrics survey.
- Your account will be active 1–2 days after you receive an email that it has been manually created.

Before you begin...

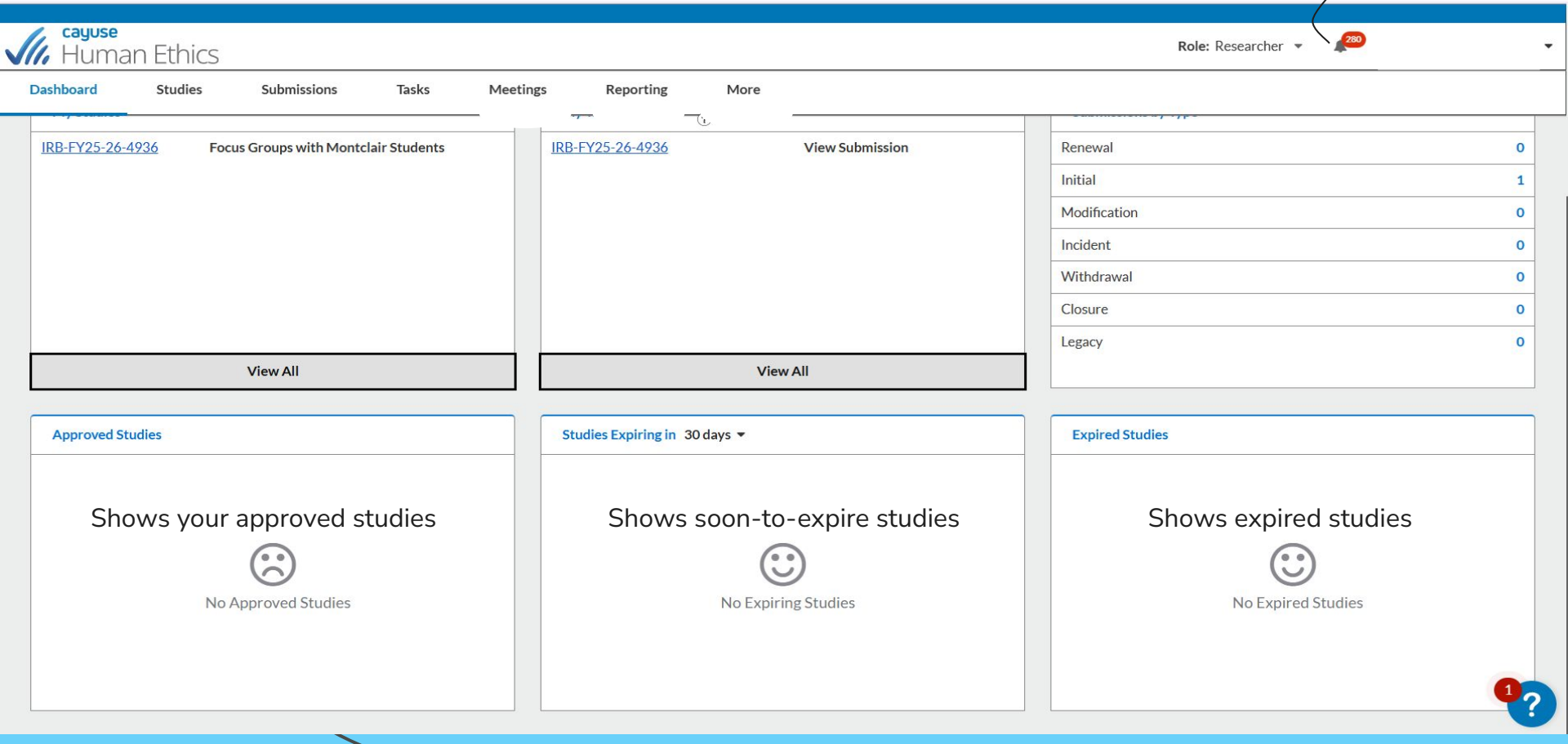
- You may have the best results using Chrome (not necessary)
- Must enable pop-ups
- You likely will not complete your submission all in one sitting - save your work as you go

Your Dashboard



Your Dashboard

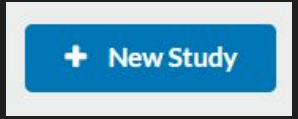
Notifications will appear here. Click bell to view



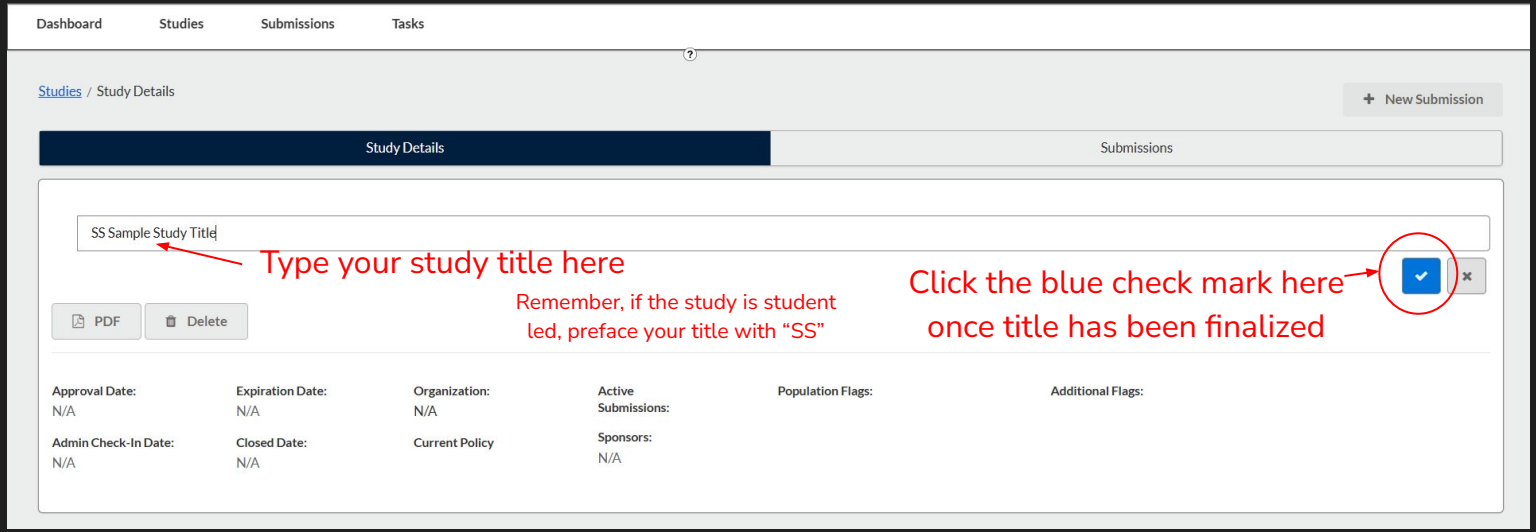
Study vs. Submission

- Study refers to your entire research project
- Submission refers to specific submissions per study [e.g. initial, modification, renewal (*admin check-in*), and closure]

Steps to creating an initial submission



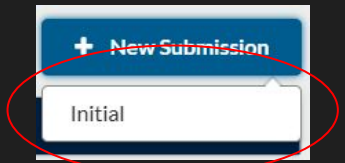
1. Click on blue “+New Study” button on top right hand side
2. Give your study a title. Click on blue checkmark on right-hand side to confirm study title
   a. If it is a student-led research project, preface your title with “SS” ex: “SS Sample Study Title”

