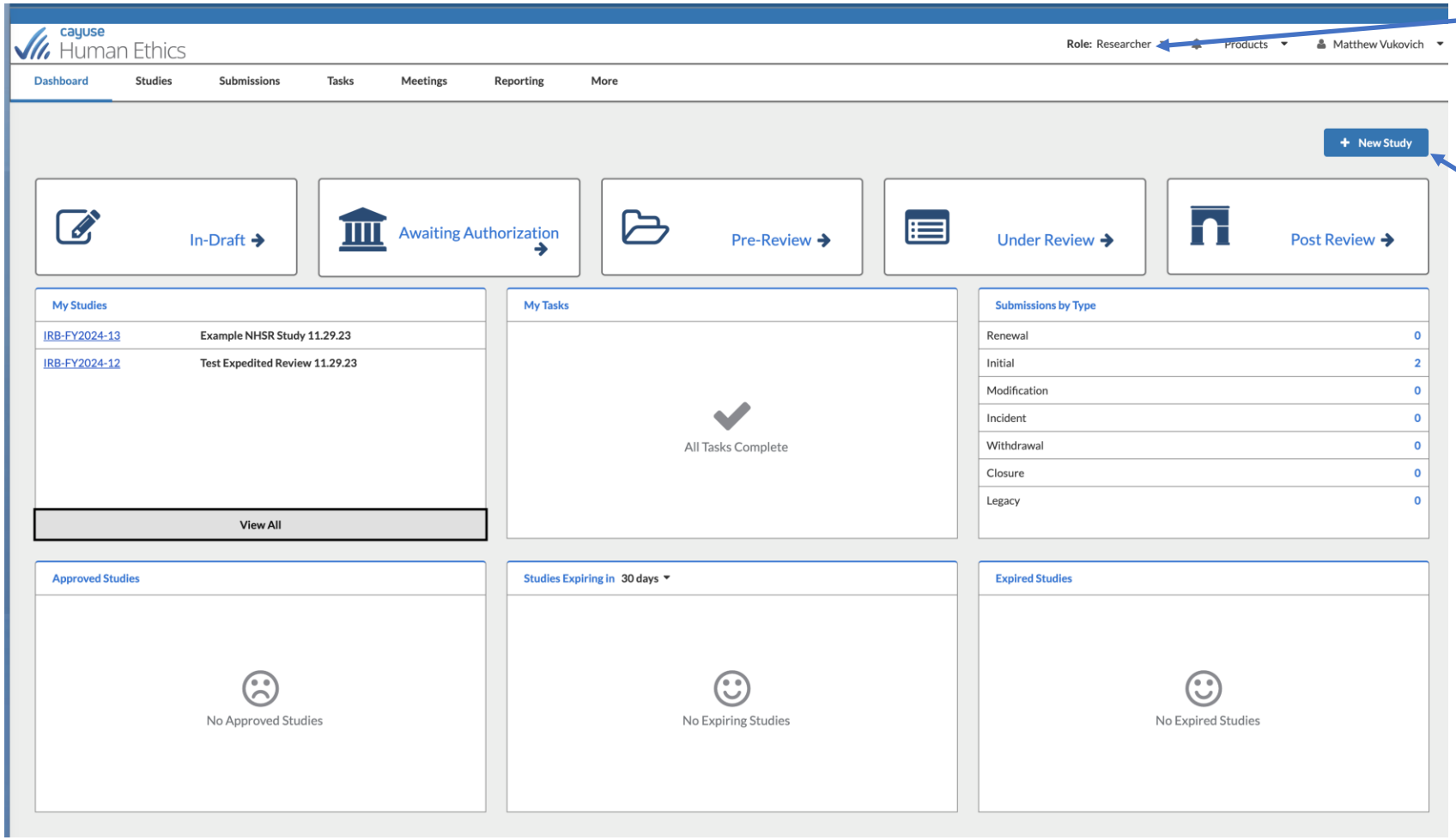
South Dakota State University

Tutorial for Submitting an Application for review by the SDSU IRB in Cayuse

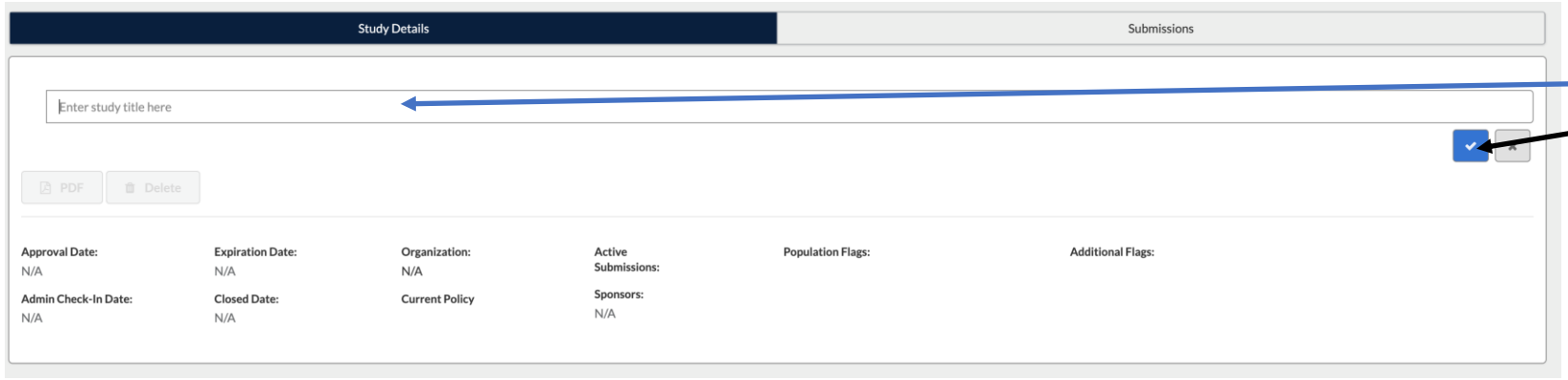


Opening screen after logging in with SSO credentials.

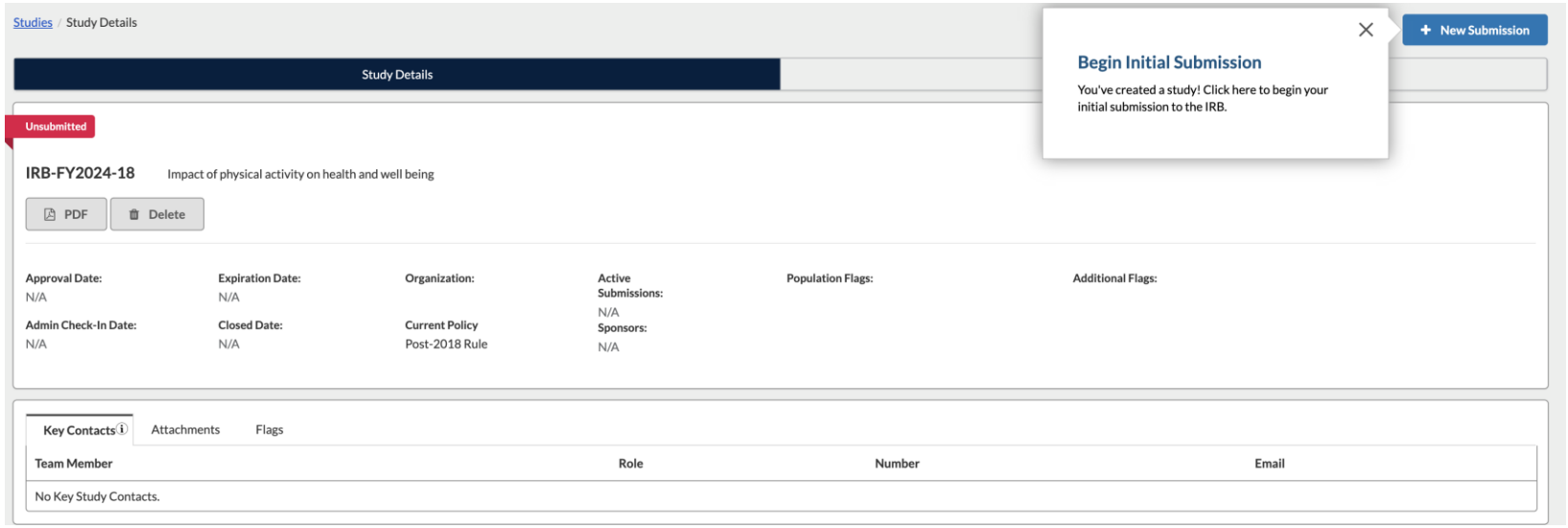
To submit a new application for review, ensure the role selected is that of Researcher.

