Institutional Review Board
215 Administration Bldg.
Memphis, TN 38152-3370
Office: 901.678.2705
Fax:901.678.2219

Cayuse IRB

Screenshot Manual

Table of Contents

What is Cayuse IRB?

Cayuse Institutional Review Board (IRB module is an electronic system for preparing, submitting, and routing studies for IRB approval. All information is stored in the system and can be accessed securely for any location. User receives electronic notification when action is required on their part, allowing the study to proceed smoothly thought each step of the process.

Cayuse IRB:

- Provides a comprehensive electronic compliance solution.
- Eliminates the need for paper forms.
- Is accessed using a secure connection via your web browser.
- Helps to ensure timely submissions by automatically generating reminder notices for continuing reviews.
- Allows institutions to design custom forms that request only the information that is relevant to the study, based on information provided by the researchers.
- Allows multiple researchers and administrators to view and work with forms at the same time.
- Tracks and compares changes between different versions of a submission.
- Enables convenient and efficient coordination of meetings and distribution of meeting minutes.
- Links IRB submissions to funding proposals in the Cayuse SP module, if licensed.

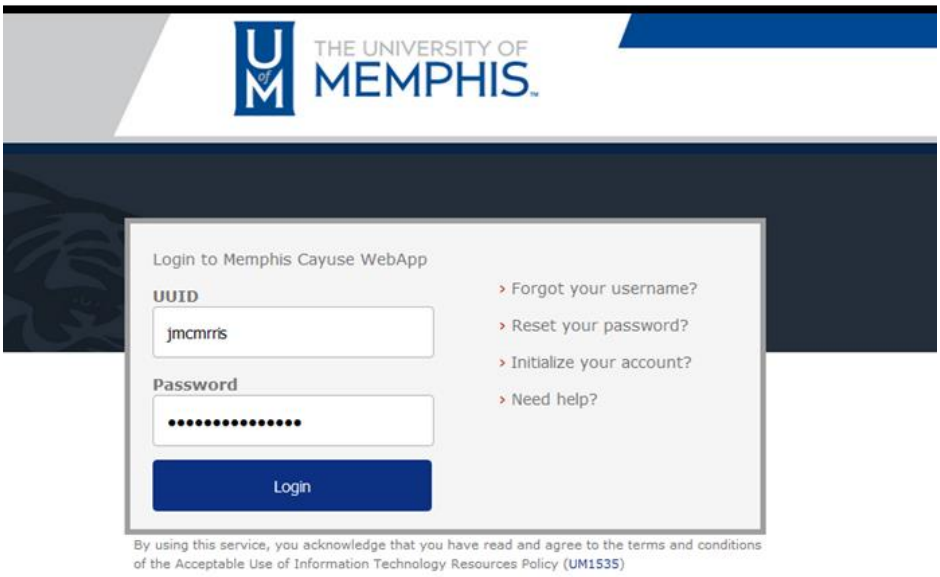
Cayuse IRB users also have the ability to see a brief overview of cayuse under the **Help -> View Dashboard Tutorial** or **Help -> View Visual Search Tutorial**

NOTE: This guidance document is only for Cayuse IRB. All other Cayuse related questions should be directed to cayusesupport@memphis.edu or osp@memphis.edu

Logging into Cayuse

Go to **memphis.cayuse424.com** .com and log in using your UM credentials. If you are a student and do not have accessed Cayuse IRB, you will need to request access by emailing cayusesupport@memphis.edu.

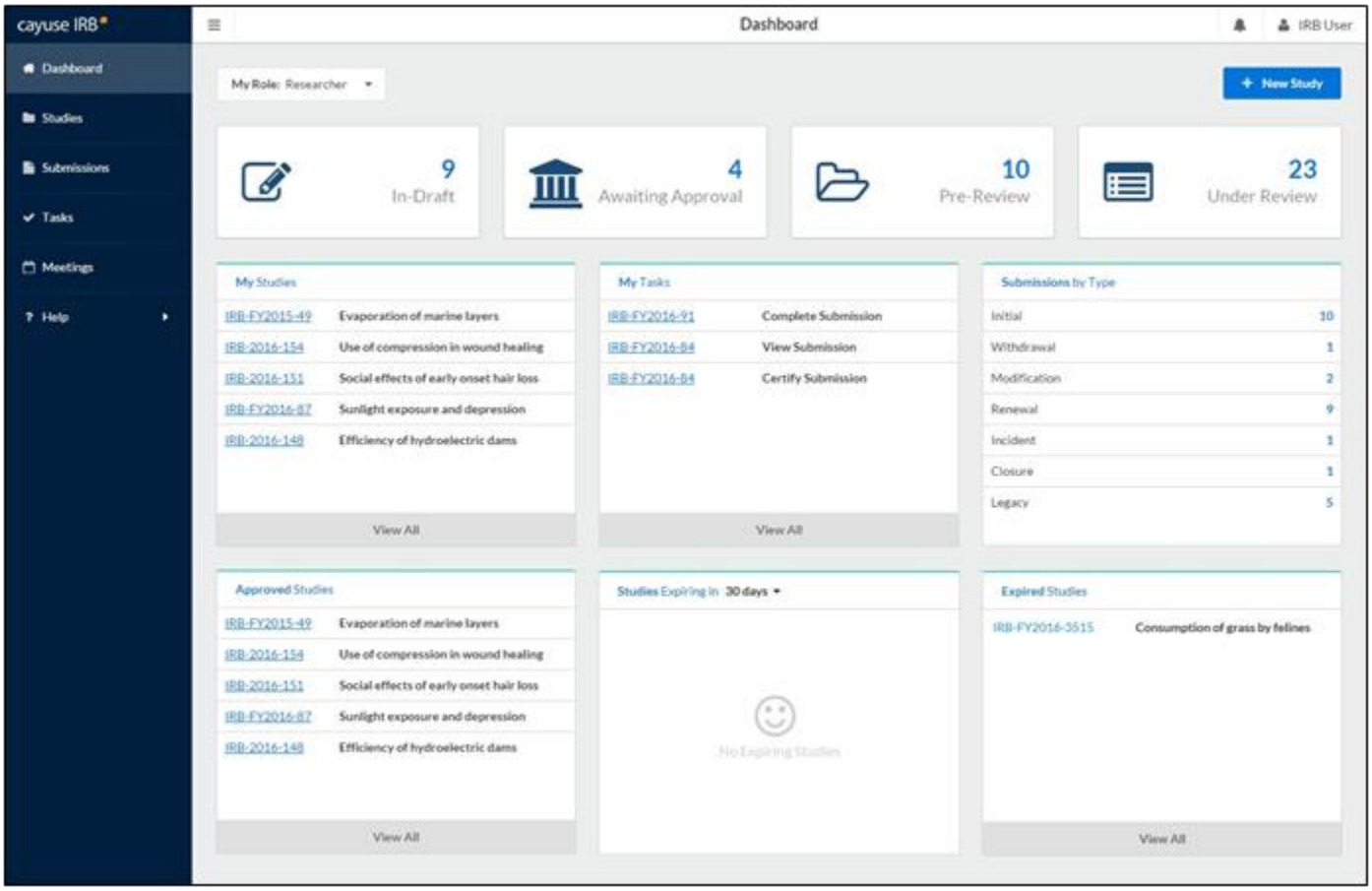
Please allow 48 hours for your account to be created. Once your accounts is created, someone from the Cayuse Support team will email you with confirmation.