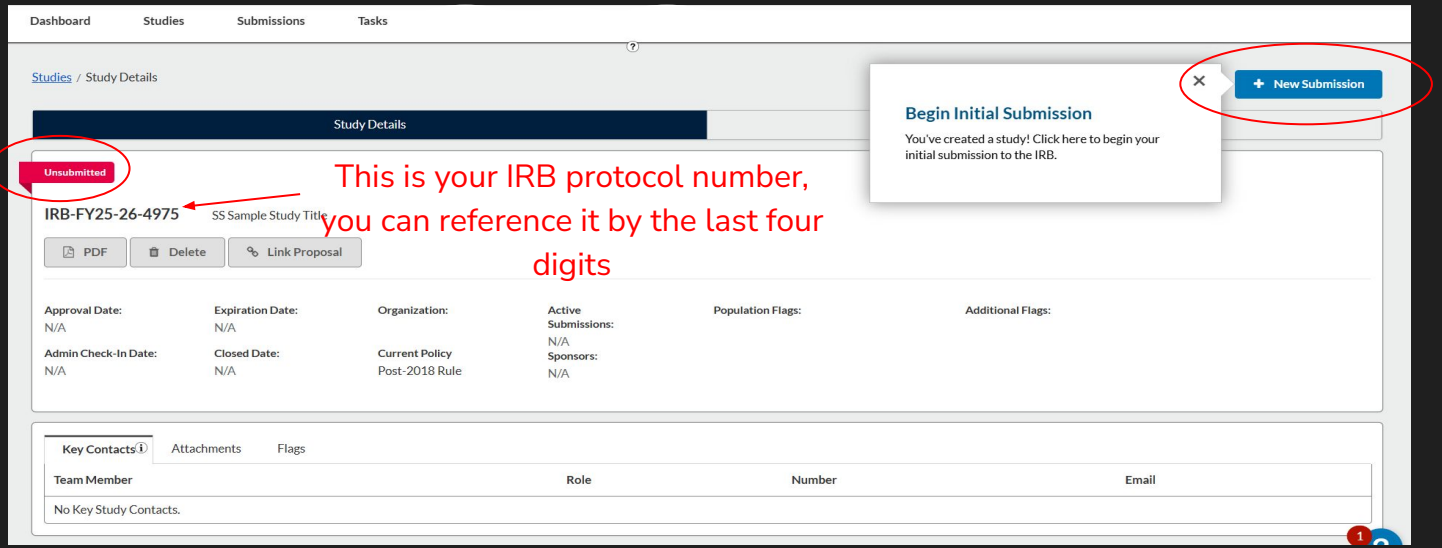


Steps to creating an initial submission

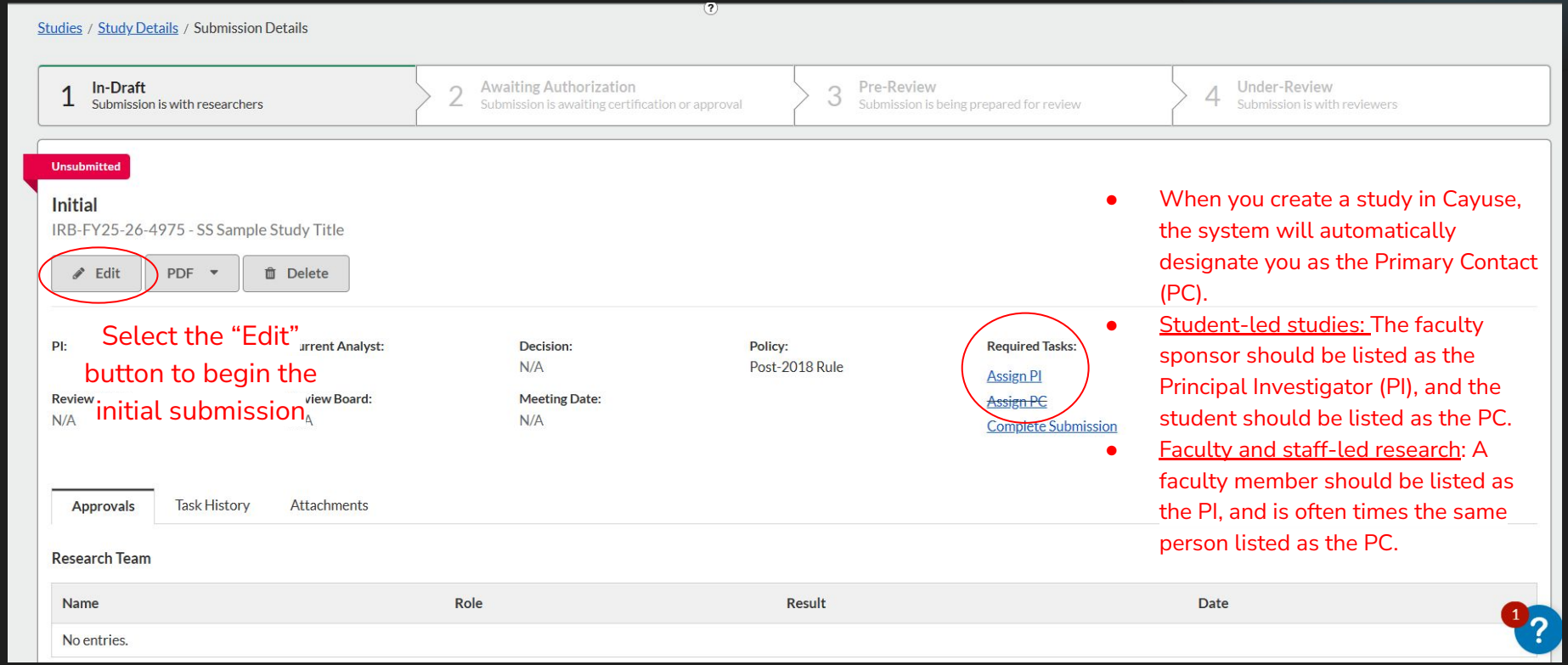
3. You will see an IRB number such as “IRB-FY25-26-4975” and you will see a red banner on left side which states “Unsubmitted”
4. Click on blue “+New Submission” button on top right hand corner

A drop down will appear with the word “Initial,” click on it



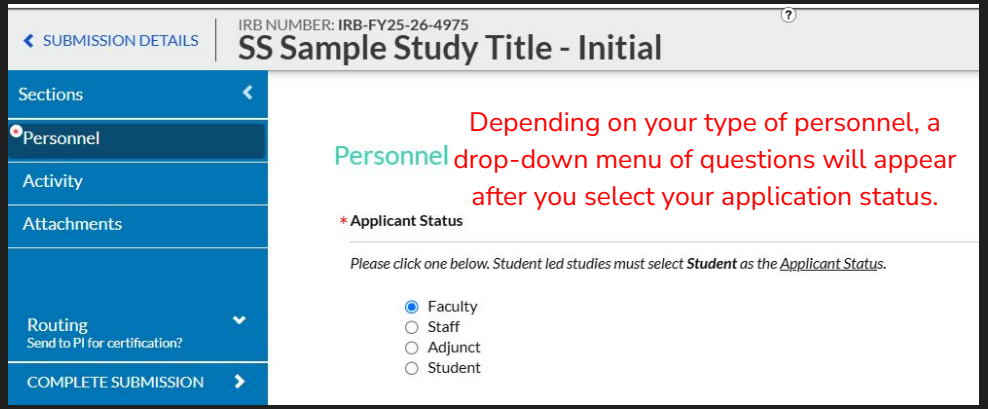


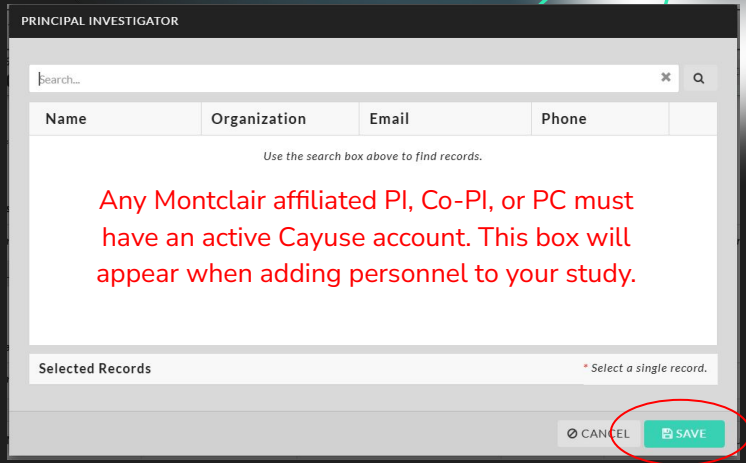
Start your Initial Submission

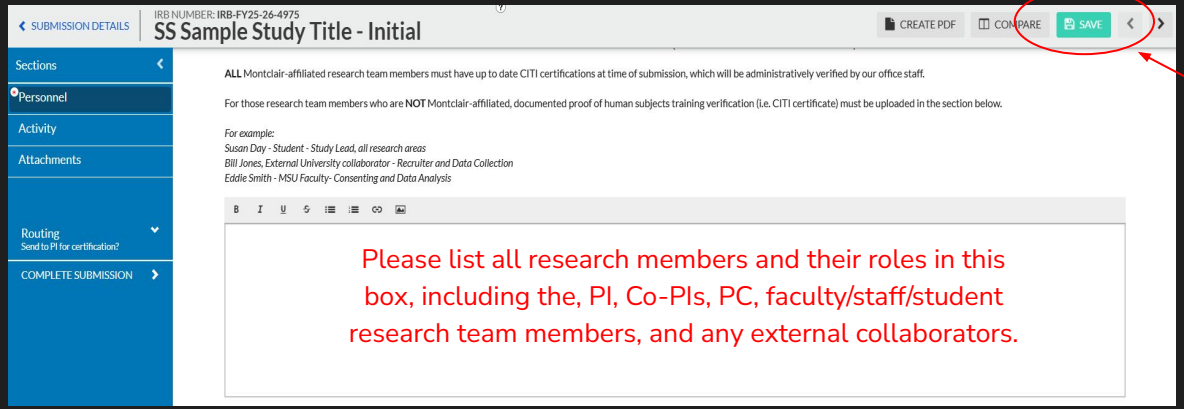


- When you create a study in Cayuse, the system will automatically designate you as the Primary Contact (PC).
- Student-led studies: The faculty sponsor should be listed as the Principal Investigator (PI), and the student should be listed as the PC.
- Faculty and staff-led research: A faculty member should be listed as the PI, and is often times the same person listed as the PC.