To submit a new application, or if you are unsure if your study needs reviewed select + New Study

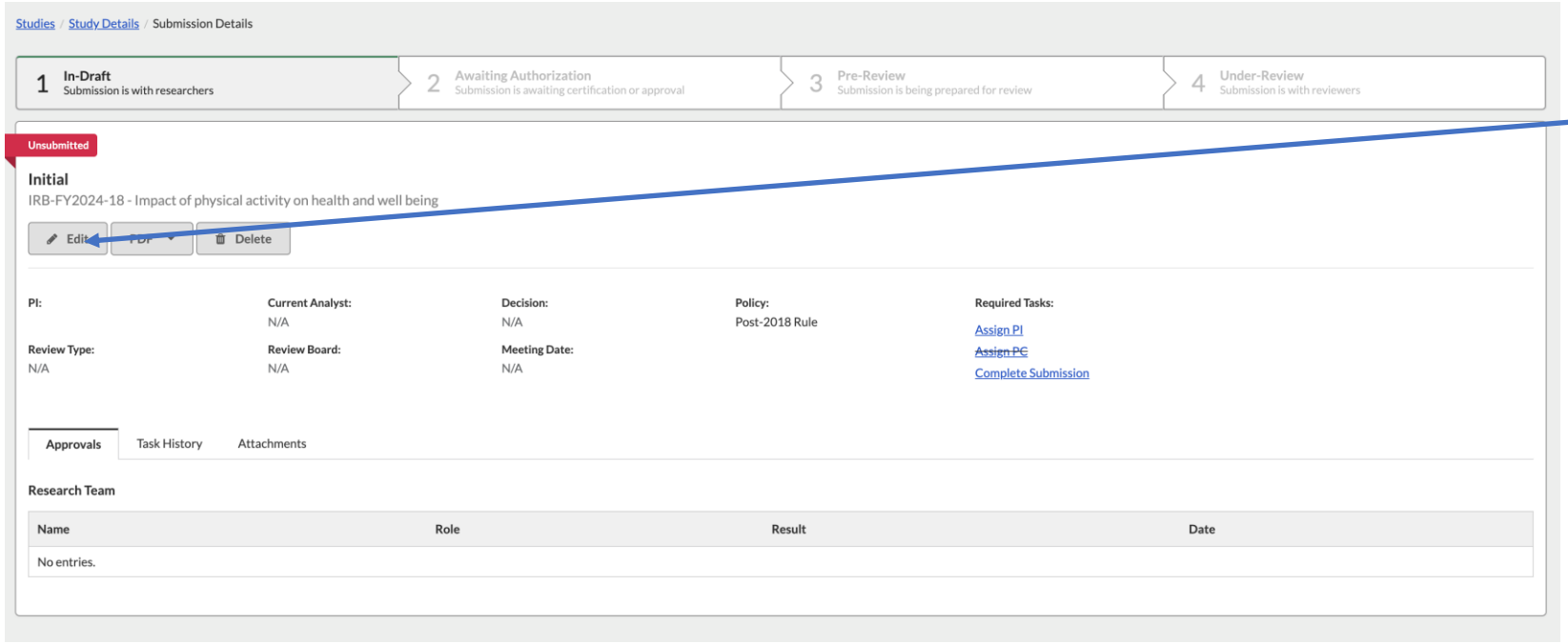
The Human Ethics dashboard allows you to check on the status of your application from submission to acceptance and post—review.



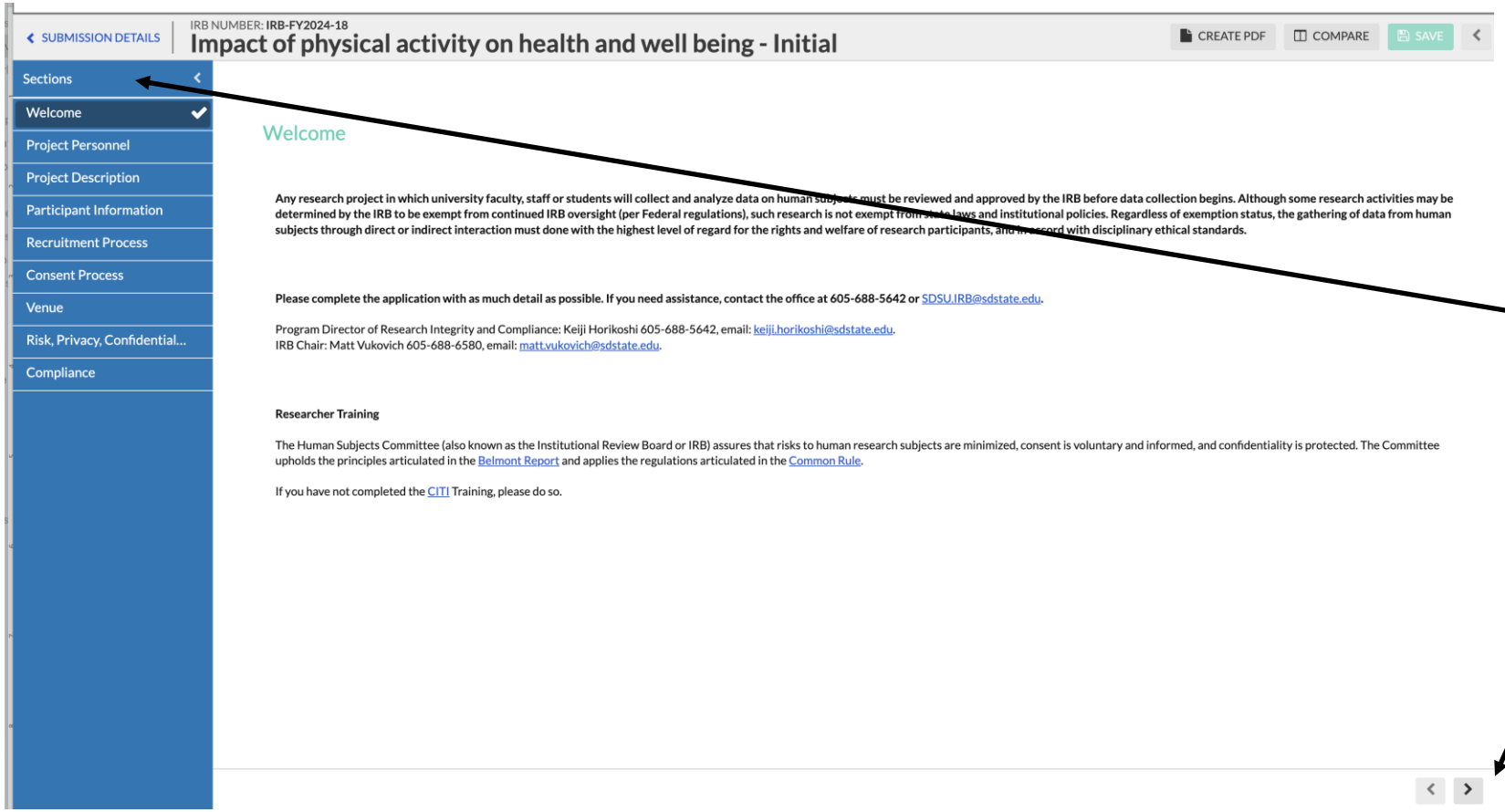
Enter the title of the study.
Click checkmark.