When you first log in you will see the Cayuse home screen. You will need to click on Cayuse IRB (Human Studies Compliance)

Home screen Dashboard

When you enter Cayuse IRB, you will be taken to your **Dashboard**. You will see a display of an overview of all the studies you are involved with and/or require your attention. Your dashboard offers a way to view and filter studies, location in the submission process and pending task.

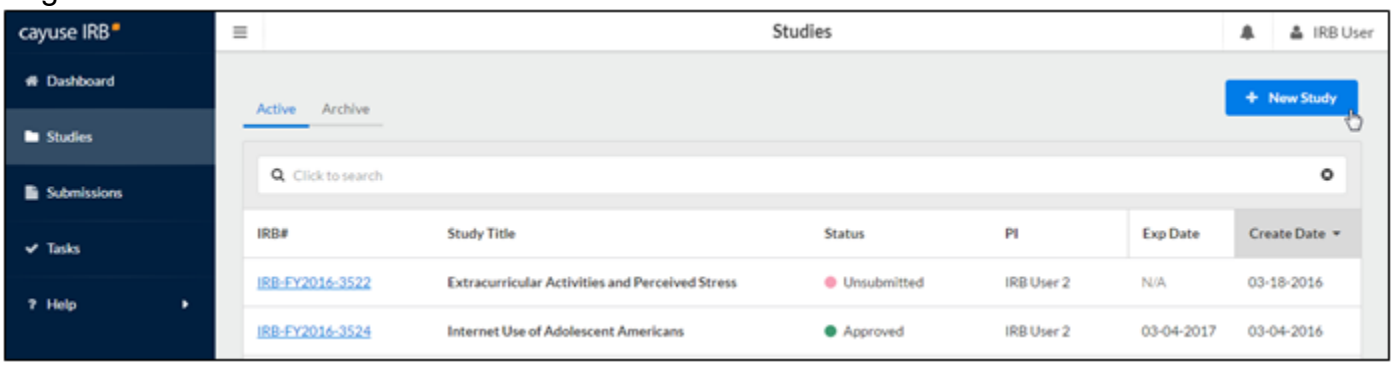


The four status bars across the top allow you to determine where your study is in the submission process

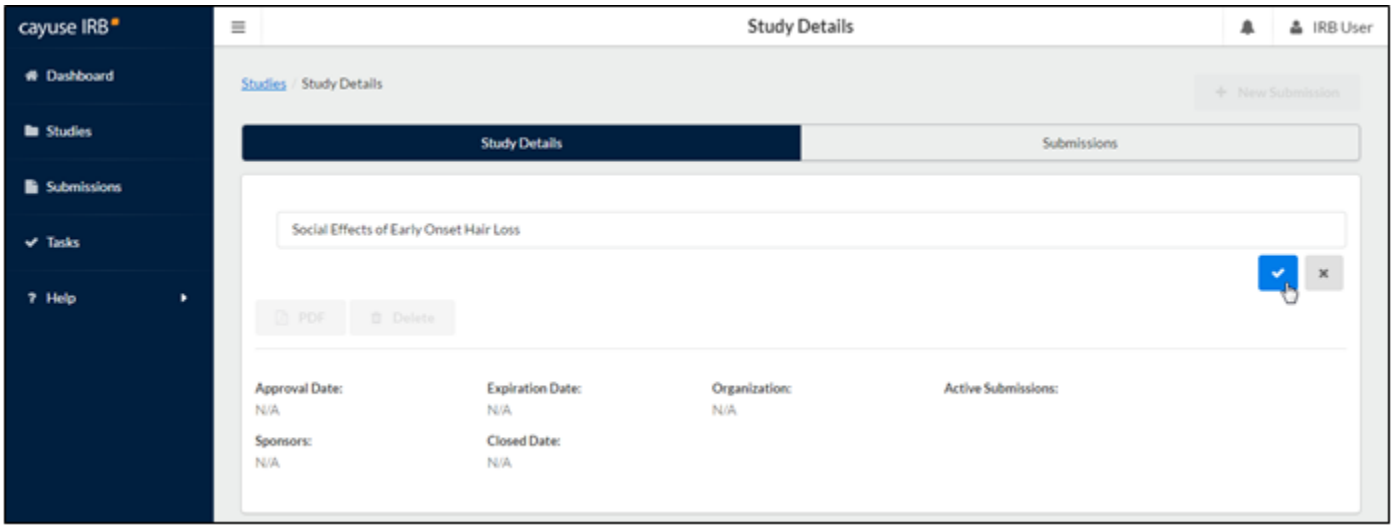
- **In Draft**: takes you to the submission page and displays all of the submission that are currently in draft. You may see a status of Unsubmitted, Reopened or Required Changes.
- **Awaiting Approval:** takes you to studies that require your certification. Studies will appear in this section when members of the research team is still pending their certification. Example: PI has certified the submission, but still pending certification from a Co-PI. User can see when other users are pending certification or when certification was completed
- **Pre- Review**: You study has been received by the IRB Analyst. The Analyst will review your submission and either make comments in your submission or send your protocol to the reviewer
- **Under Review**: You protocol submission is under review. The reviewer will either approver your protocol submission or request changes.