Initial Submission – Personnel

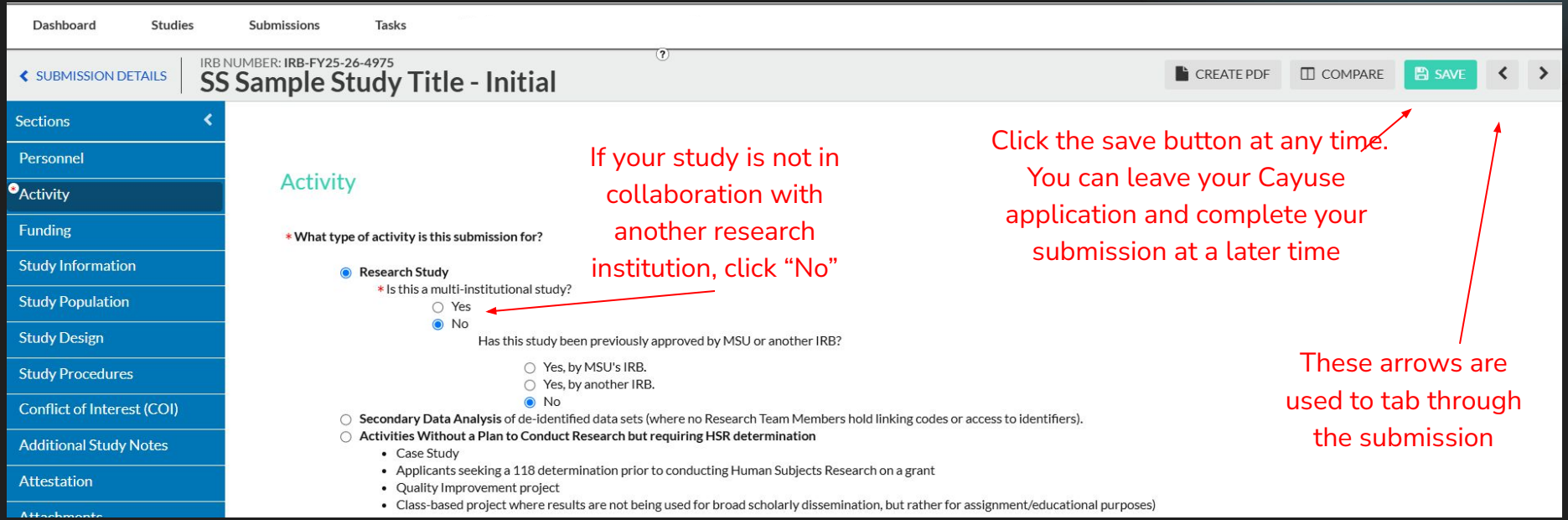






Be sure to click the “Save” button after selecting your personnel and completing each section.

Initial Submission – Activity

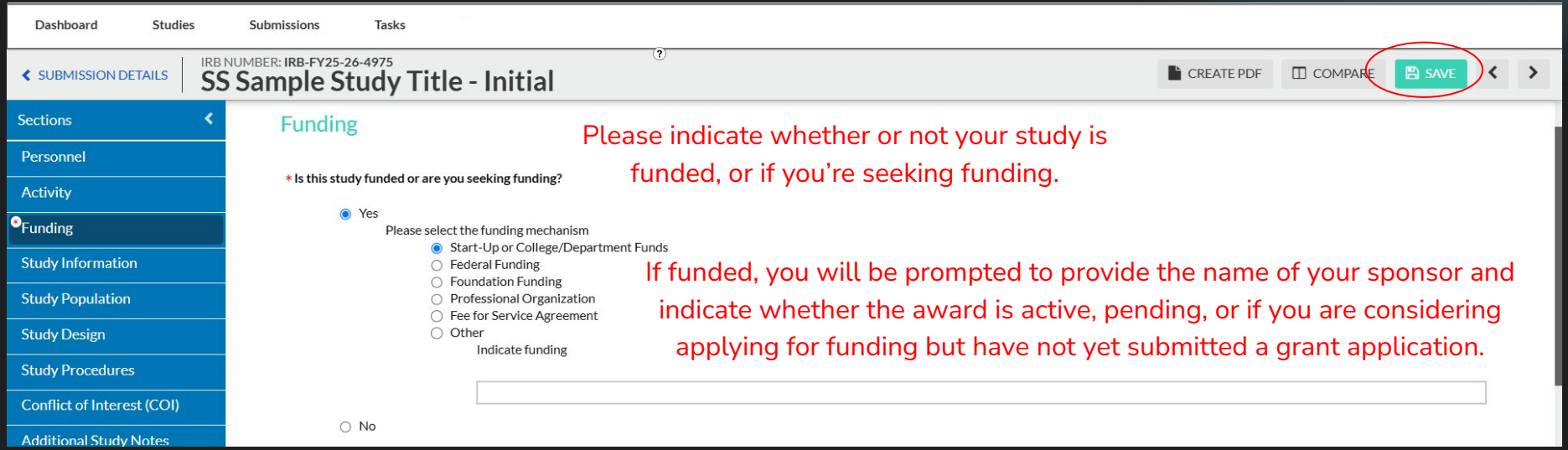


If your study is not in collaboration with another research institution, click “No”

Click the save button at any time. You can leave your Cayuse application and complete your submission at a later time

