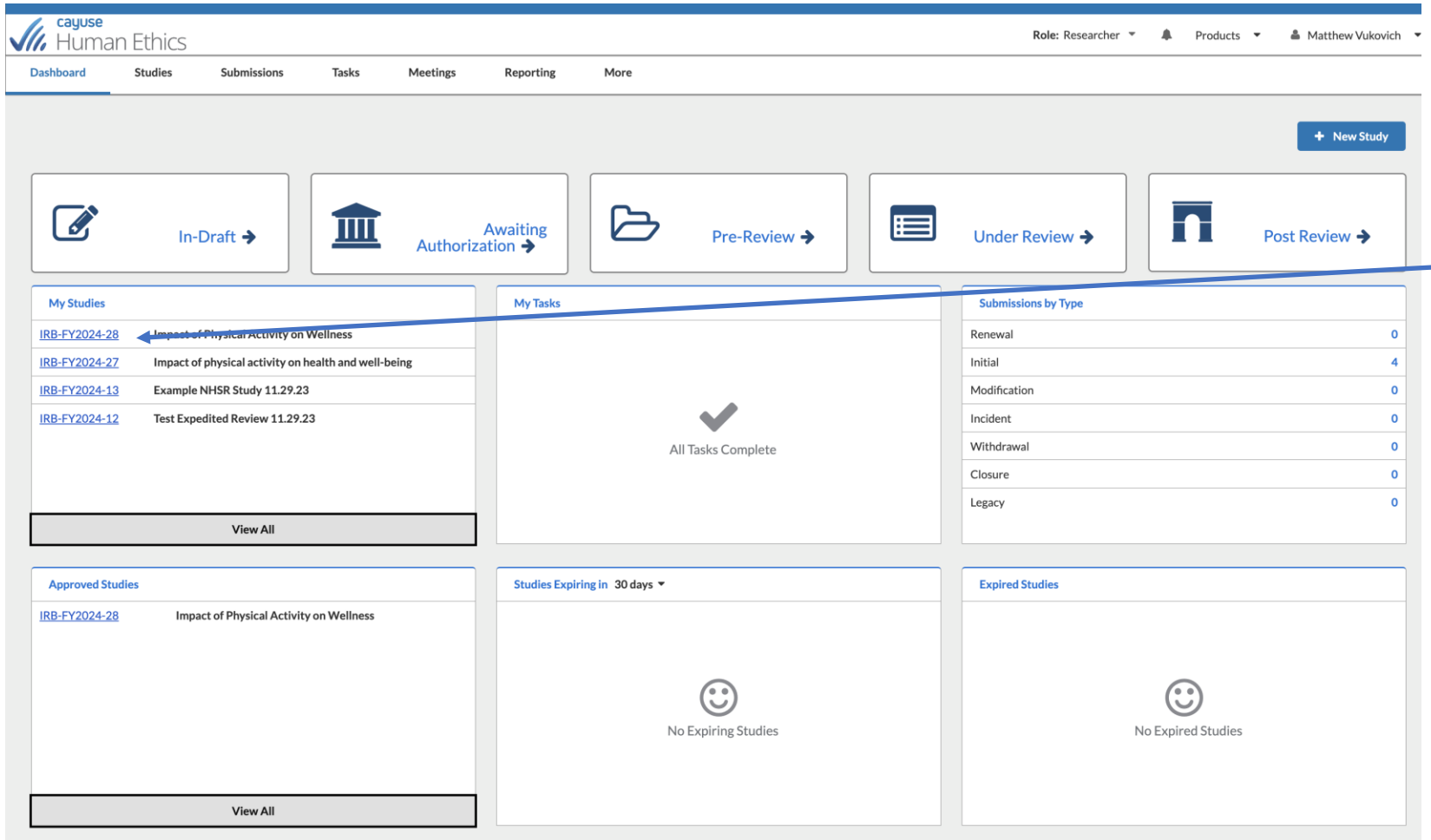
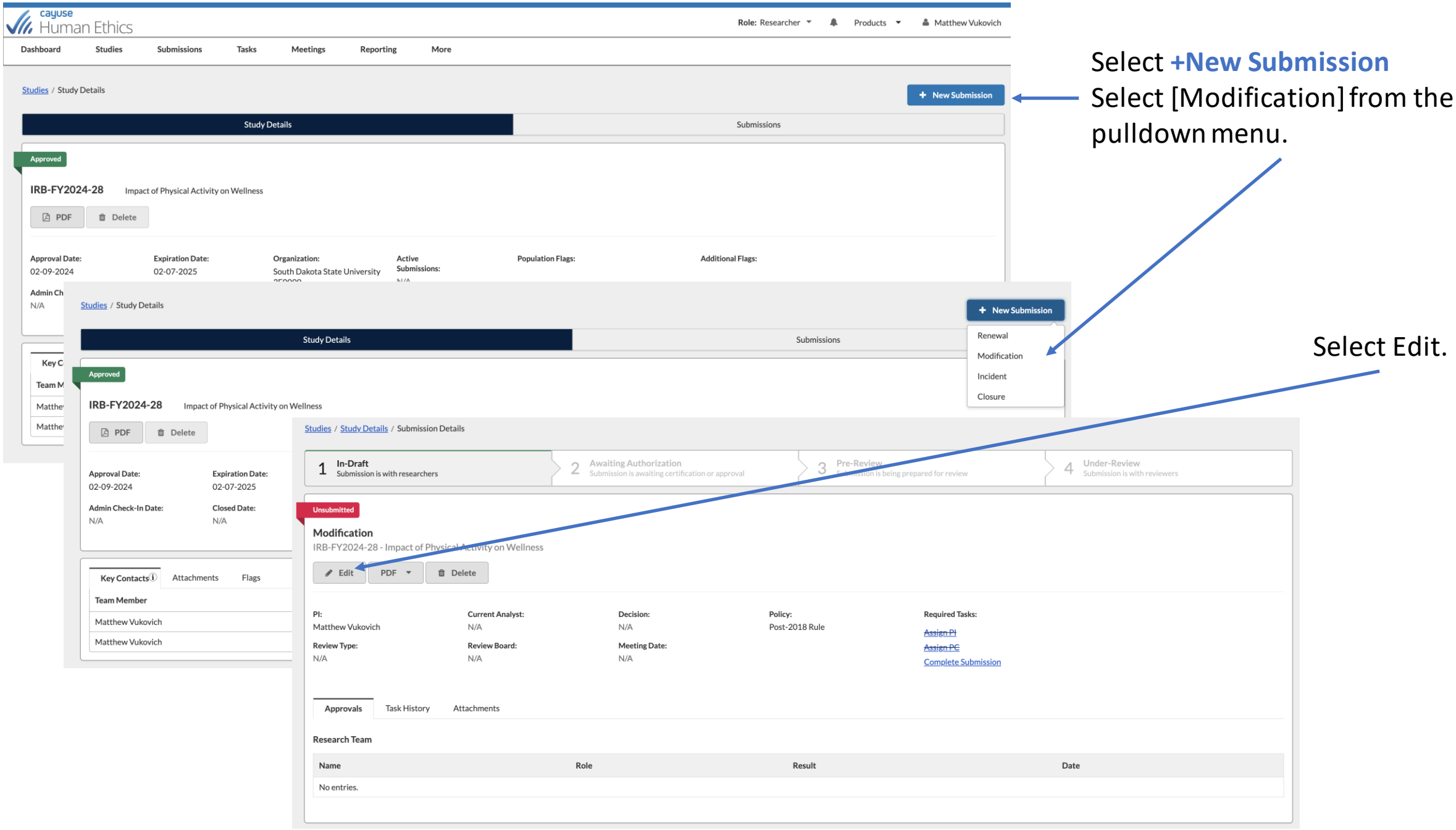
SOUTH DAKOTA
STATE UNIVERSITY