Select the [+New Submission] button.
Then select [Initial] from the drop-down menu.

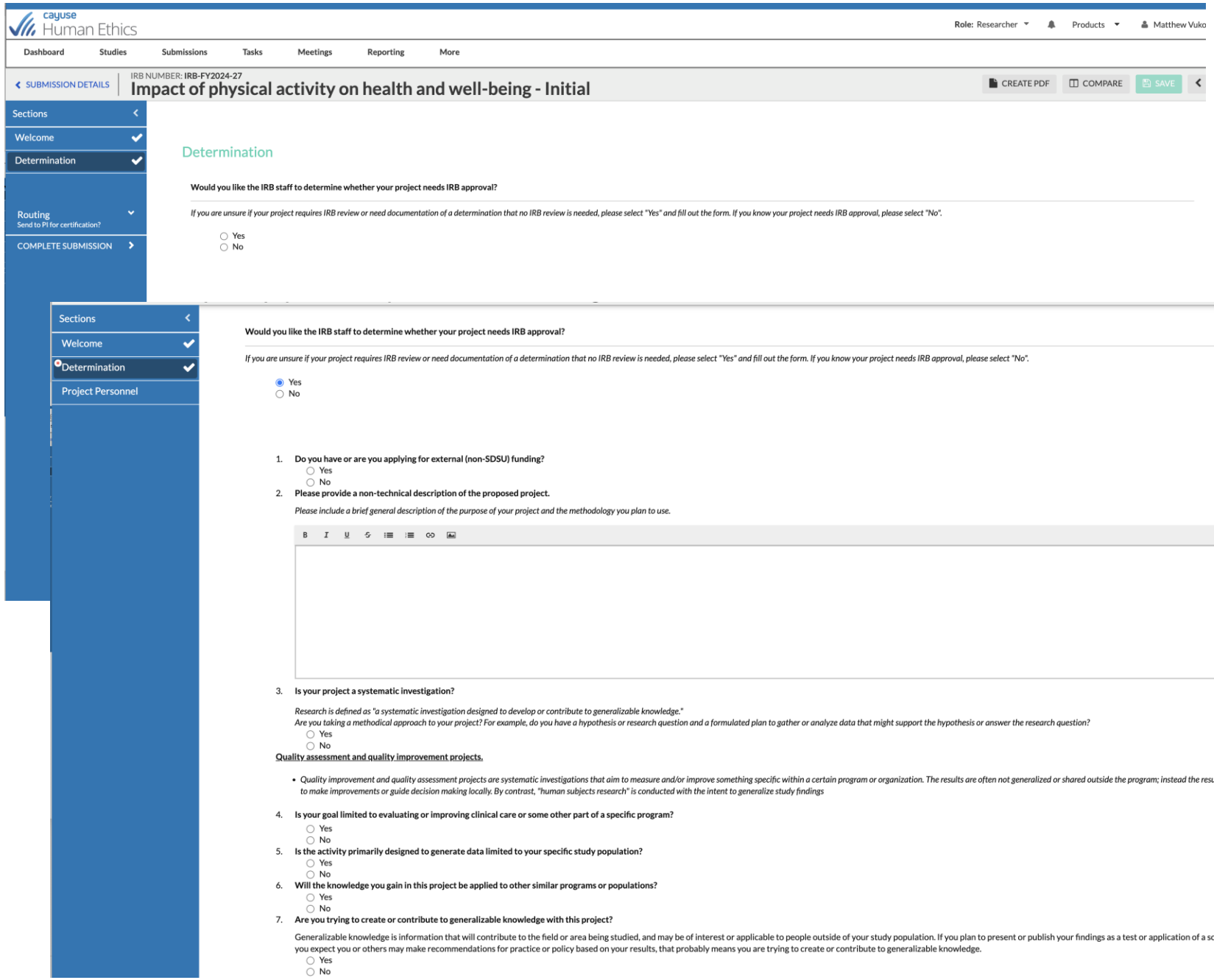


Select the [Edit] button to begin entering the information about your study.



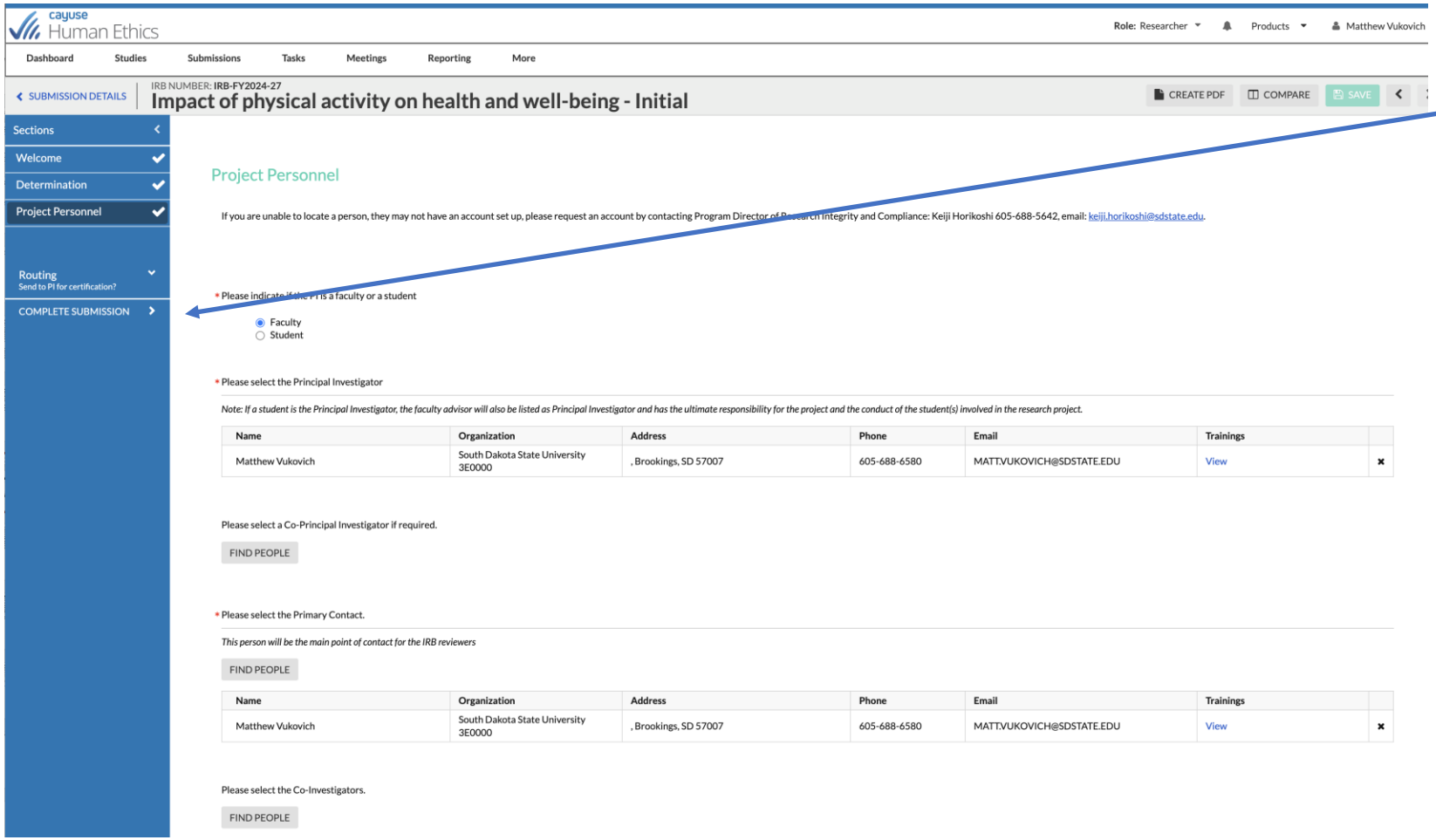
Some of the sections will be informational while others will request information about your study. When a section is completed, select the arrow button to move to the next section. Or you can click on the section heading in the left menu.