These arrows are used to tab through the submission

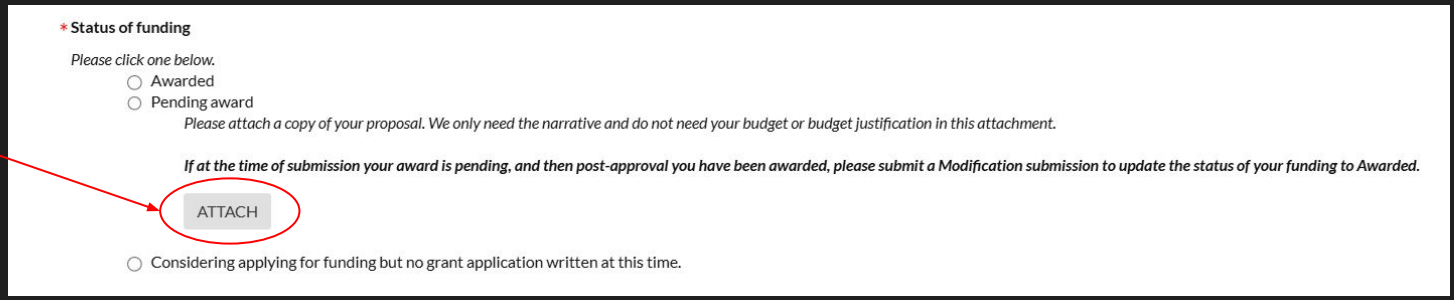
Initial Submission – Funding



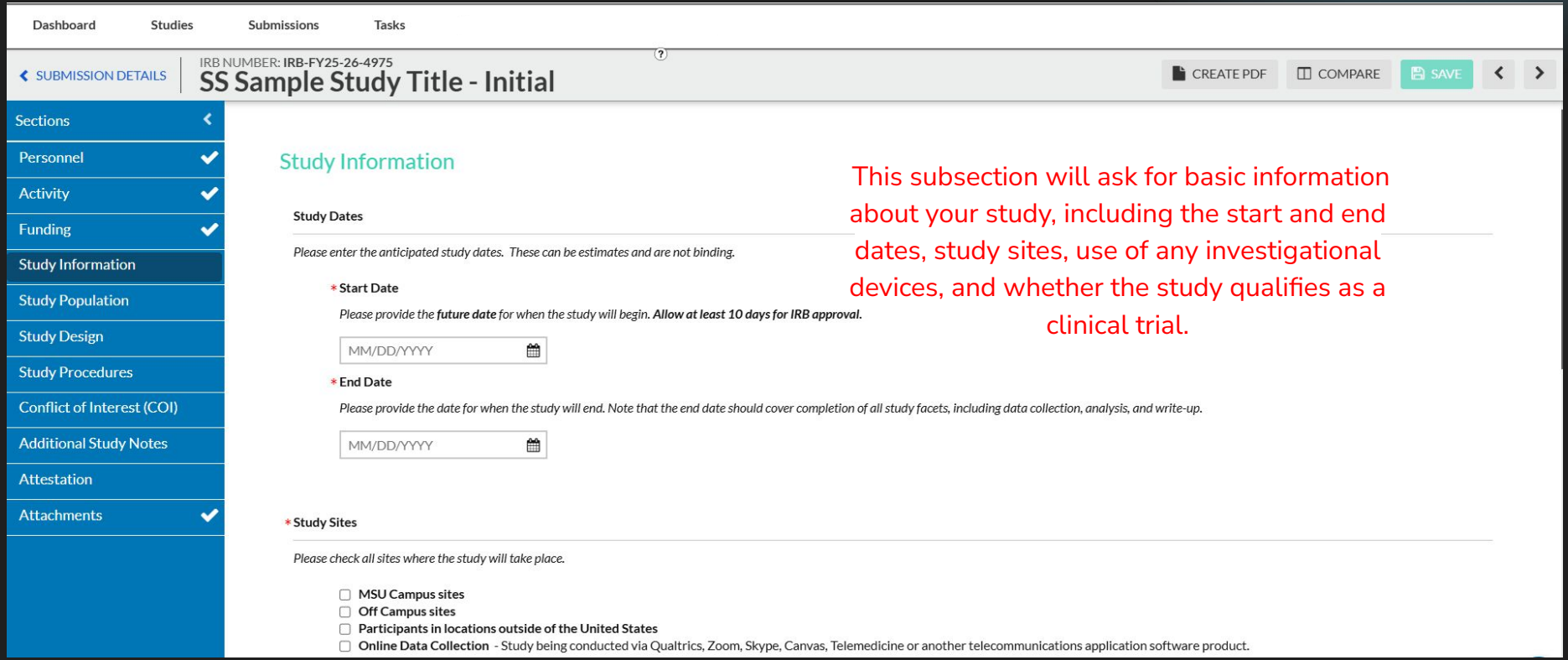
Please indicate whether or not your study is funded, or if you're seeking funding.

If funded, you will be prompted to provide the name of your sponsor and indicate whether the award is active, pending, or if you are considering applying for funding but have not yet submitted a grant application.

You will also be asked to attach a copy of the proposal you submitted to the sponsor.

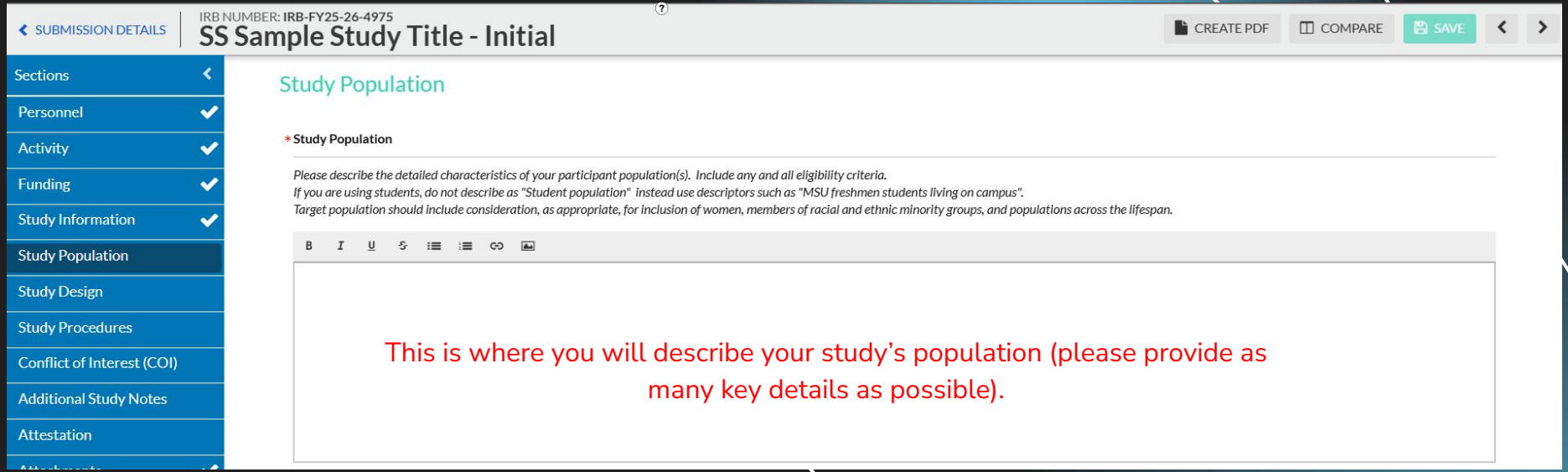


Initial Submission – Study Information



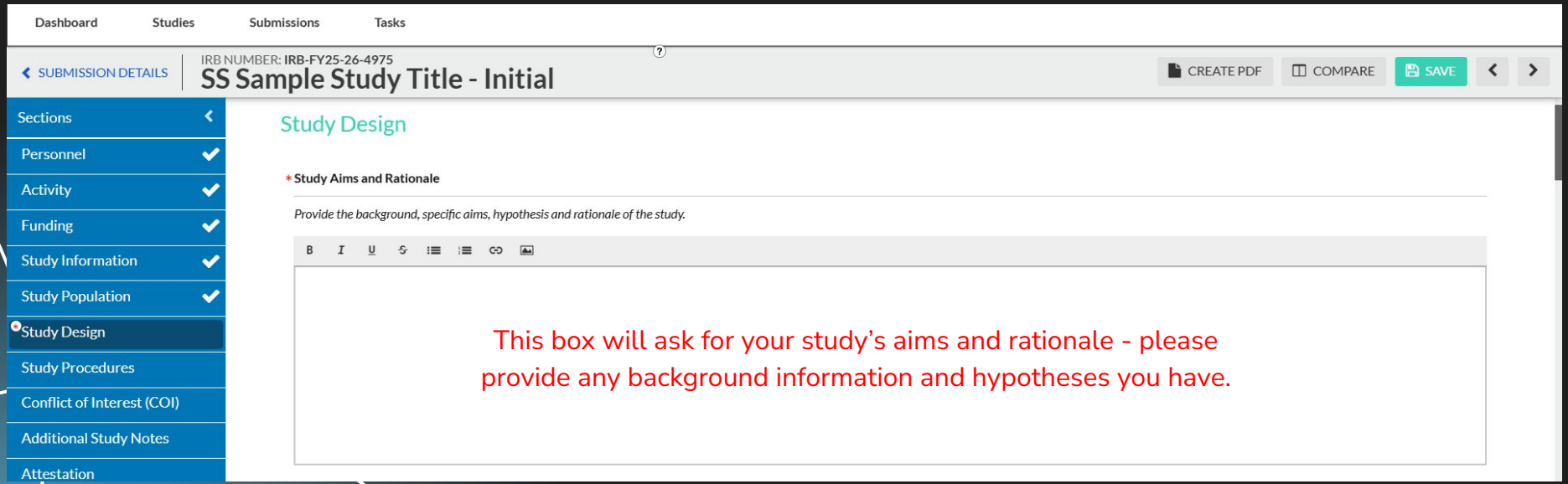
This subsection will ask for basic information about your study, including the start and end dates, study sites, use of any investigational devices, and whether the study qualifies as a clinical trial.

Initial Submission – Study Population



You will be asked a series of questions about your research population, including whether you are working with vulnerable or specifically targeted populations, the age range of participants, and the projected total enrollment.

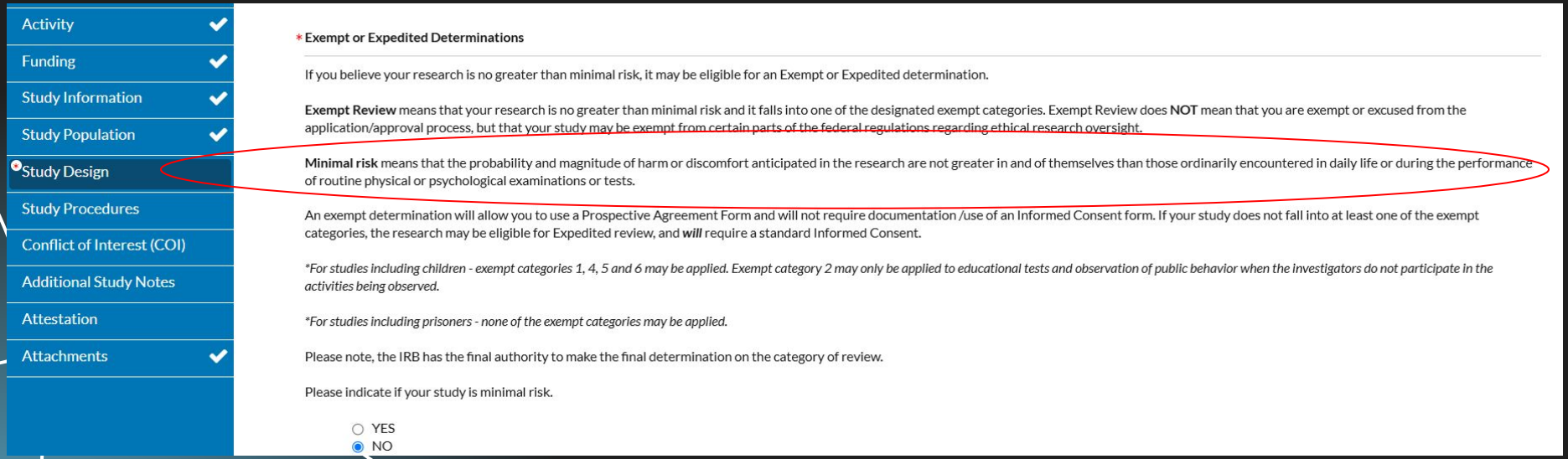
Initial Submission – Study Design



Recruitment materials should follow Montclair templates found on our website:

- You will be asked to provide a description of your recruitment processes, overall research methods and timeline, anticipated benefits of the study, plans for disseminating findings, and data security procedures.
- You must attach all recruitment materials as documents in this section.