Creating a New Study

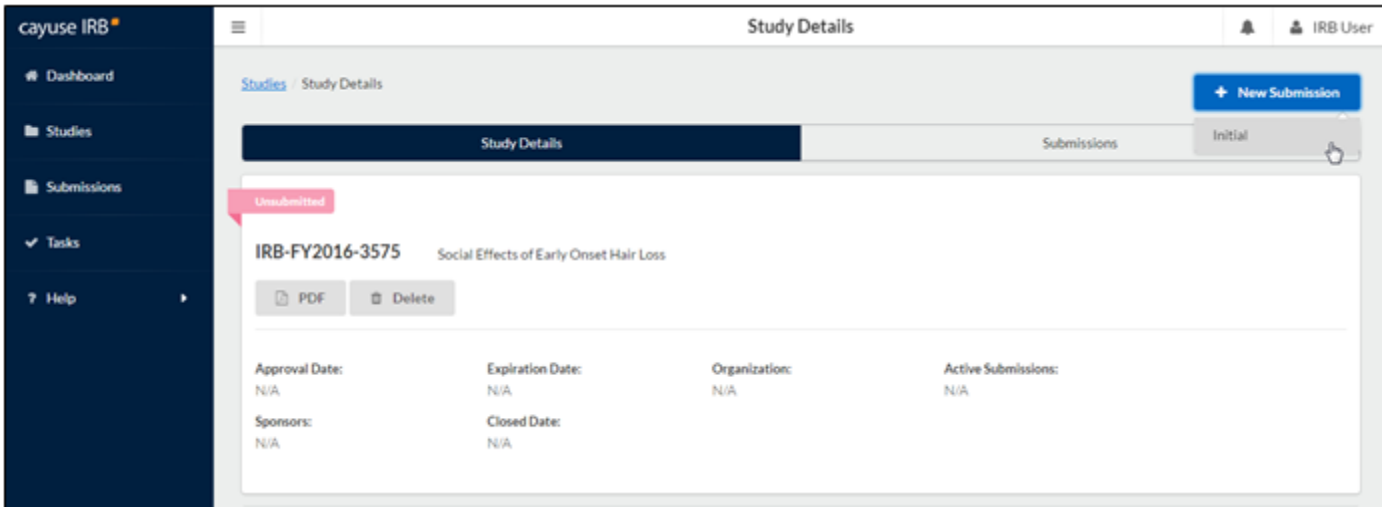
To create a new study, click the **"New Study"** button in the upper right your Dashboard or Studies Page.



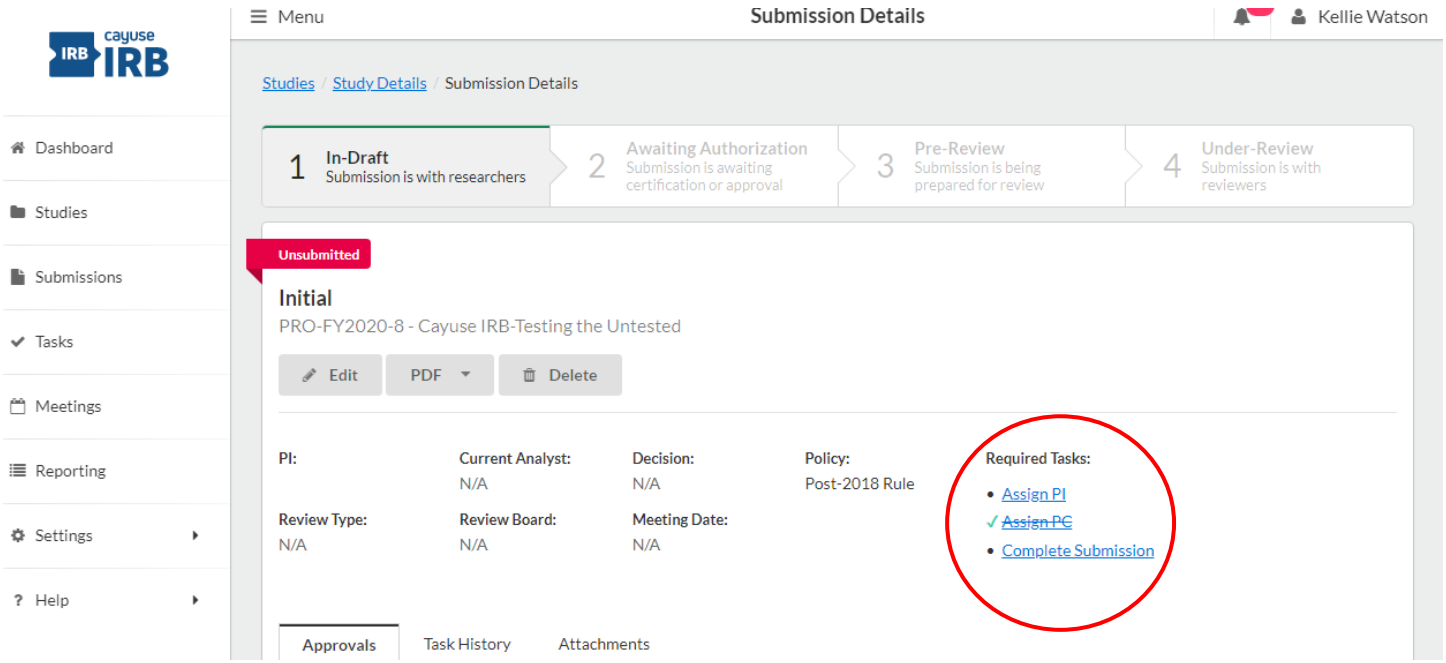
Enter the title for your Study then click the **Save** (blue check) button.