Tutorial for Submitting a Modification for review by the SDSU IRB in Cayuse



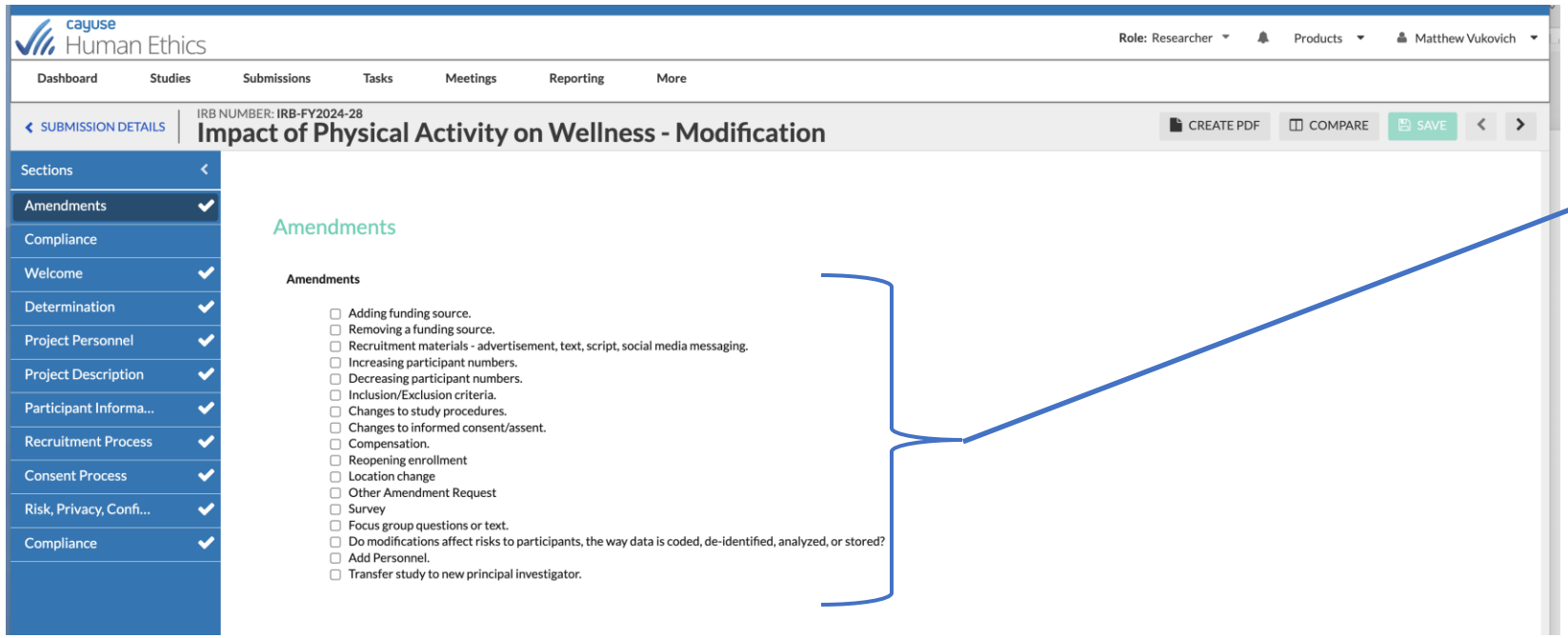
Dashboard view of Cayuse Human Ethics module.
To modify an approved study, select the study from the **My Studies** menu