Initial Submission – Study Design



You will be asked to determine whether your study is no greater than minimal risk. If it meets this criterion, your study may qualify for exempt or expedited review. Exempt research may use a Prospective Agreement form in place of a standard Informed Consent form. Expedited and full board studies must follow standard Informed Consent procedures. Please note that the IRB makes the final determination of the appropriate review category for your research.

Initial Submission – Study Procedures

Sections
- Personnel ✓
- Activity ✓
- Funding ✓
- Study Information ✓
- Study Population ✓
- Study Design ✓
- Study Procedures
- Conflict of Interest (COI)
- Additional Study Notes
- Attestation
- Attachments ✓

* **Screening Tools**

Are you using any screening instruments to select your participants?

○ Yes
○ No

In this section, you will be asked to identify the types of consent forms and screening tools you are using. All tools must be attached so that the IRB can review the materials participants will see. Please upload in Microsoft Word document format.

* **Consent , Assent, & Waiver Documents**

Use the Montclair Templates found on our IRB website. Please include all required consent and assent documents. If you are collecting consent online include both the online link and your consent in WORD DOC FORMAT. All consents need to be provided in Word format - not PDFs.

- ☐ Adult Consent Form, In-Person or Online *(all studies other than Exempt category, see Study Design section)*
- ☐ Prospective Agreement Form *(valid for Exempt category studies only, see Study Design section)*
- ☐ Consent form non-English speaking participants
- ☐ Debriefing Form
- ☐ Parent/Guardian Consent
- ☐ Child Assent
  - Required element in research with children unless PI documents rationale why this is not feasible (e.g. age, cognitive capacity)
  - Should be written in terms of understanding for the chronological and cognitive age of minors in the study
- ☐ Requesting a waiver or alteration of standard informed consent/child assent procedures.

Scan here to access Montclair consent templates:

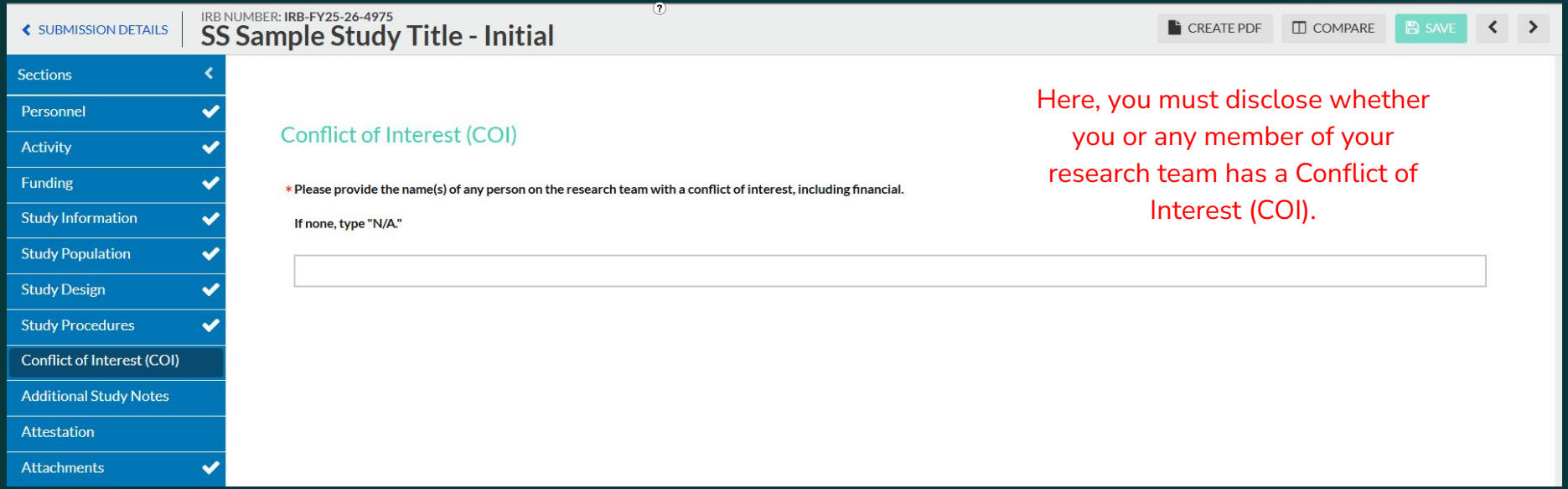
* **Attach all Consent, Prospective Agreement Forms (PAF), Assent, Debriefing documents ect., here.**

Please label each document with type, i.e. Adult Consent 01-20-2021, Parent Consent 01-20-2021, PAF 01-20-2021. **All docs need to be in WORD doc format.**

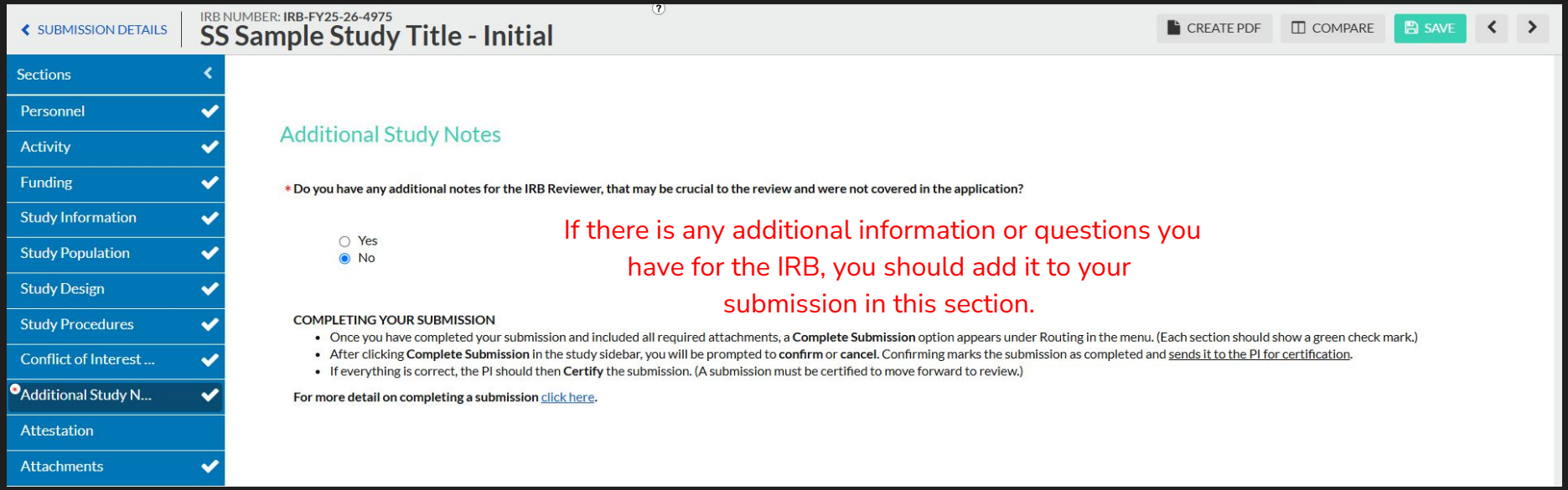
ATTACH

You will likely have to attach several things to your submission. You may attach a link or a document.