As you enter the information requested, the application uses built in logic to walk you through the necessary sections.

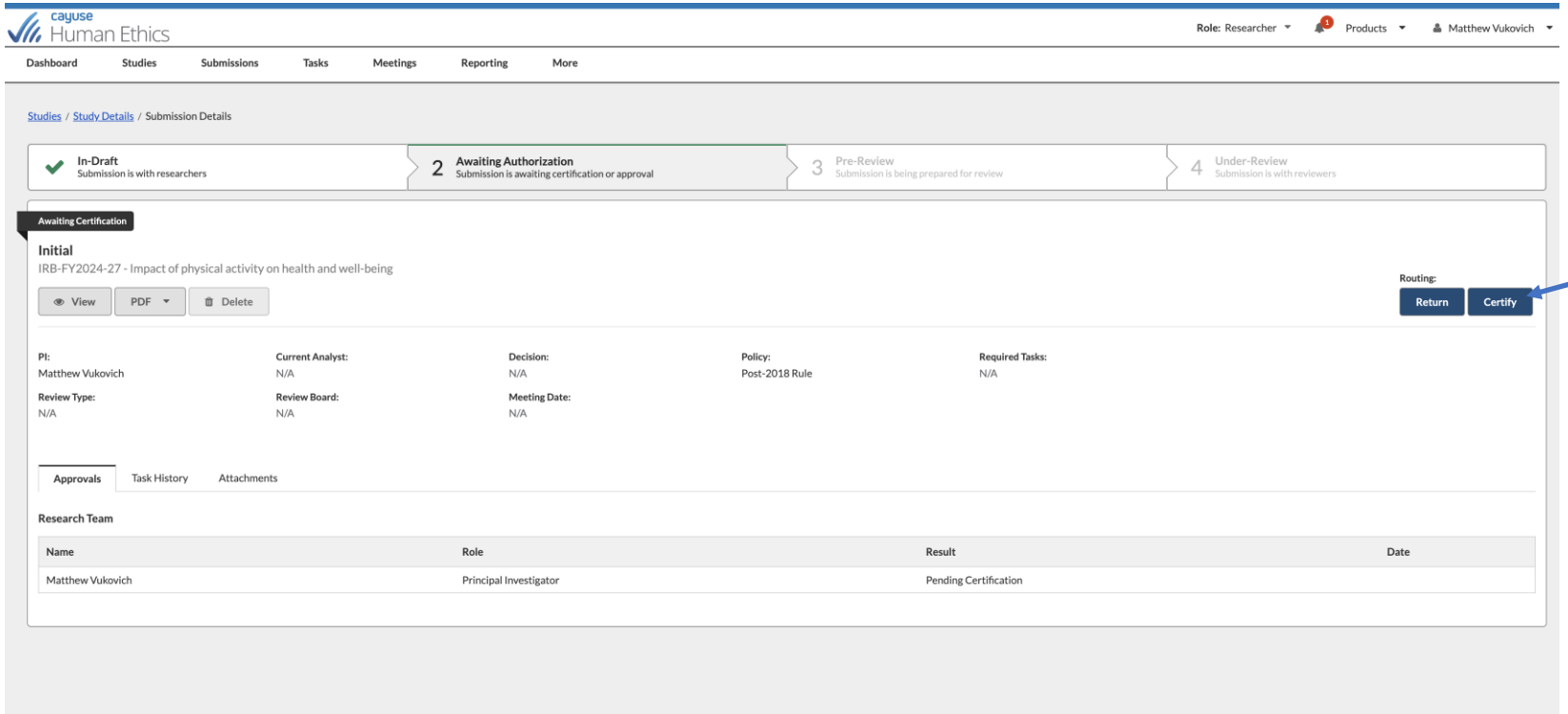


If you are unsure if your study requires IRB review, select [Yes] and answer the questions. You will also need to complete the Project Personnel Page.

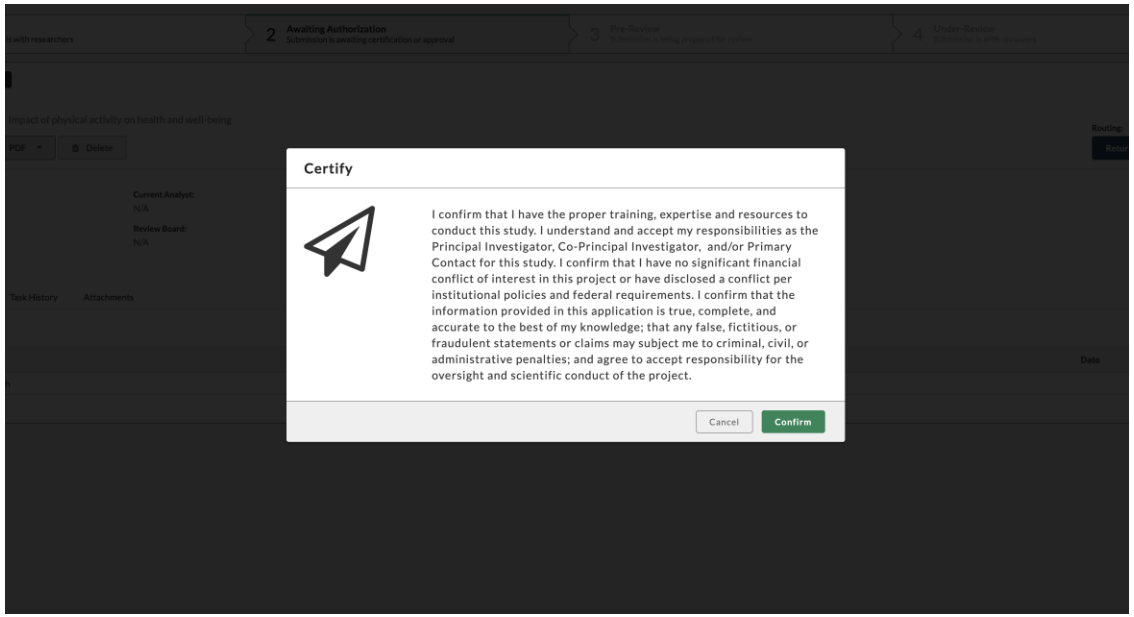
If you select [No], the Project Personnel Page will be the first section to complete.



If you originally selected [Yes] to on the Determination screen:
Once the Project Personnel section has been completed, select Complete Submission.