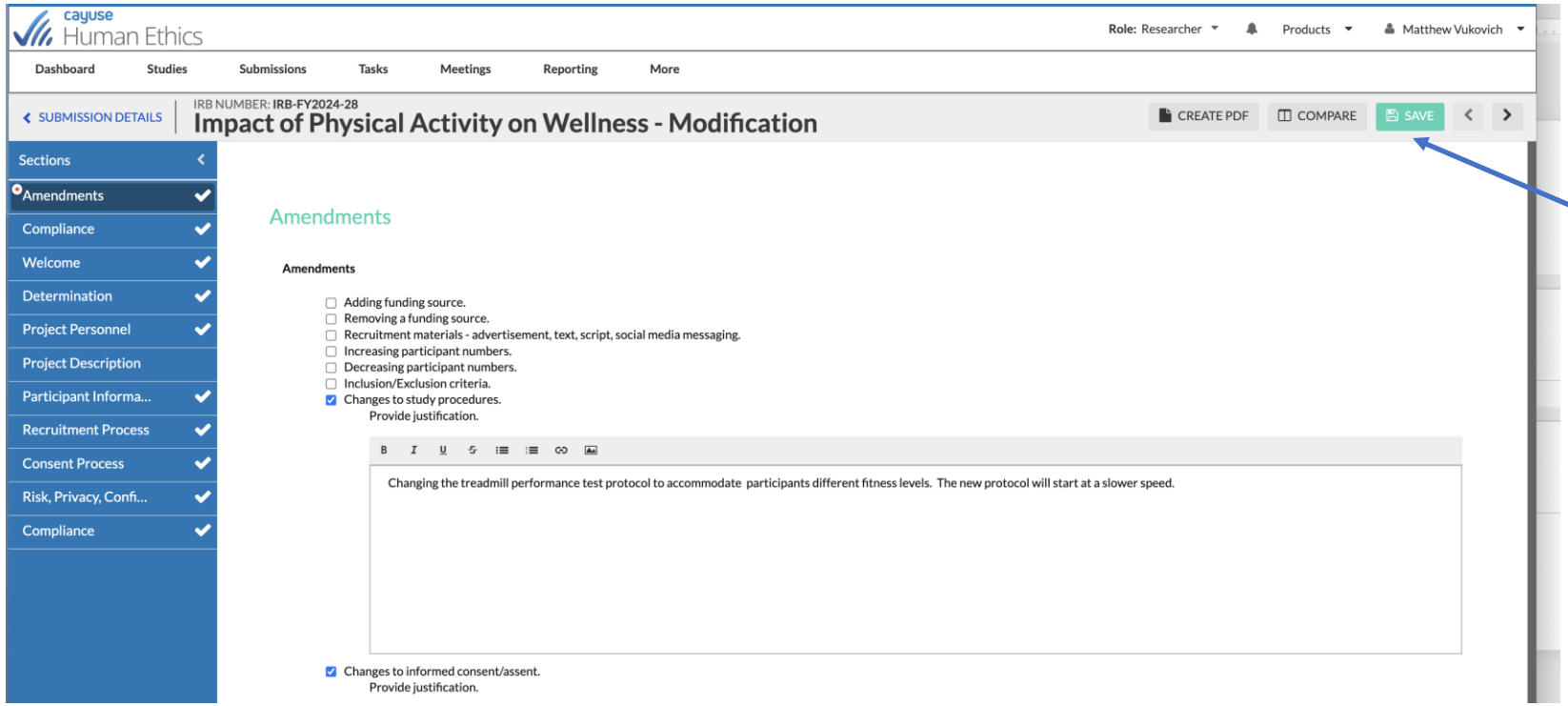
Select **+New Submission**

Select [Modification] from the pulldown menu.

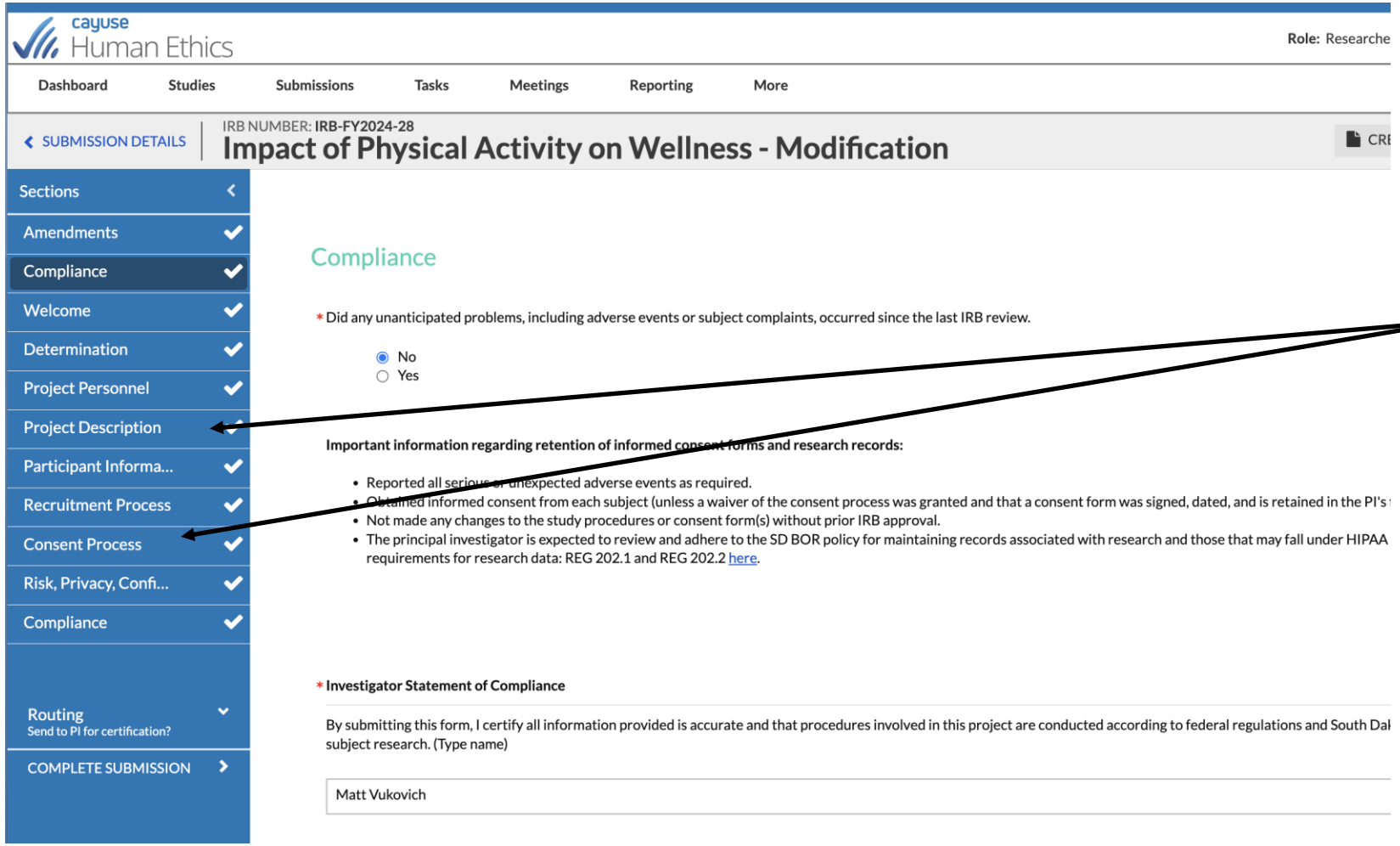
Select Edit.



Select which type of modification you would like to make. You can select more than one modification.