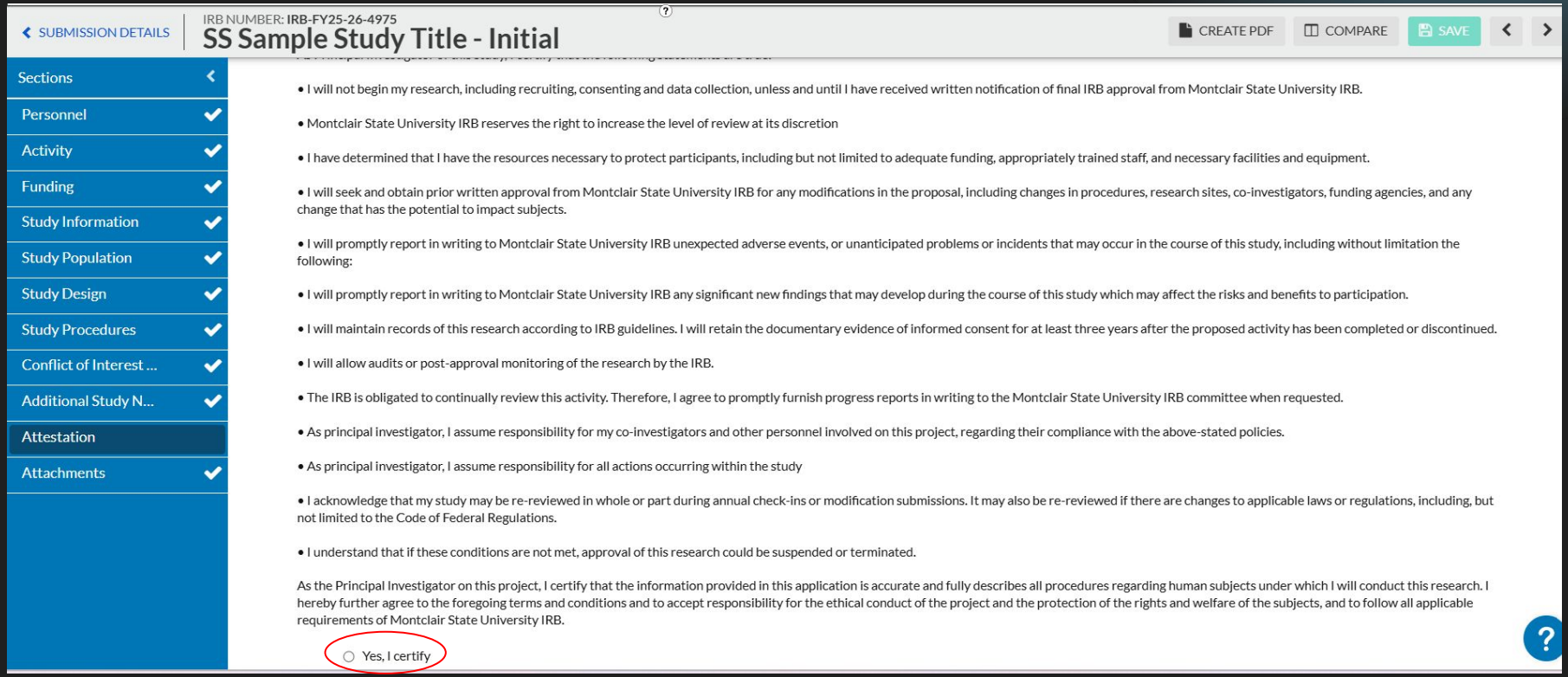
Initial Submission – Conflict of Interest (COI)



Initial Submission - Additional Study Notes

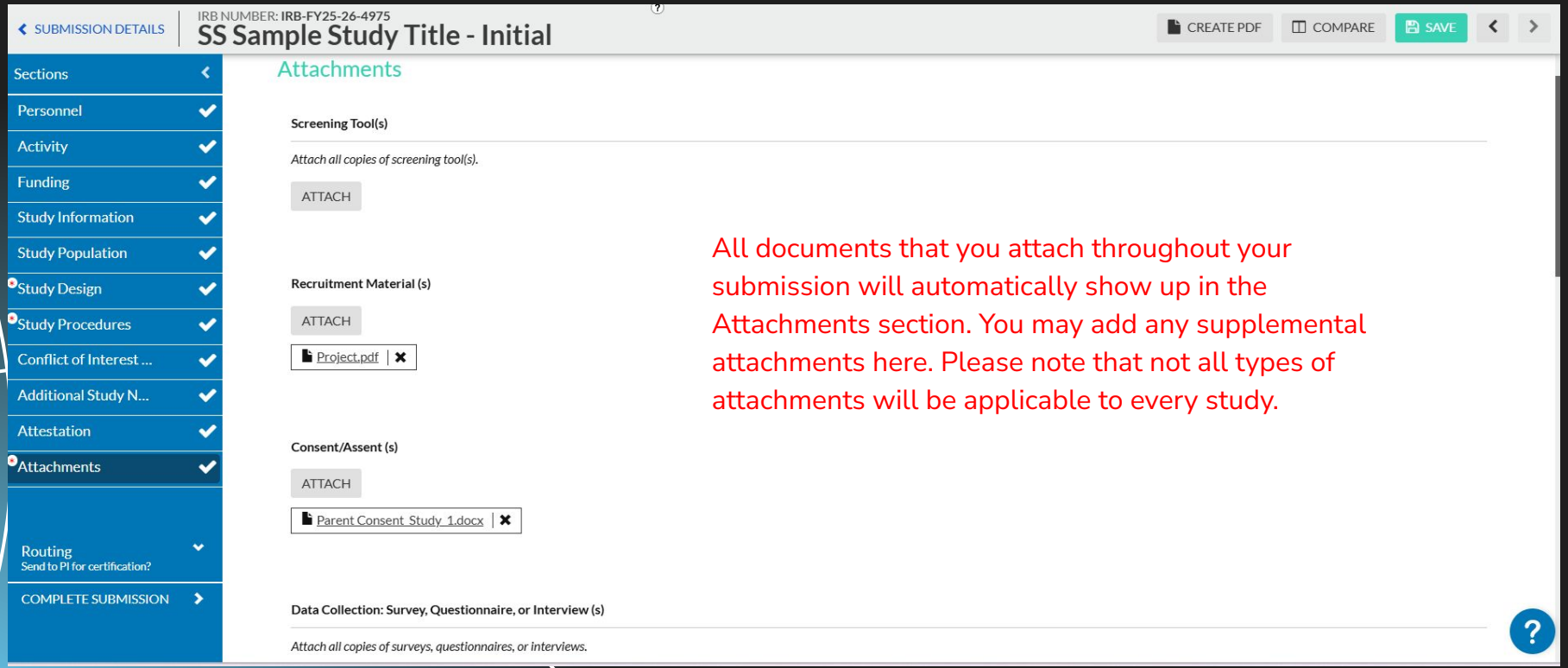


Initial Submission – Attestation



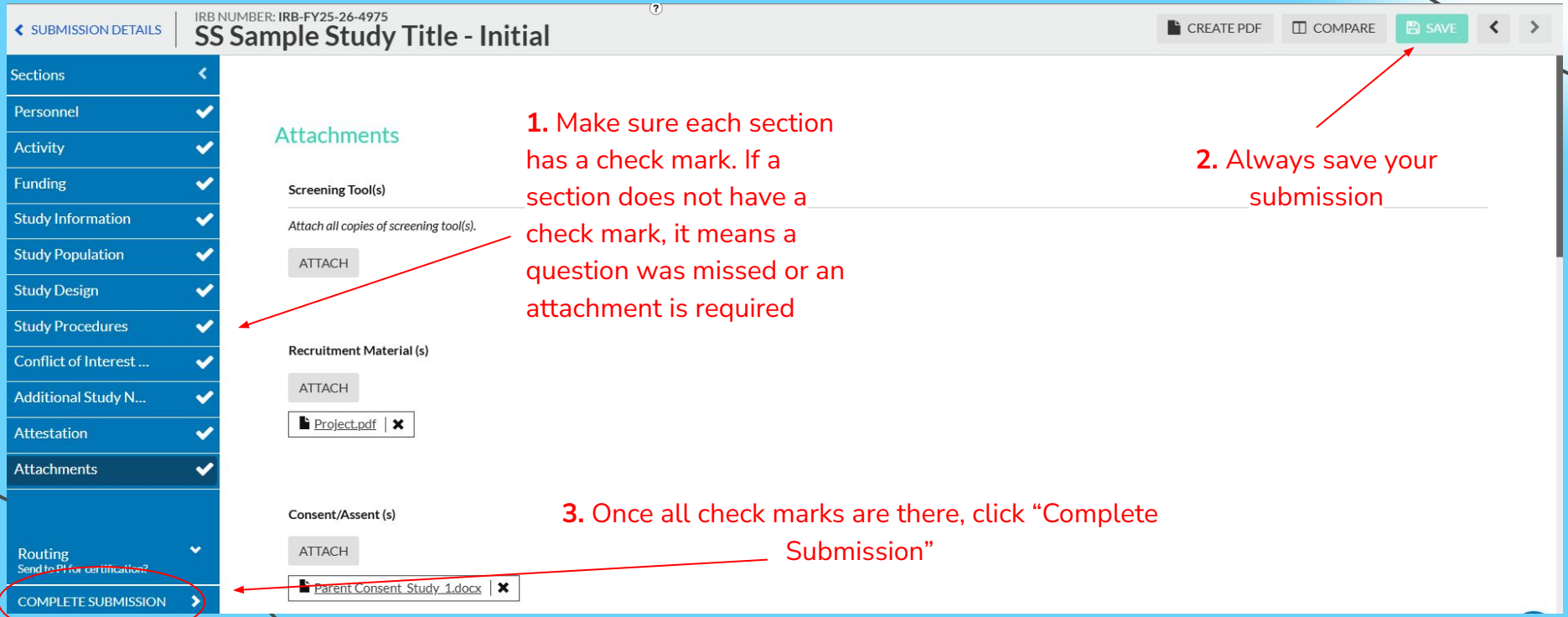
PIs must certify their understanding of the responsibilities of a Principal Investigator. After reviewing the attestation, click “Yes, I certify.”