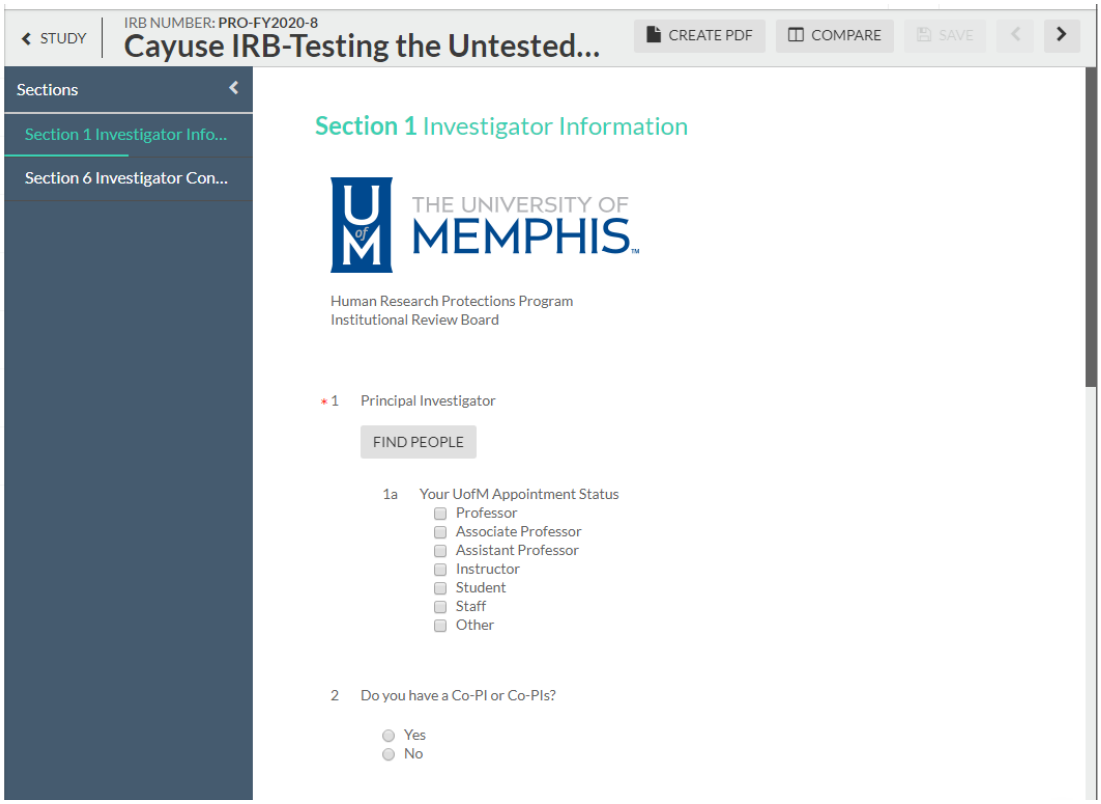
After creating your study, you will be taken to the Study Details for this study. To begin working on your study, click on the **"New Submission"** button in the upper right corner and select Initial.



The initial submission appears below the study details page. The person who creates the study is assigned as the Primary Contact by default.



Click the **Edit** button to begin working on the initial Submission. This will bring you into the submission form, where you will begin filling out your protocol. You can save your protocol and return at a later time to complete your submission



Completing the Submission

When completing your study, the submission prompts you for the information required for the University of Memphis IRB template. There are multiple sections the must be completed in the initial submission.

Section 1: Investigator Information

Question 1: The first task to complete is assigning the Principle Investigator (PI). To do you click on **"Find Me"** and search the name of the person who will serve as the PI and check their UofM affiliation. Note, if the PI is a student then their faculty advisor is required to be on the submission as well.

Questions 2-4: Answer appropriately as it related to this protocol submission in regards to Co-PIs and Co-Investigators

- If Co-PIs or Co-Investigators are Faculty/Staff or Students at the UofM you can use the **"Find Me"** button to add them to your protocol. Please note that if Co-PIs or Co-Investigator are added to the protocol, they will be responsible for certifying the submission.

Question 5: Does your study have a sponsor?

- If your study is funded use the "Find Sponsor" button to search for your sponsor.

Question 6: Do you need a Determination?