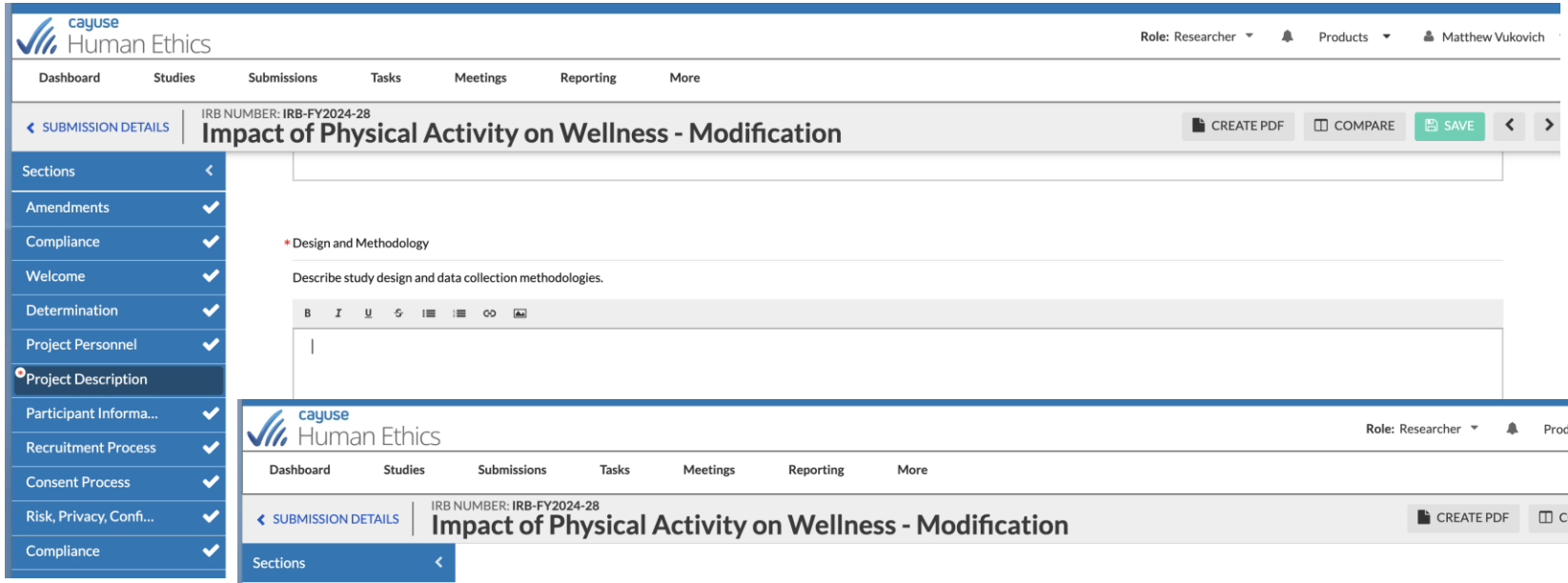


For each modification or amendment to the study, provide a justification. Select [Save] after each change.