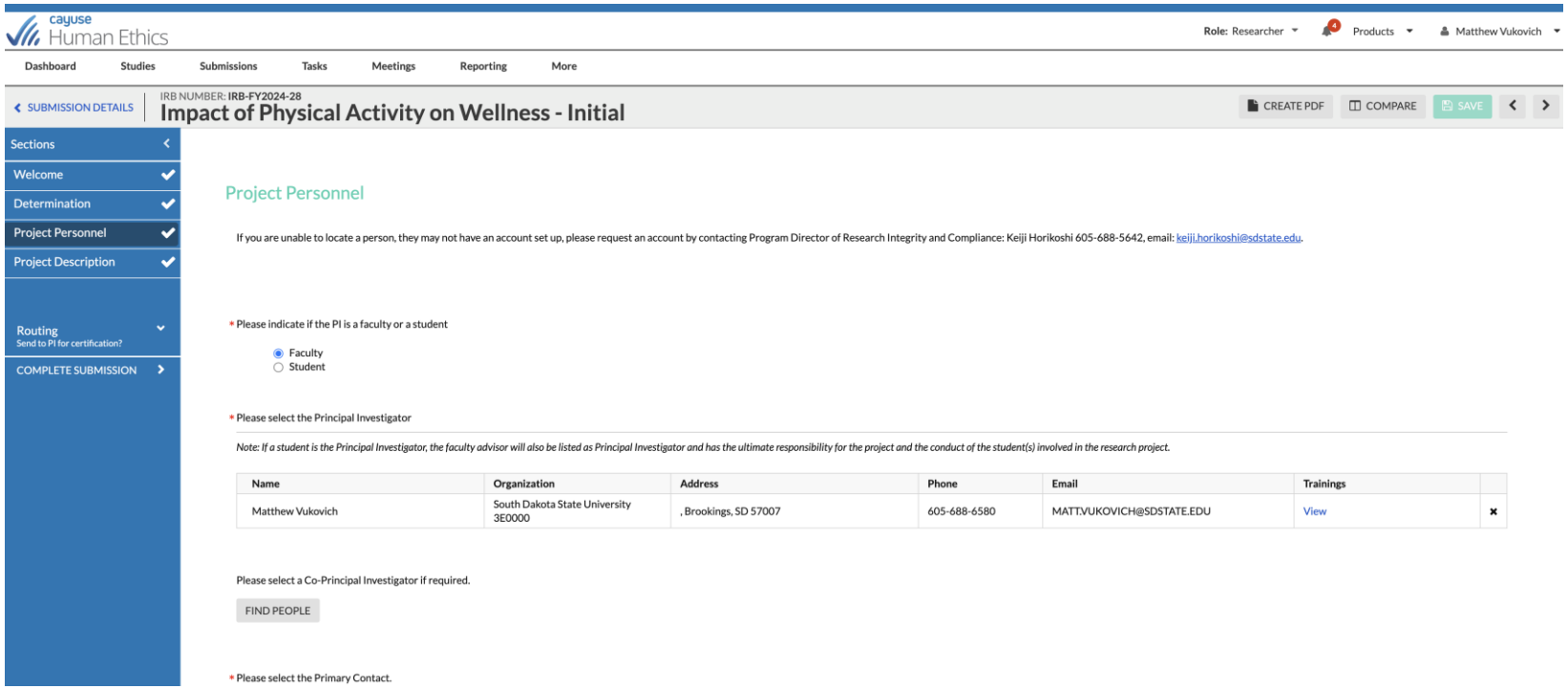


Once submission is completed, the next screen will ask you to Certify the project.

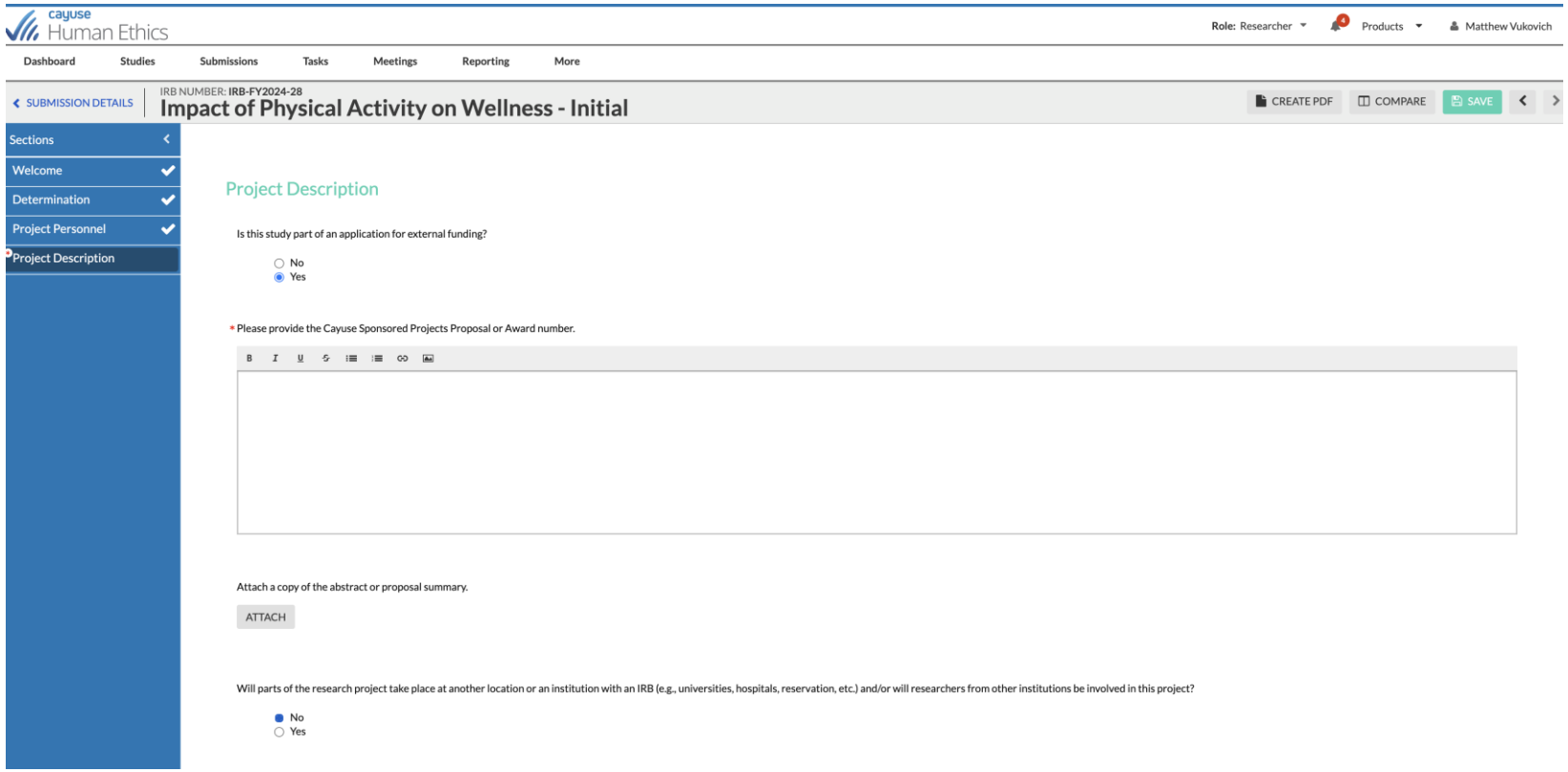


After selecting [Confirm], the application will be sent to the IRB to review and determine if the project is human subject research and if it requires review.

You will be able to track the progress of the application on this screen.



If you selected [No] in the Determination section, you will be directed to complete the Project Personnel Information, followed by questions specific to the project [Project Description].