- If you are unsure if your proposed research falls under the definition of humans Subjects research, then select **"Yes. Proceed with determination questions"**. Sections 1,2 and 6 will populate
- If you know your proposed research is human subjects research, then select **"No. Proceed with your protocol submission."** Sections 1,3,4,5 and 6 will populate

Section 2: Determination Questions

1. Will any information from this project be submitted to the FDA or held for inspection by the FDA?
- ☐ Yes
- ☐ No

2. Are the data or specimens studied as part of this project obtained in a systematic manner?
- ☐ Yes
- ☐ No
- ☐ Unsure

3. Is the intent of this study to contribute to 'generalizable knowledge'?
As examples of level of contribution: a) is the intent of this research to contribute to the science through peer-reviewed journal publication? b) Is the intent of this research to add to the body of knowledge at a national meeting with a poster presentation?
- ☐ Yes
- ☐ No
- ☐ Unsure

4. Will the study involve intervention or interaction with living persons?
- ☐ Yes
- ☐ No

5. Will the study involve accessing (looking at or reviewing) identifiable private information of a living person?
- ☐ Yes
- ☐ No

6. Are the data coded in a way where a link exists that could allow the data to be re identified by the investigator?
- ☐ Yes
- ☐ No

7. Does this study involve only secondary analysis of existing data?
Secondary data is data that was not collected by the Investigator(s) (lead investigator and collaborators).
- ☐ Yes
- ☐ No

8. **Study Aims**
Indicate why the study is being performed. Examples: a) to assess an existing program's quality, b) to complete a Master's or Doctoral graduation requirement, c) to test a hypothesis, etc.

9. **Background and Significance**
What Observations or prior scientific findings serve as the basis for this study? Why is it important to conduct this study?

10. **Study Design and Methods**
How will the study be conducted? How will the results be analyzed to determine that study aims have been met?

11. Additional information or comments for the reviewer.

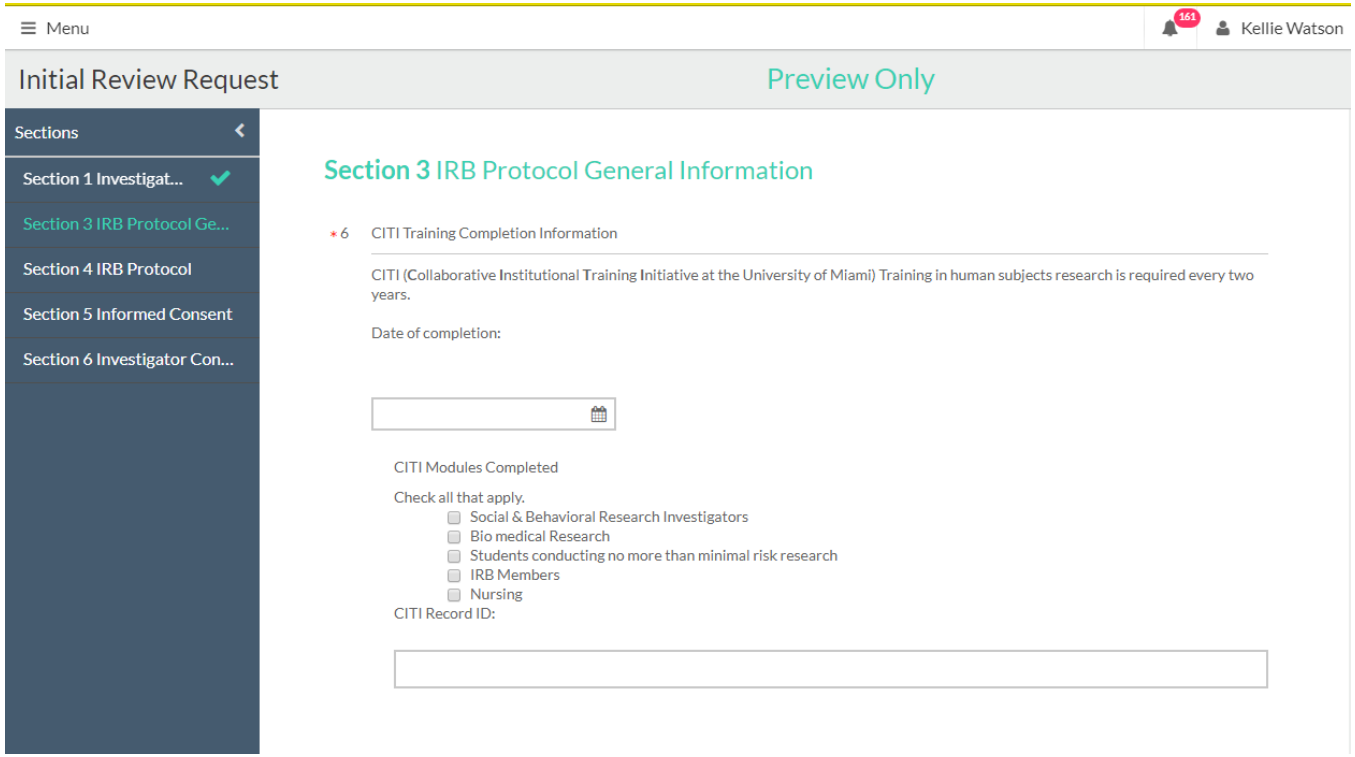
12. Attach any additional materials required to make a determination including any surveys or assessment materials to be used.

Section 3: General Information

When submitting a full protocol submission, you are required to complete human subjects training at CITIprogram.org. Once you complete your training it is valid for 2 years.