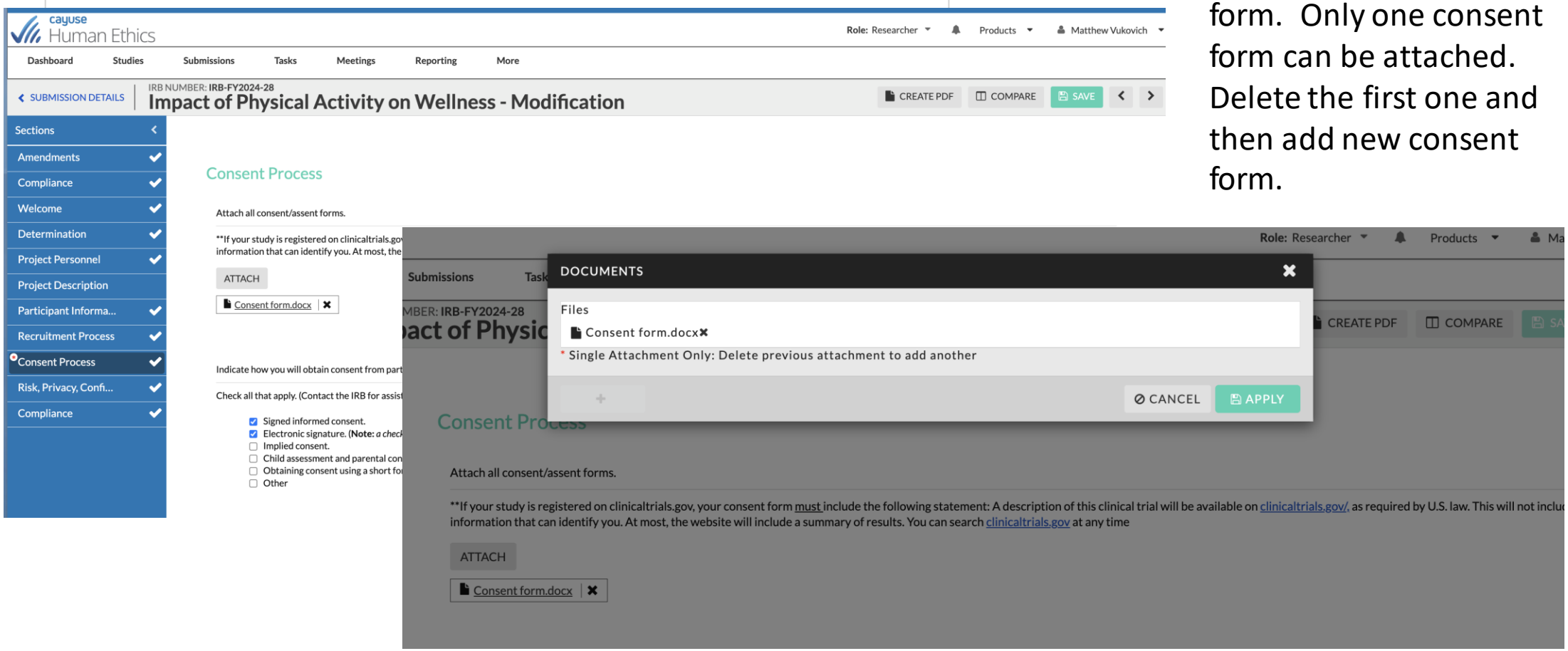


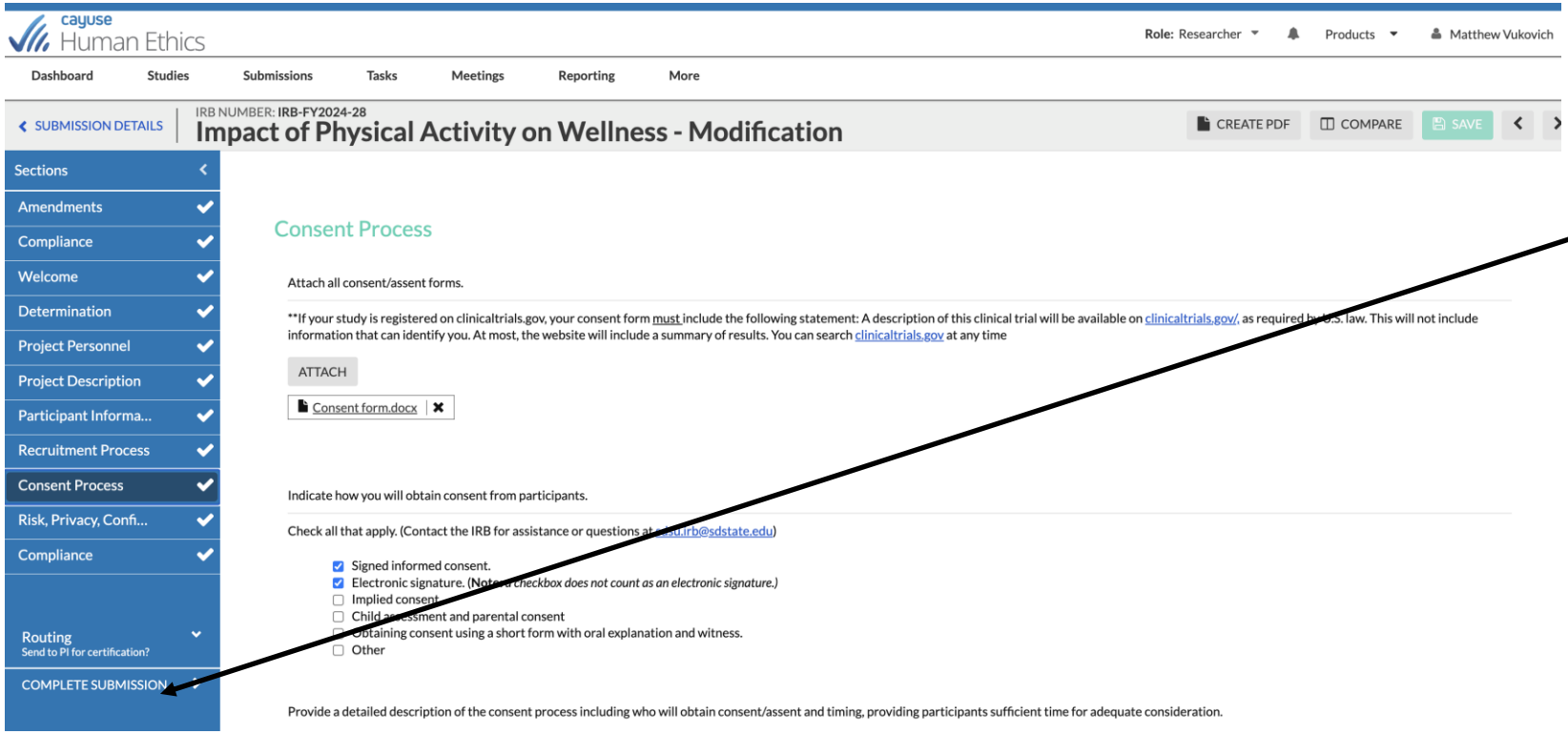
Once compliance statement is completed, select the menu that corresponds to the modification that was selected in the first screen. In that example, changes to study procedures and changes to informed consent were selected.

Update the design and methodology.

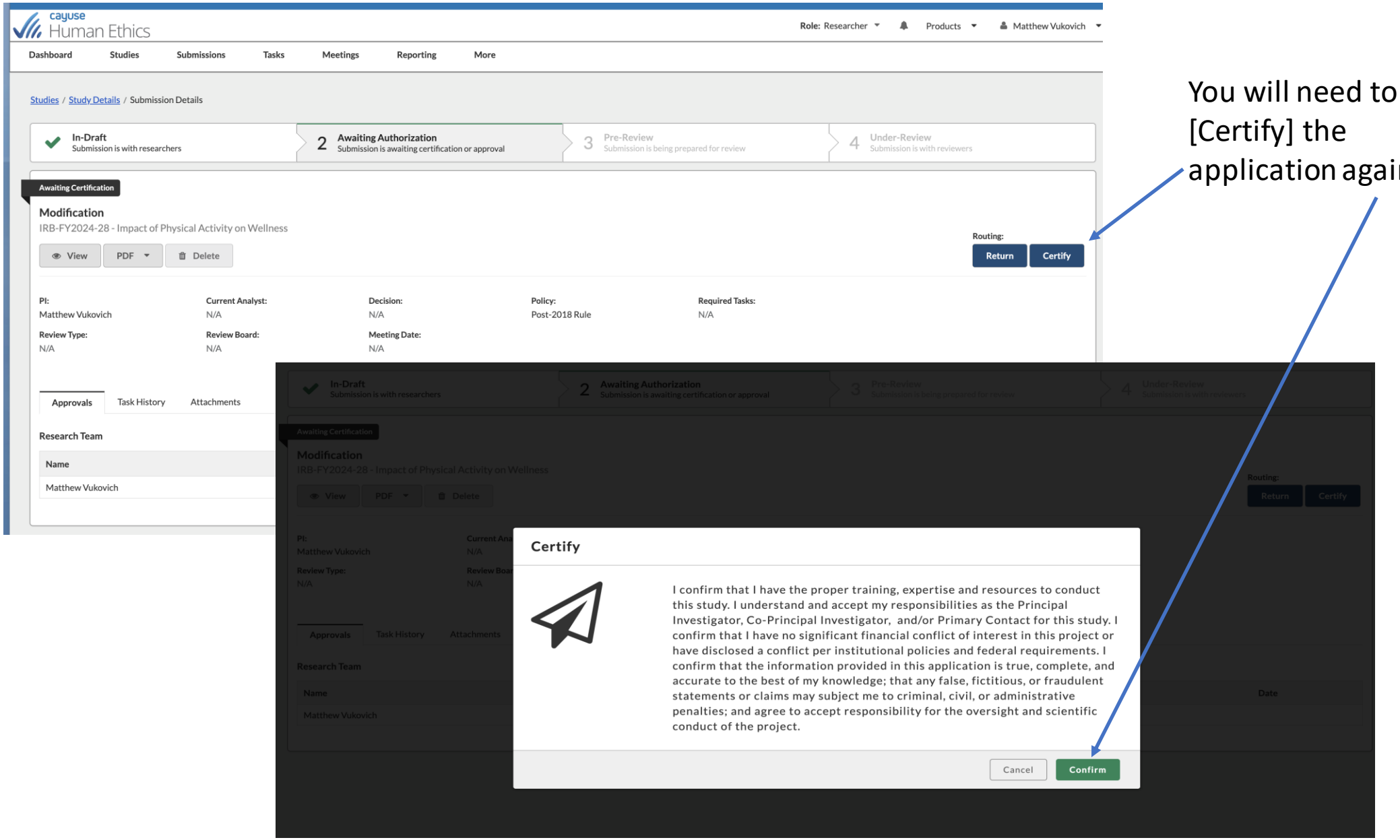


Attach new consent form. Only one consent form can be attached. Delete the first one and then add new consent form.