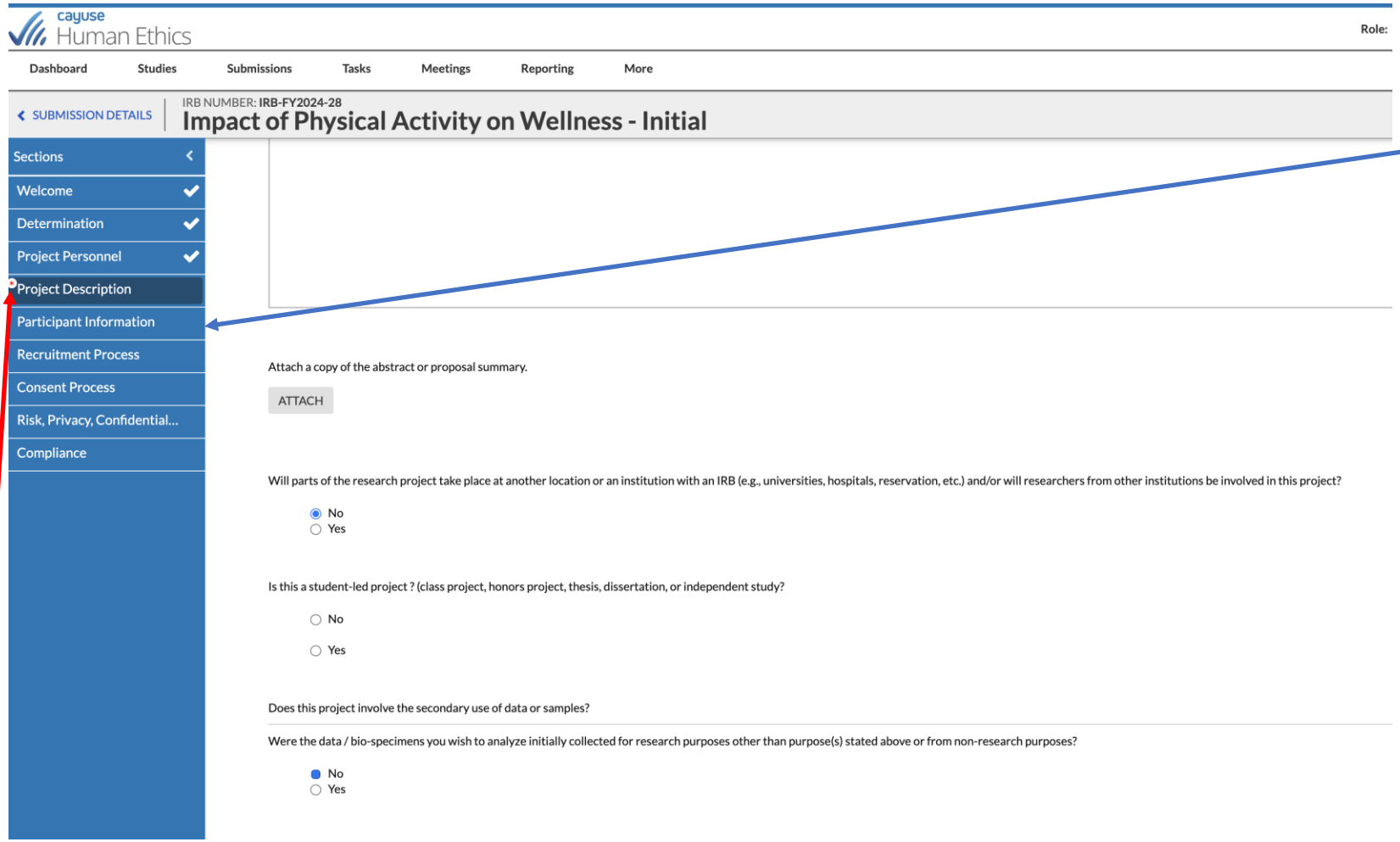


Project Description

As you answer questions there will be additional popup questions based on your answers.

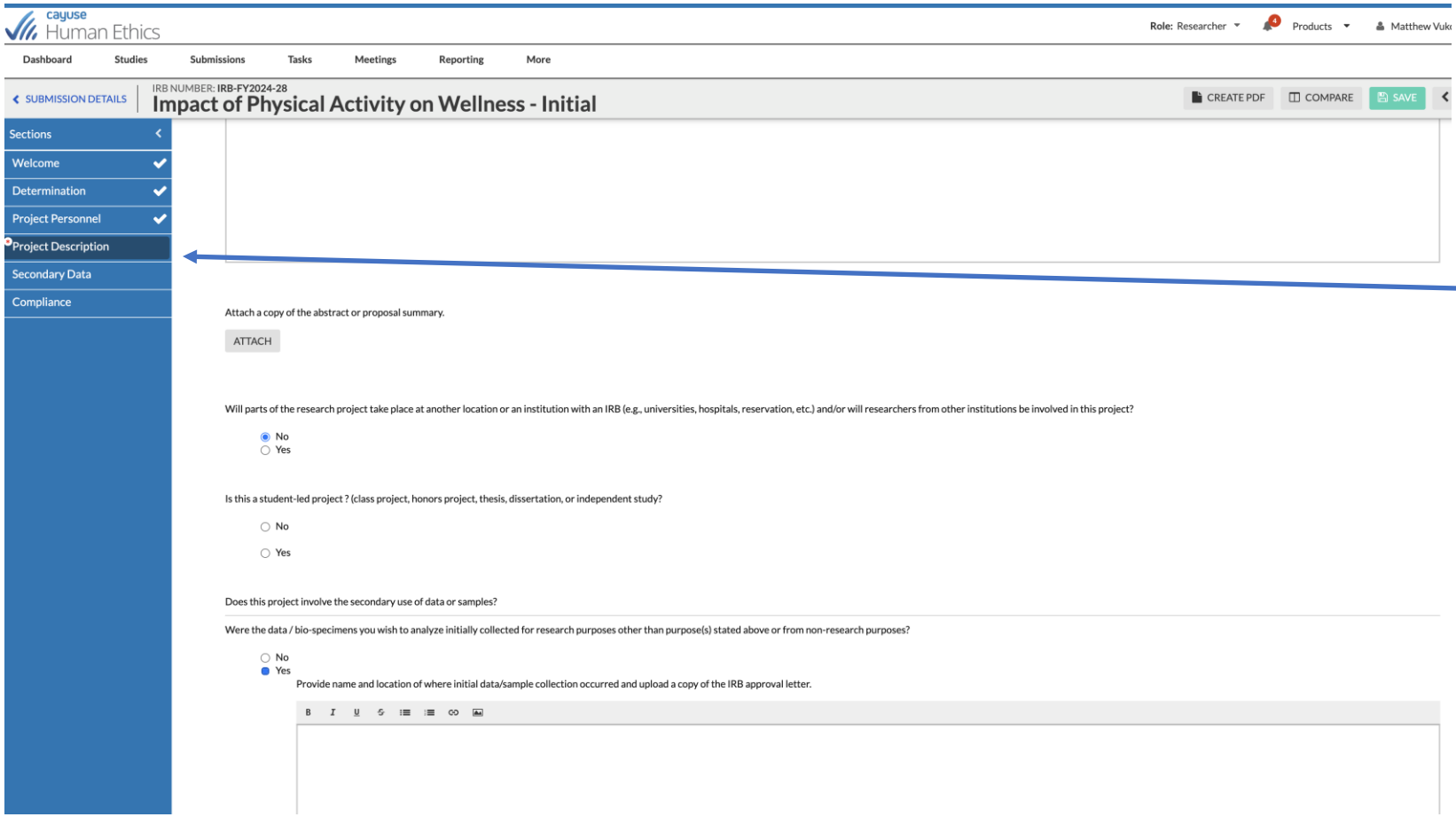
Questions will address study purpose, methodology, data analysis, if external IRBs are involved, etc.

If the application is part of an externally funded project, provide the routing number from the SDSU Routing document or the Cayuse Proposal Number.



If you select [No] to the question, “Does the project involve the secondary use of data or samples?”, you will see additional sections appear on the left menu.

As sections are completed, a checkmark will appear.
If a red asterisk (*) appears, there is a required question that needs to be completed.