Human Subject CITI training modules

- Biomedical Research
- Social and Behavior research
- Student conducting no more than minimal risk research
- Nursing
- IRB member



Section 4: Protocol Questions

6. Anticipated number of subjects for the entire project.

7. Submission type

- ☐ Exempt study
- ☐ Secondary Analysis of Existing Data
- ☐ All other studies

8. Purpose of the study

a) ***Study Goal.*** Provide a concise statement of the study hypothesis(es) or goal(s).
b) ***Literature review.*** Briefly describe how the pertinent body of literature supports the study goal. Include citations and references.
c) ***Possible contribution.*** Describe the potential benefits of the proposed research study to the literature.

9. Methods and Procedures

a) ***Study design.*** Provide a summary statement of the design methodology used. For example, stating that the study is a randomized clinical trial using a double blind procedure with a placebo control. Another example would be a reanalysis of de-identified archival data.
b) ***Materials.*** Provide a concise description of all special equipment, instruments, or measures in this section. Also, label and attach copies of data collection tools at the end of this Initial Review Request.
c) ***Procedures.*** Provide a chronological description of the experience of being a participant in this study. For archival data, describe how the data is secured, stored, and used. Include the process by which consent will be obtained.
d) ***Indicate which procedures and treatments are associated with the present study and those which are not part of the study (i.e., pre-existing programs, interventions, or classroom exercises).***
Attachments: Instruments and Measures

10. Secondary analysis of existing data

The specific information is necessary when identifiable data about human subjects will be obtained. Data are identifiable if they include direct or indirect identifiers such as name, e-mail address, UID Number, race, gender, nationality, age etc.
a) List source of the data and an explanation of why the data were originally collected.
b) Describe in detail the data you plan to access and analyze.
c) Indicate the requirements of the data supplier and how access to the data will be granted or obtained. If access to the data is governed by a data use agreement, provide a copy of the agreement.
d) Describe procedures that will protect data you are given access.
Data information: Data Use Agreement, Data Sharing Agreement, Variables List etc.

11. Investigator Qualifications

a) Describe the lead investigator's qualifications and experience in conducting this particular type of research.
b) If physical or psychological assessments are being administered who will administer the assessment and score the results and what are their qualifications for doing so? Is the training in human subject protection of those administering assessments adequate?

12. Human Subjects

a) ***Characteristics.*** Describe the characteristics of the participant population. Include the age range(s), gender, ethnicity, health status, any physical, mental, cognitive or emotional limitations, and any other relevant variables.
b) ***Vulnerable Populations.*** Indicate if subjects include students, prisoners, pregnant women or any other class of subjects that might be especially vulnerable and require special consideration.
c) ***Pre-existing relationship to subject pool.*** If subjects are students, describe the relationship between students and researcher. If there is a pre-existing relationship between the researcher and the subject pool, please describe that relationship in detail.
d) ***Selection.*** Describe criteria for inclusion and exclusion of subjects in the study. Provide a detailed explanation for each exclusion and inclusion criterion.
e) ***Justification for the proposed sample size.*** This number helps reviewers understand the expected sample size. Please explain why this number was chosen for your sample size. Any increases to sample size require a modification to the study.

Cont.

13. Recruitment

Describe how subjects will be identified and recruited.

Provide detailed description and examples, where relevant, of any material to be presented to potential participants prior to their receipt of the informed consent/assent documents.

Recruitment Materials

Attach advertisements, postings on social media, posters, scripts for radio/TV, other electronic ads, scripts for verbal recruitment, copies of email recruitments and any text that will be provided to potential participants. It should be clear in all recruitment materials that you are conducting research. See Sample Recruitment flyer on IRB website.
Sample documents: sample_recruitment_flyer.doc

14. Subject Compensation

a) Describe any economic or other incentives for participation including reimbursement for time and travel.
b) If study participation requires subject to complete multiple sessions, payments must be pro-rated over
the course of the study. (Example: In a study where subjects are paid $50 per session, Tom completes only two sessions, then he should be paid $100 for his participation)
c) If the study incentive involves earning course credit, list alternative ways to earn the same credit.

Risk Benefit Analysis

15. Potential Risks

a) Describe all potential risks: physical, psychological, social, legal or other associated with each procedure. Assess the probability, severity, potential duration and reversibility of each risk.
b) Identify those risks that are minimal and those which are more than minimal.
c) Describe the procedures used to minimize any potential risks.

16. Potential Benefits

a) Describe the direct potential benefits to the subject. If there are none, this should be so stated.
b) Describe the potential societal benefits of the study in terms of human health/welfare, the advancement of knowledge or the good of society.

17. Differential Evaluation of Risks and Benefits

Justify the research study based on your evaluation of the risk/benefit assessment. When composing this section, imagine you are standing in front of a panel of researchers who are all skeptical about your research. Your task is to reassure them that the benefits of your research outweigh the risks.

18. Privacy

The research proposal should outline strategies to protect privacy, including how the investigator will access participant information.
In developing strategies for the protection of subjects' privacy, consideration should be given to:

- ✓ The methods used to identify and contact potential subjects.
- ✓ The settings in which an individual will be interacting with an investigator.
- ✓ The appropriateness of all personnel present for research activities.
- ✓ The methods used to obtain information about subjects.
- ✓ The nature of the requested information.
- ✓ Information that is obtained about individuals other than the "target subjects," and whether such individuals meet the regulatory definition of "human subject" (e.g., a subject provides information about a family member for a survey).
- ✓ Privacy guidelines developed by relevant professional associations and scholarly disciplines.
- ✓ How to access the minimum amount of information necessary to complete the study.

19. Confidentiality

The research proposal should outline in detail what variables of identifiable data will be handled, the strategies to maintain confidentiality of identifiable data, including controls on storage, handling, sharing of data as well as eventual destruction of identifiable data including signed consent forms.