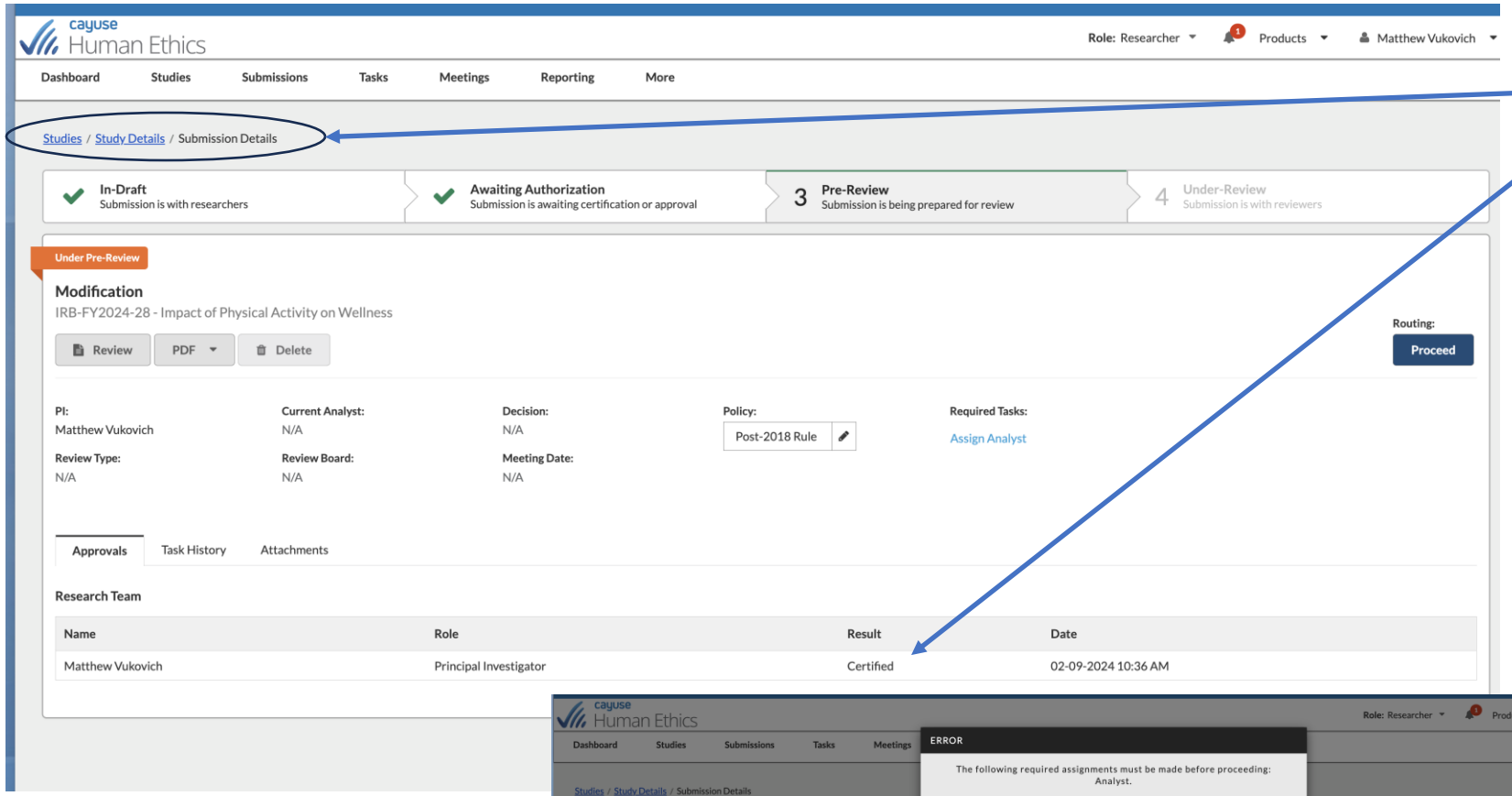


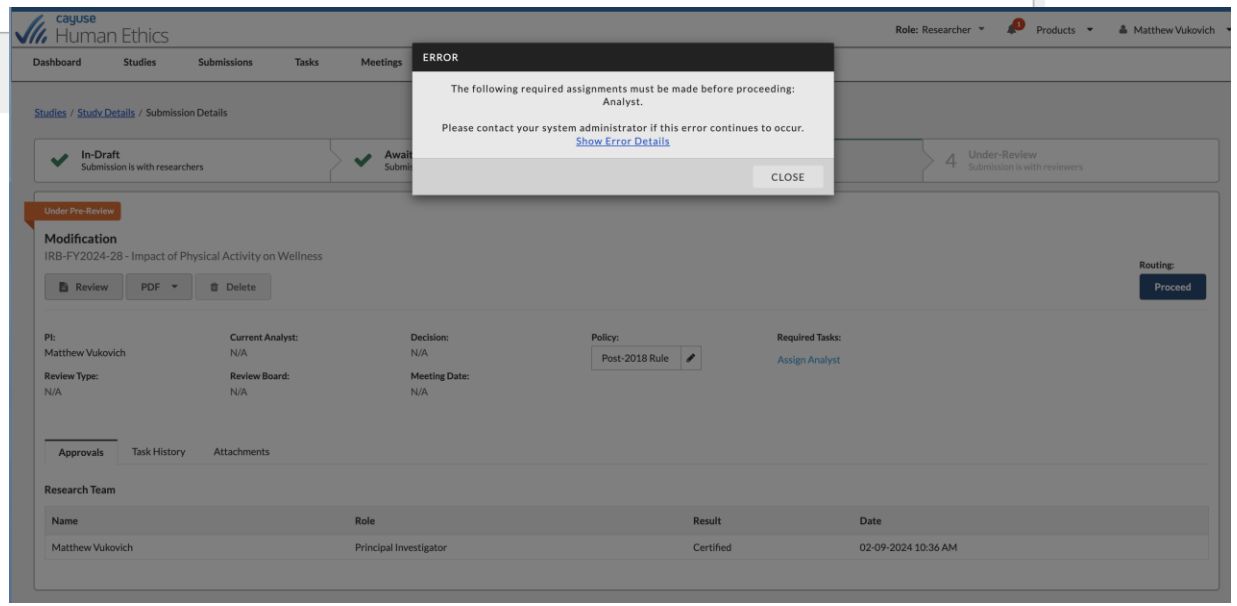


Remember to select save.
When all modifications have been made, select [Complete Submission]



You will need to [Certify] the application again.