If you select [Yes] to the question, “Does the project involve the secondary use of data or samples?”, questions specific to the acquisition and use of secondary data will appear.

Participant Information

Maximum number of participants you plan to enroll.

- You may estimate; however, the number of participants consented cannot exceed this number.
- Once a person has been consented they are considered a participant, even if they withdraw, do not complete the study, or the data is not used. We suggest you estimate more than your target sample size to account for this.
- Potential participants that are screened but not consented because they do not meet your enrollment criteria are not included in this number

Describe study population.

Protected and/or Special Subject Populations.

Check all populations you plan to focus on.

- [ ] N/A
- [ ] Pregnant women
- [ ] Children
- [ ] Prisoners
- [ ] Your Employees
- [ ] Your Students
- [ ] Emancipated Minors
- [ ] Fetuses/Neonates
- [ ] Those with limited decision-making capacity
- [ ] Individuals with limited English proficiency.
- [ ] Economically/educationally disadvantaged persons.
- [ ] American Indian or Alaskan Native

For any of the special populations checked, provide rationale, and describe all special considerations and/or steps that will be taken to ensure their protection from undue influence or coercion to participate.

Participant Information

In this section you will describe the study population and identify if any special populations will be recruited to participate. Questions about offering extra credit for students and/or compensation for participants is included.

Recruitment Process

How will you recruit participants?

Check all that apply.

- [ ] In-person
- [ ] E-mail
- [ ] Phone/text message
- [ ] Web-post
- [ ] Flyer
- [ ] Letter
- [ ] Research pool
- [ ] Snowball Sampling
- [ ] Word of mouth
- [ ] Social Media
- [ ] Other

Please attach your recruitment materials including emails, social media posts, flyers, etc.

Recruitment materials should include:

- Purpose & topic of the research
- What participants will do in
- the study (including how long it will take)
- Simple eligibility criteria (over 18, USD student, etc.)
- Location of the research (e.g., online, on-campus, specific off-campus location, etc.)
- Researcher name and contact information (email address, phone number, etc.–lab contact information is OK instead of personal)

ATTACH

Describe the recruitment process, including where and when it will take place.

B I U S

<u>Recruitment Process</u>. Describe the recruitment process and the methods used. You will need to upload the recruiting materials. Select [ATTACH], a popup will allow you to attach the recruitment materials.

Consent Process

Attach all consent/assent forms.

**If your study is registered on clinicaltrials.gov, your consent form must include the following statement: A description of this clinical trial will be available on clinicaltrials.gov/, as required by U.S. law. This will not include information that can identify you. At most, the website will include a summary of results. You can search clinicaltrials.gov at any time

ATTACH

Indicate how you will obtain consent from participants.

Check all that apply. (Contact the IRB for assistance or questions at sdsu.irb@sdstate.edu)

- [ ] Signed informed consent.
- [ ] Electronic signature. (**Note:** *a checkbox does not count as an electronic signature.)*
- [ ] Implied consent.
- [ ] Child assessment and parental consent
- [ ] Obtaining consent using a short form with oral explanation and witness.
- [ ] Other

Provide a detail description of the consent process including who will obtain consent/assent and timing, providing participants sufficient time for adequate consideration.

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Consent Process

Attach your consent/assent documents and answer the questions specific to the consent process.

Risk, Privacy, Confidentiality, and Data Protection

Are there potential risks to the research participants in any of the following areas?

- [ ] Physical (i.e., discomfort, pain, injury, illness, or disease; may result from administration of stimuli, controlled substances, or devices. Engaging a subject in a social situation which could involve violence may also create a physical risk).
- [ ] Psychological (includes the production of anxiety, depression, guilt, shock, and loss of self-esteem. Sensory deprivation, sleep deprivation, use of hypnosis, deception or mental stresses are examples of psychological risks.)
- [ ] Economic (such as direct costs; loss of wages or income for participating; or breach of confidentiality that may result in loss of employment or damage to a subject's employability).
- [ ] Social (i.e., embarrassment, loss of respect, negative labeling, or harming relationships within a subject's business or social group; breach of confidentiality regarding drug and alcohol use, mental illness, and sexual behavior).
- [ ] Legal (requiring activities for which the subject may be criminally or civilly liable; or disclosing illegal activity or information that would be reportable to authorities or might render the subject prosecutable under the law, such as child abuse, alcohol abuse, alcohol abuse by a pregnant woman, danger to self or others).

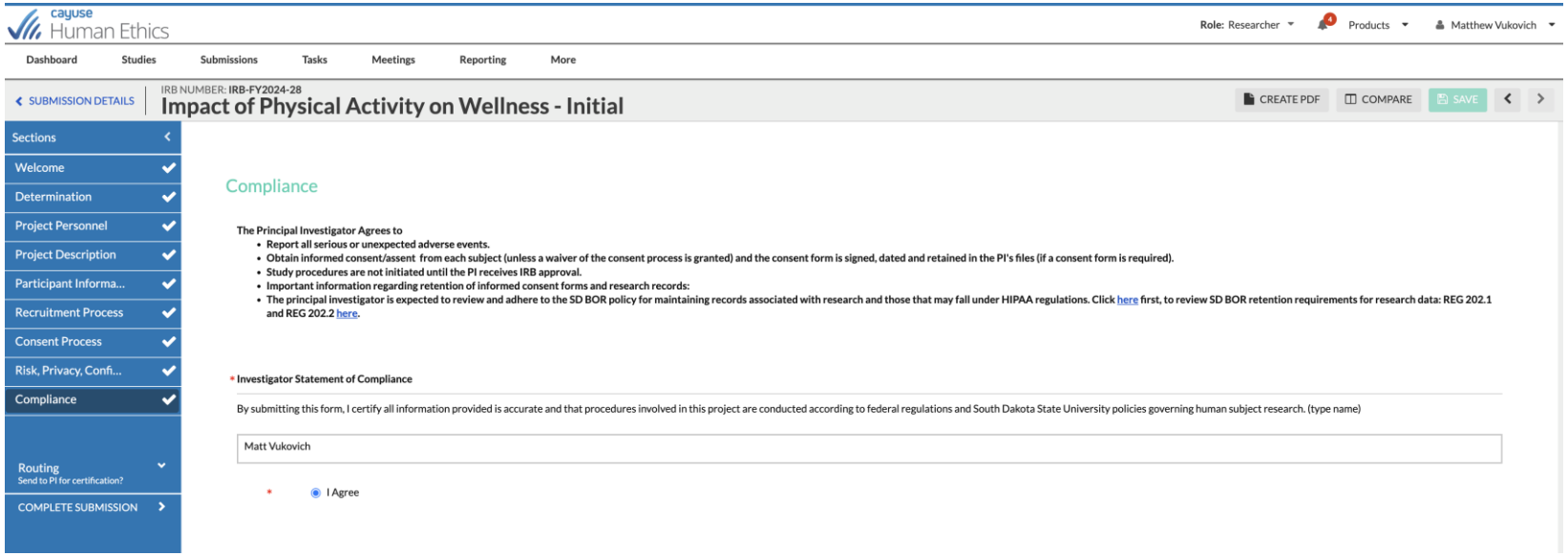
Will the research involve incomplete disclosure (deception) to subjects?