20. Collaboration, Engagement & Sponsor Relationships

a) Describe all collaborative relationships necessary to complete your research. Include letters of support from the collaborator(s). This letter must come from a person with director-level authority within the collaborating institution. When the collaborator has an Institutional Review Board, please include a copy of the IRB application sent to collaborating institution.
b) Indicate in your study when U of M IRB approval must be issued before the collaborator will commit to the study.
c) Specify what data will be provided to the collaborator(s) and sponsor(s).
Collaboration Attachments
Letters of support, IRB approvals / protocols from collaborating institutions

21. Proposal

If your study is sponsored, please insert or attach a copy of the funded proposal under this section.

Section 5: Informed Consent

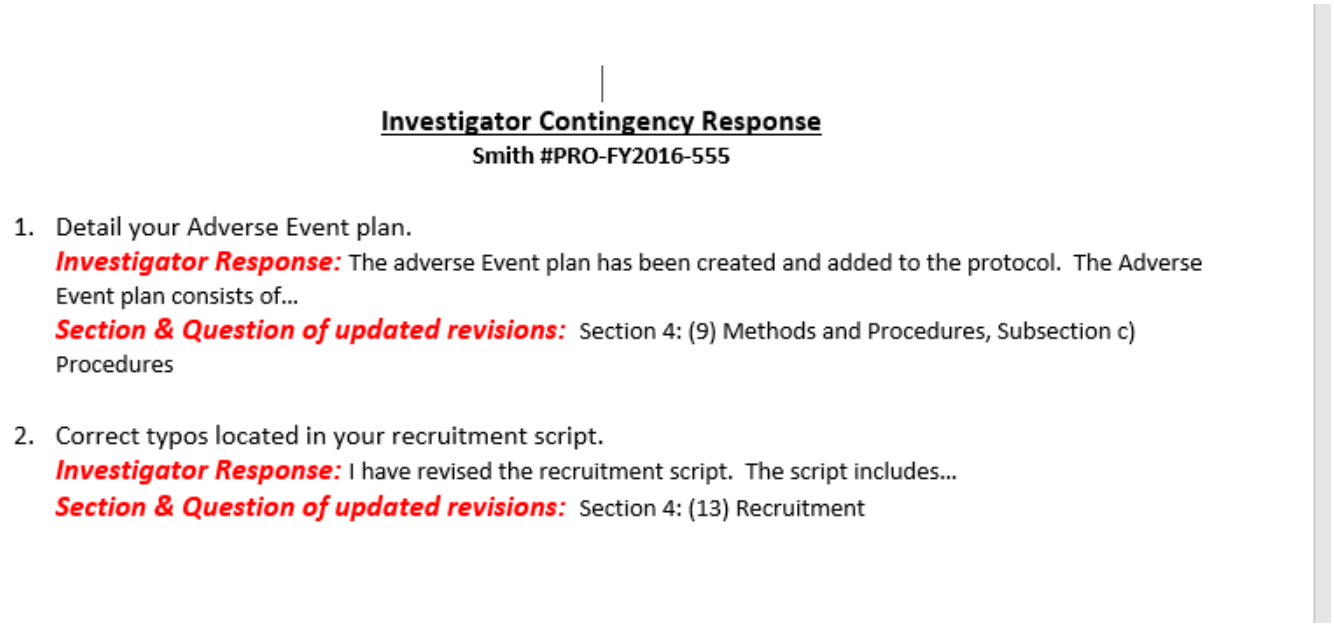
The Revised Common Rule states that informed consent must begin with a "concise and focused presentation of the key information" that would assist subjects in deciding why they may or may not want to participate in the research. It needs to be organized and presented in a way that facilitates comprehension. [§46.116(a)].

Full Board and Expedited review-categorized research require informed consent for human subjects to participate in research. Such consent must be given by the subject and parent/guardian if the subject is under the age of eighteen (18) years. Voluntary and fully informed consent must be obtained and documented in writing unless a waiver is requested and granted.

Exempt review-categorized research also requires obtaining voluntary consent to participate. This consent will provide subjects with pertinent information such as stating that the activity involves research, and the University of Memphis has approved the research. Also, as is appropriate, include information such as contact for investigators, description of the procedures, risks, and benefits, and IRB contact information

Section 6: Investigators Response to Contingencies

When submitting your revisions to a protocol, inform the IRB how you addressed each of the contingencies for the previous version of the submission. Copy and paste the last issued contingency list in a Word document and include your response and related section/question directly underneath each respective contingency. This document can be attached as an MS Word or a PDF file. You can also copy and paste your contingency response in the text box. If you have nothing to add in the text box below, please type “N/A."