Initial Submission – Attachments



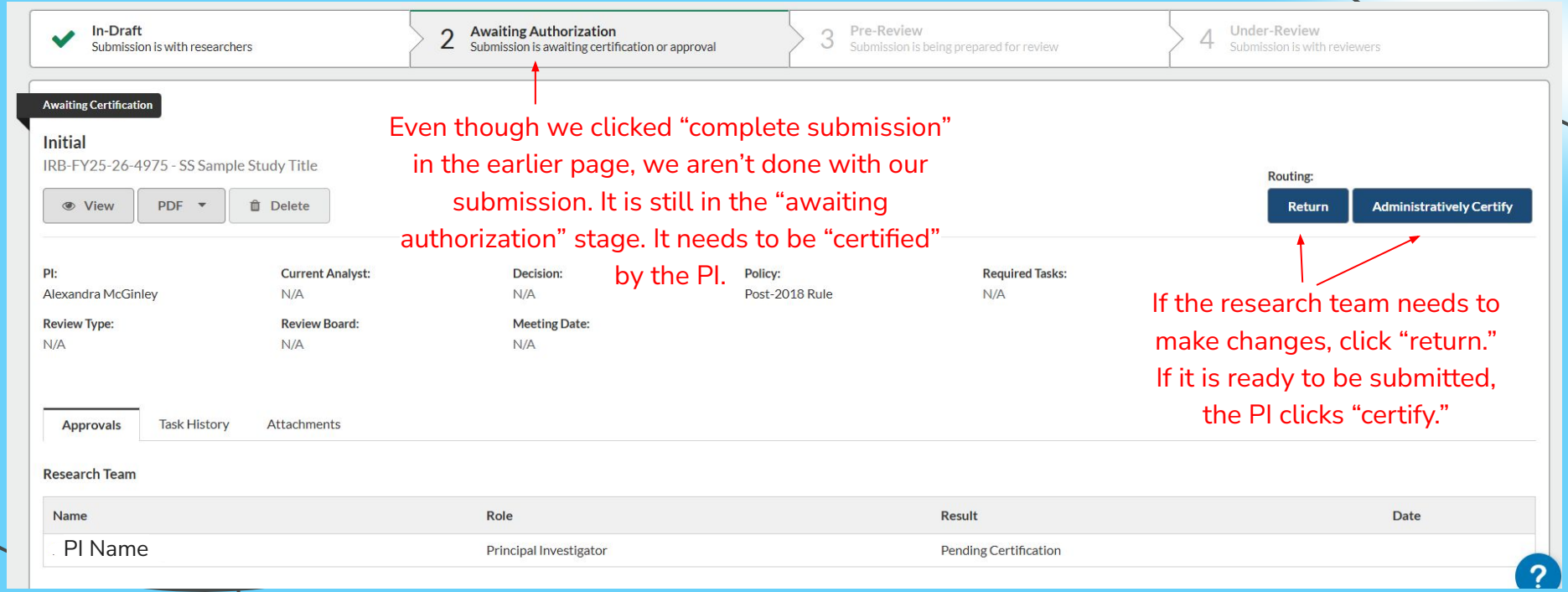
All documents that you attach throughout your submission will automatically show up in the Attachments section. You may add any supplemental attachments here. Please note that not all types of attachments will be applicable to every study.

Ready to complete your initial submission?



Awaiting Authorization

Now we are back to the general “Study page.” On the study page, you can see the status of your submission

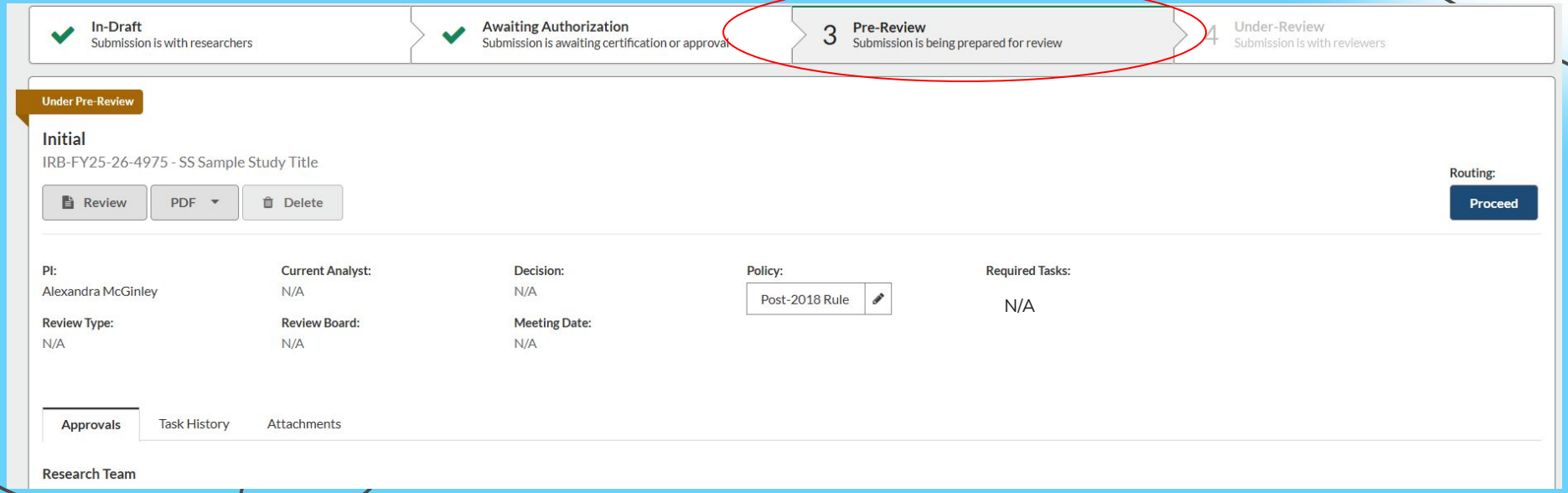


Even though we clicked “complete submission” in the earlier page, we aren’t done with our submission. It is still in the “awaiting authorization” stage. It needs to be “certified” by the PI.

If the research team needs to make changes, click “return.” If it is ready to be submitted, the PI clicks “certify.”