- ○ No
- ○ Yes

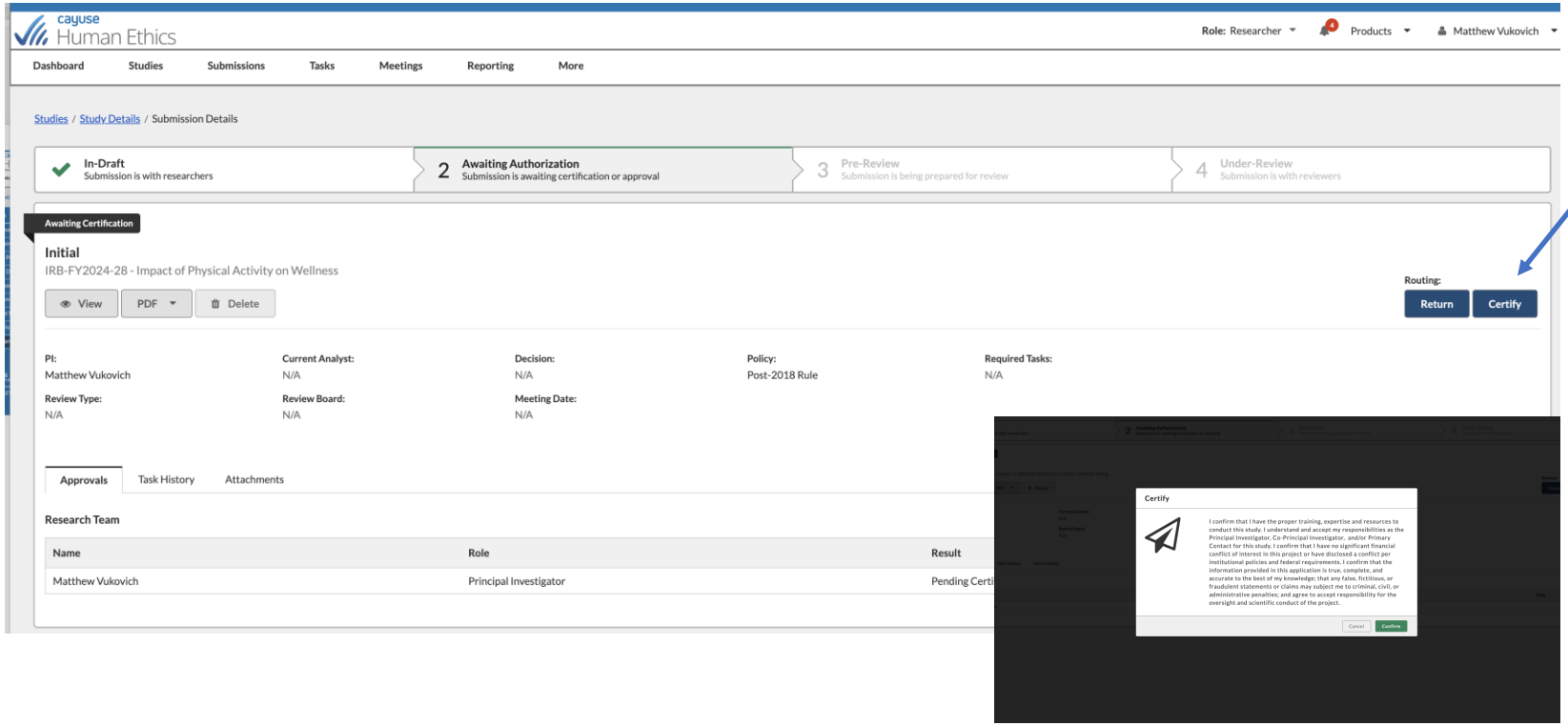
Identify all sources of data you plan to collect.

Check all that apply.

- [ ] Survey
- [ ] Interview or Focus Groups
- [ ] Records
- [ ] Databases
- [ ] Observations
- [ ] Biological specimens
- [ ] Sensor
- [ ] Measurements
- [ ] Other



After completing the compliance section, select [Complete Submission] and confirm submission.



Once submission is completed, the next screen will ask you to Certify the project.
After selecting [Confirm], the application will be sent to the IRB. Your supervisor will also be asked to certify the project.

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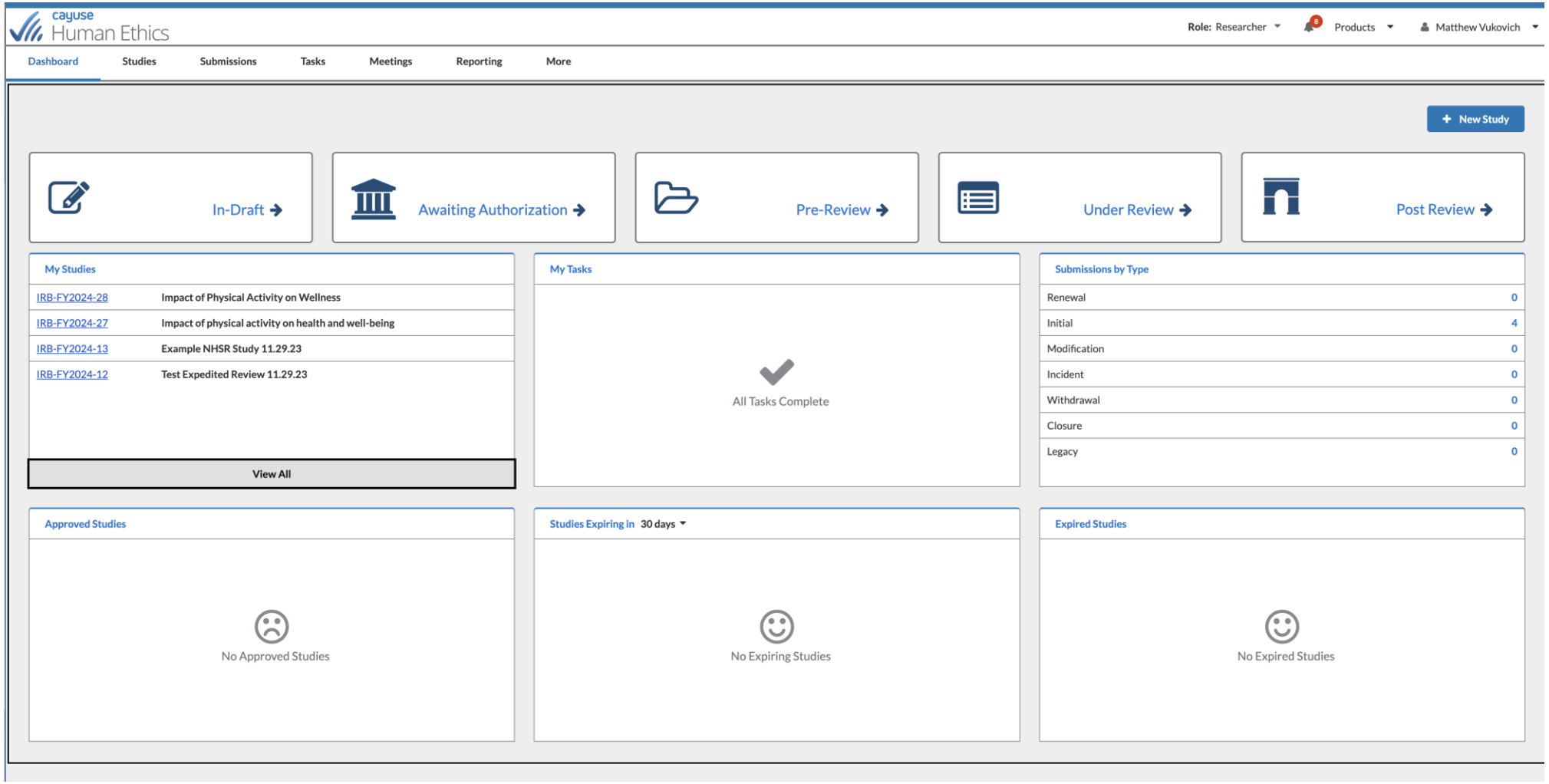

The dashboard allows you to track your submissions and to see if the IRB has any tasks, issues, or questions for you to address.