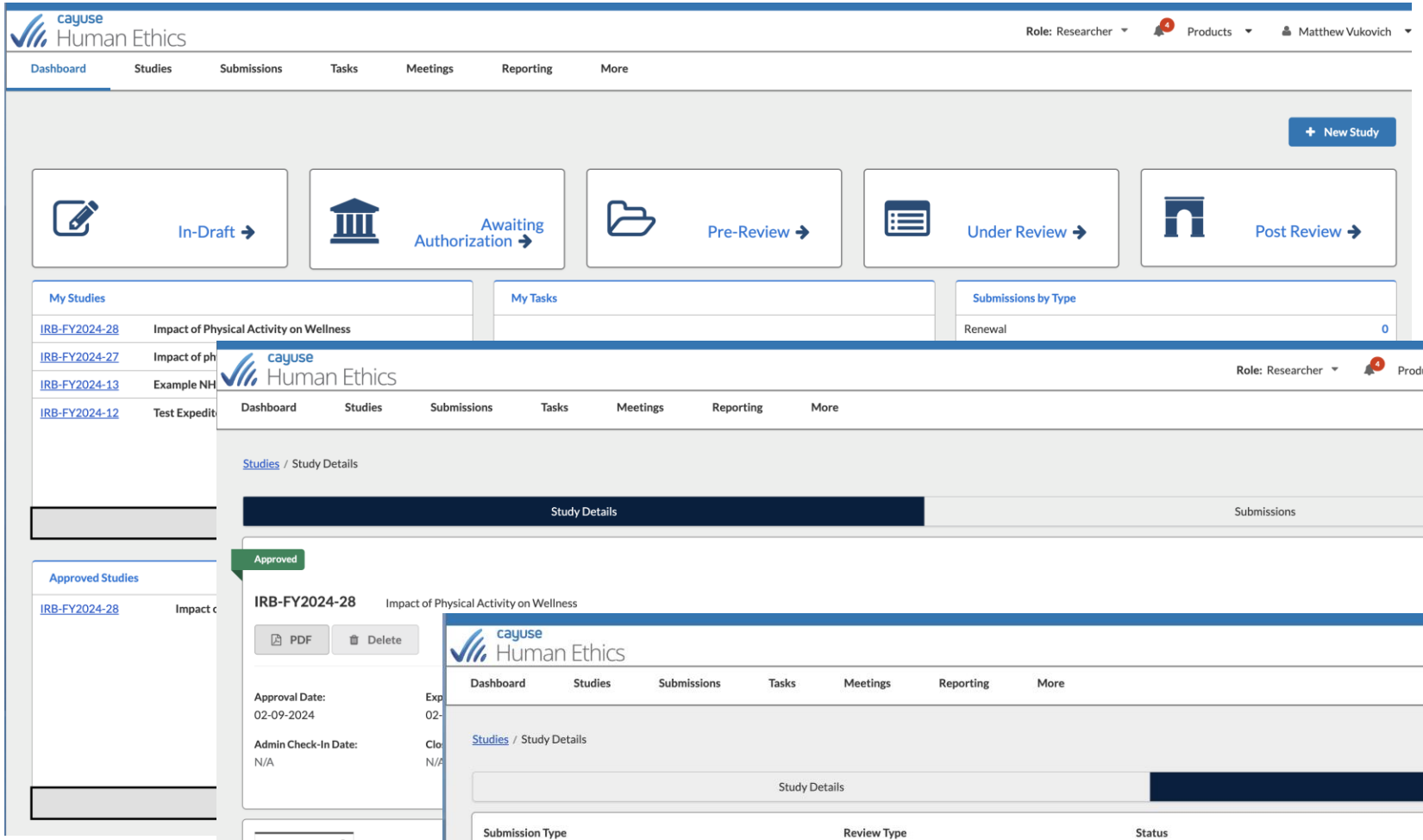




After certifying, the Submission Details screen appears. It is awaiting authorization.

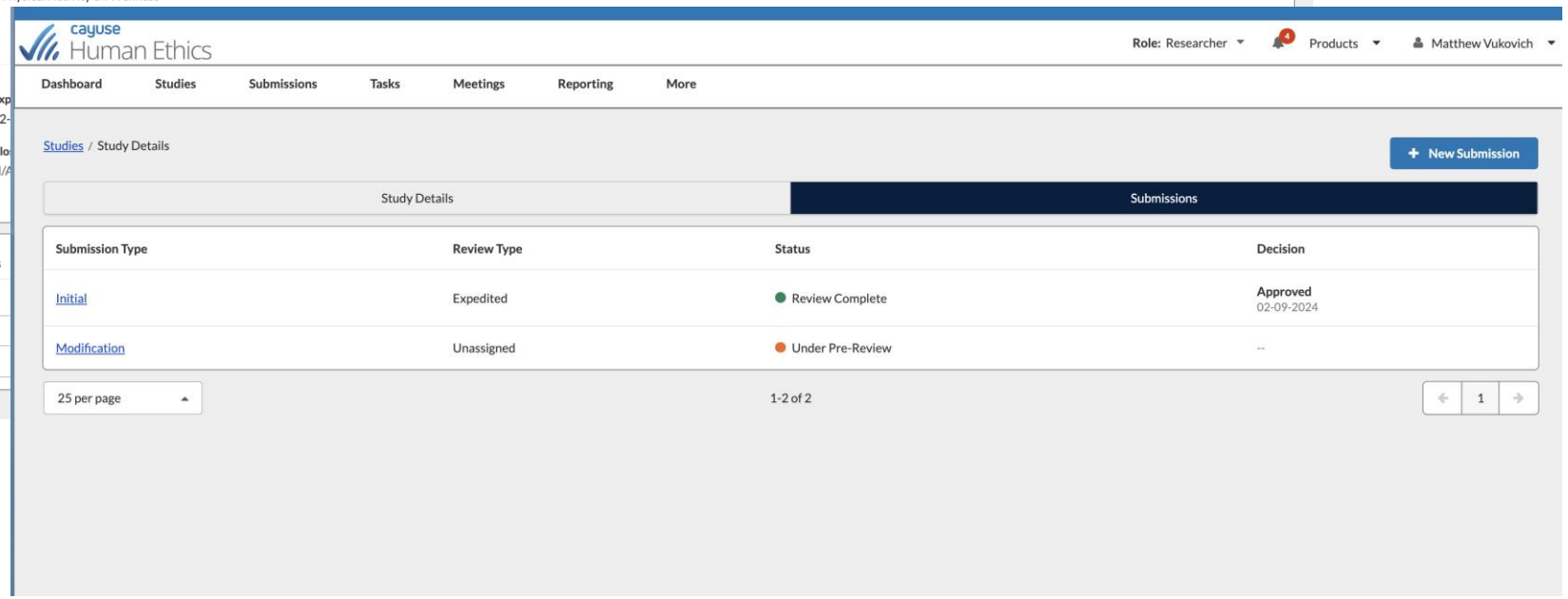
If you select proceed, the following error message pops up indicating the IRB analyst needs to be assigned and application reviewed.