Pre-Review

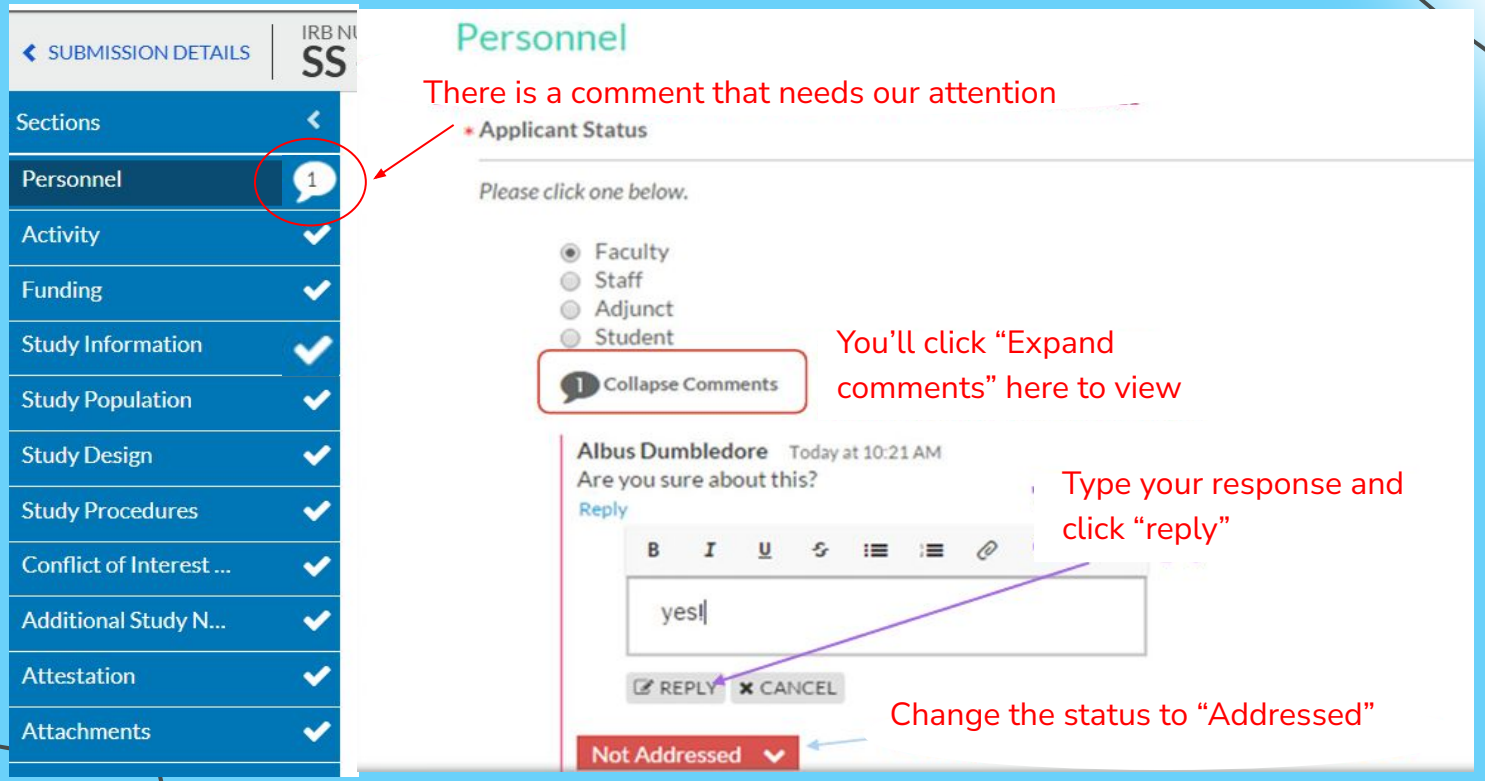
The submission has been sent to the IRB staff and is now in pre-review!



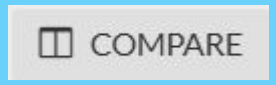
Making revisions and replying to IRB comments

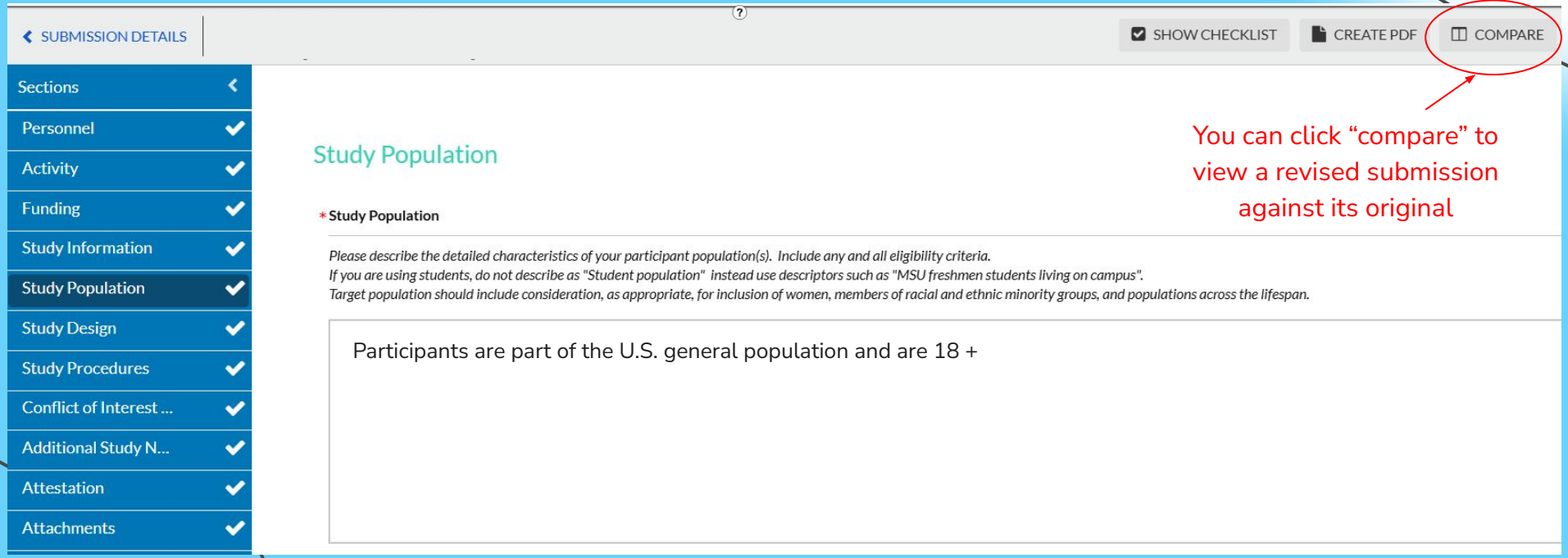
- In most cases, your submission will be returned to you for revisions
- When making revisions, you should make the requested changes directly to your submission, as well as reply to the analyst/reviewer comments to provide clarification and/or acknowledge the revision
- You will receive an email notification when revisions are required, and you will find your ‘tasks’ on the dashboard
- **If you are a student and your faculty sponsor is the PI, please let them know that they must certify in order for the submission to move forward for IRB review**

Addressing Comments



Compare Button

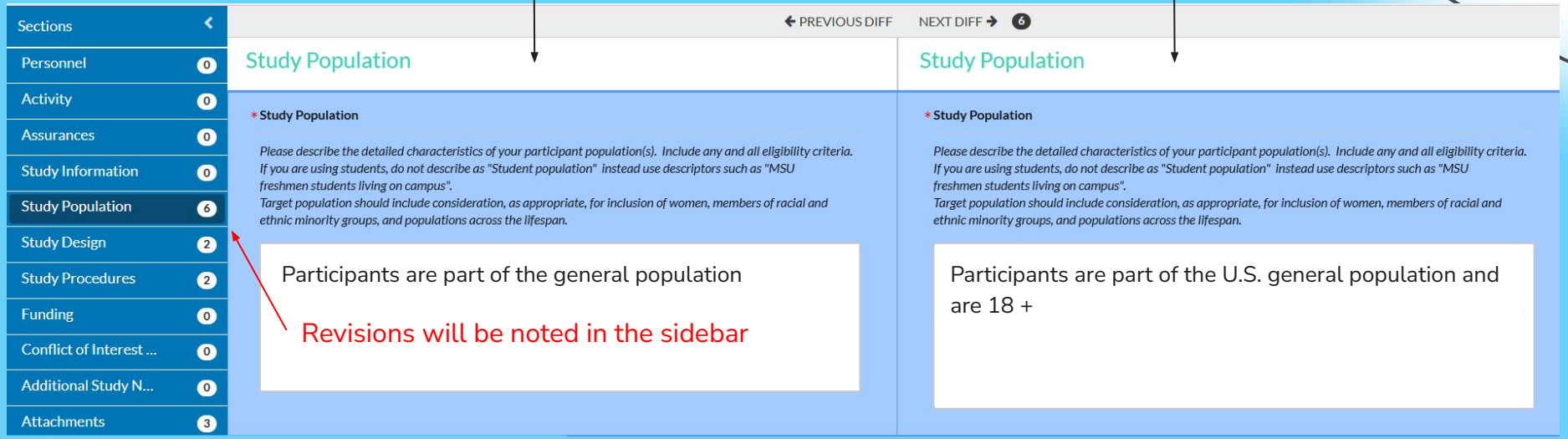




Compare Button

Previous Submission

Current Submission



What are notifications?

- Emails that will alert you that your submission requires attention
- Notifications will appear in-system AND be sent to your Montclair email
- When you are required by the IRB to make corrections or revisions, it will show up in your “Tasks” section of the dashboard

How will I know my study has been approved?

- You will be notified via email with an approval letter
- The study will appear on your dashboard under “Approved Studies”
- All approved documents will appear under your approved study - those are the documents you must use during your research. **Any changes to documentation, methods, or your protocol MUST be submitted to and approved by the IRB via a Modification submission**

Keep in mind...

- Complete CITI Training
    - All research team members need to complete CITI training every 3 years
- Pick up my approval documents?
    - No, you will not be sent physical approved documents
- Use the Montclair templates for consent forms/ site approval letters
- Apply for continuing review?
    - Students will complete an annual check in while faculty will complete check in every 2 years on exempt and expedited studies. Full board studies require annual review regardless of personnel.

If you have any questions in regards to your Cayuse submission, please email irbassistant@montclair.edu and an IRB staff member will happily assist you!

For more information about Cayuse submission process, visit our website!