Your supervisor will also receive an email to certify/approve of the modification.

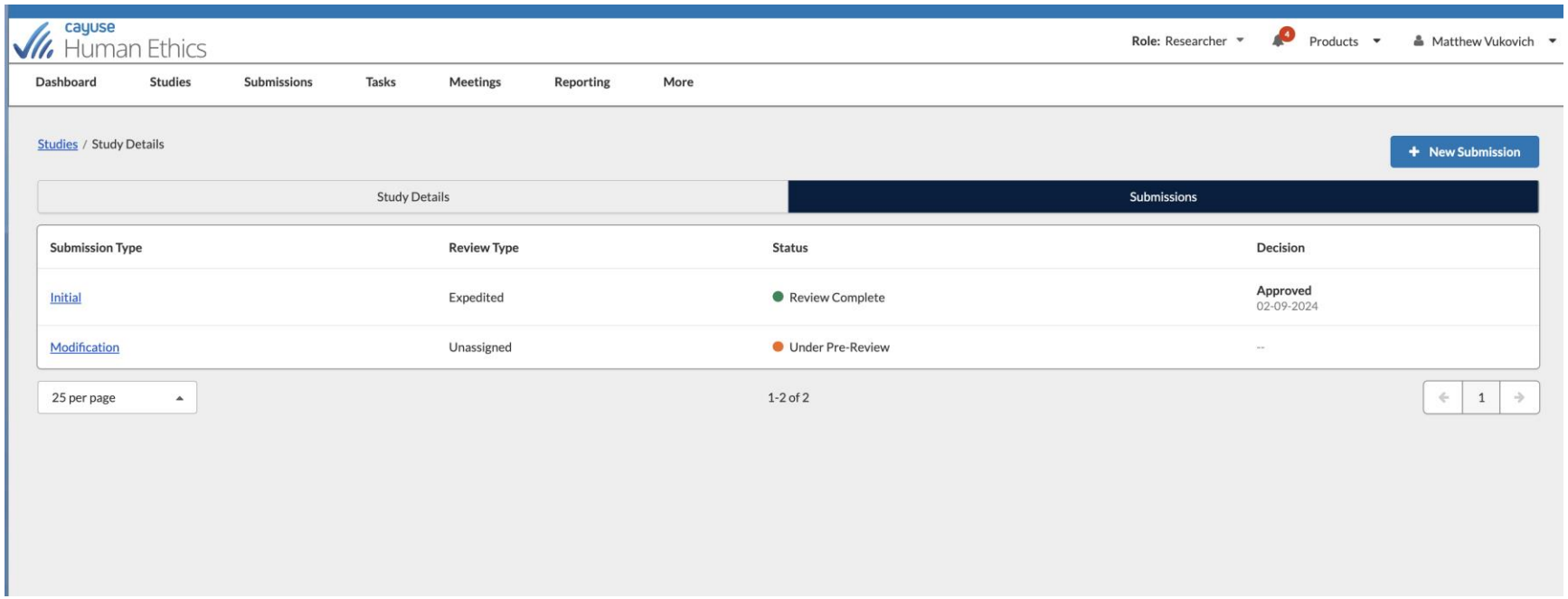


Main Dashboard.

Study Details dashboard



Submission Dashboard – shows study is under review by IRB.



During the pre-review process, the IRB analyst will determine the level of review required. Since the initial application was an expedited review, the modification will more than likely require an expedited review.

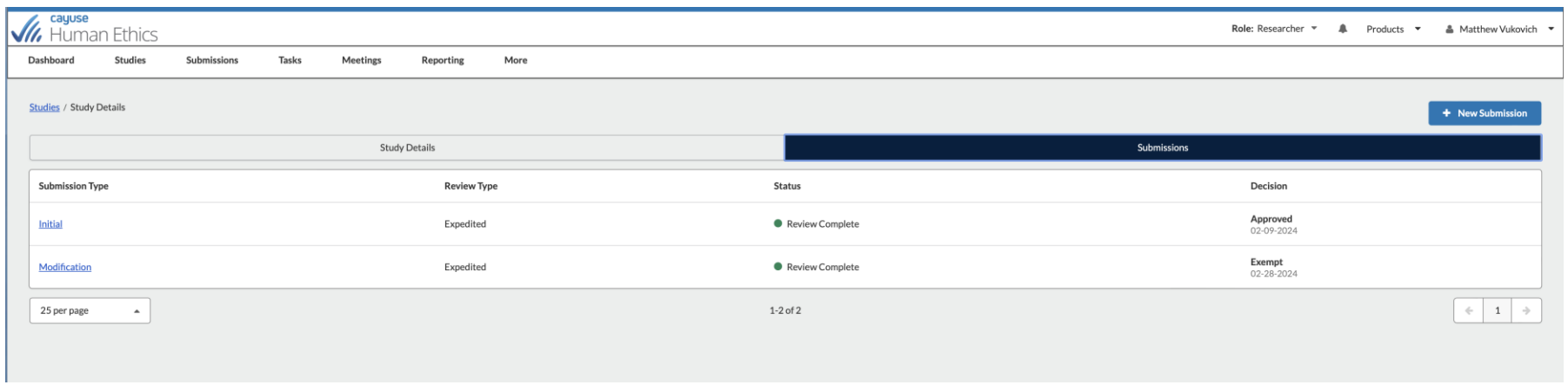
Date: February 28, 2024
PI: Matthew Vukovich
Re: Modification - IRB-FY2024-28
Impact of Physical Activity on Wellness

The South Dakota State University Institutional Review Board has reviewed the above-referenced submission and rendered the decision below.

Decision: Exempt
Decision Date: February 28, 2024
Study Admin Check-in Date: --
Review Type: The reviewed modifications fall under 45 CFR 46.104.
Category 2.(ii). Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

Findings:
Research Notes:

Key Principal Investigator Responsibilities:

- Submit any proposed changes to the Study prior to being implemented via a Modification submission for IRB review and approval.
- Promptly notify the IRB, via Incident submission, of any reportable events (adverse events/protocol deviations/unanticipated problems/subject complaints/etc.) that occur during the research, including any breach in confidentiality or data security that places participants or others at a greater risk of harm.
- Submit a Renewal Submission in advance month of Administrative Check-in or Study Expiration dates to allow for IRB review and approval to continue conducting study activities.

Once review is complete, you will receive an email notifying you of the determination. You can also see in the dashboard that the review has been completed.