Investigator Contingency Response

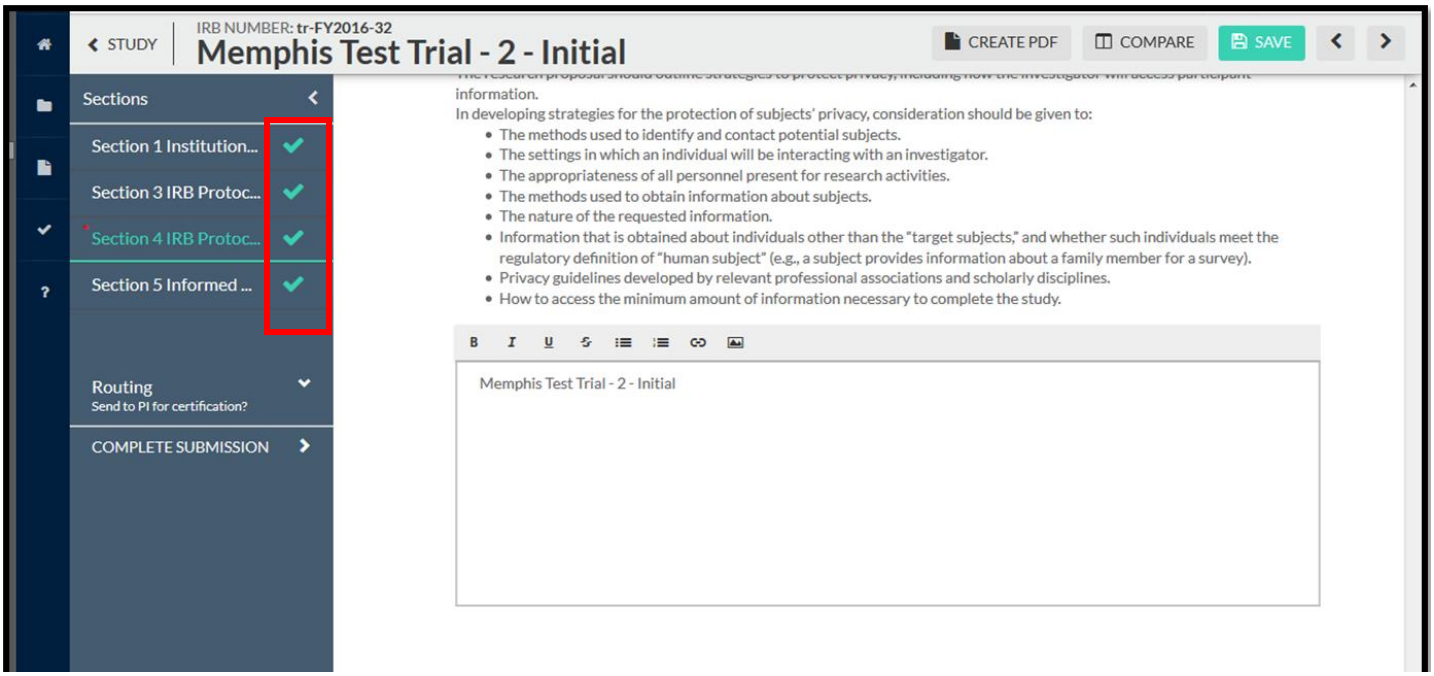
Smith #PRO-FY2016-555

1. Detail your Adverse Event plan.
   Investigator Response: The adverse Event plan has been created and added to the protocol. The Adverse Event plan consists of…
   Section & Question of updated revisions: Section 4: (9) Methods and Procedures, Subsection c) Procedures

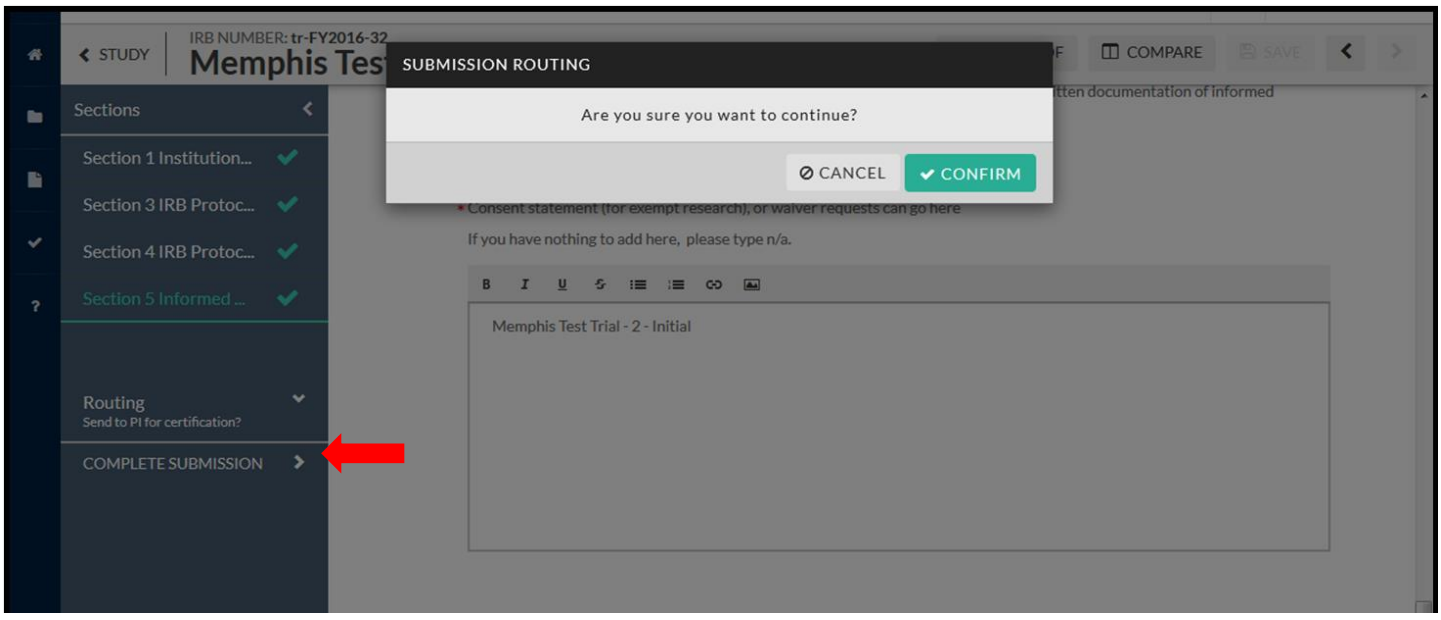
2. Correct typos located in your recruitment script.
   Investigator Response: I have revised the recruitment script. The script includes…
   Section & Question of updated revisions: Section 4: (13) Recruitment

Completing the Submission

Check to ensure all of your section are complete. To determine all required information has provided, a green checkmark will appear next to each section. If a section is missing a green checkmark, then this section is incomplete.

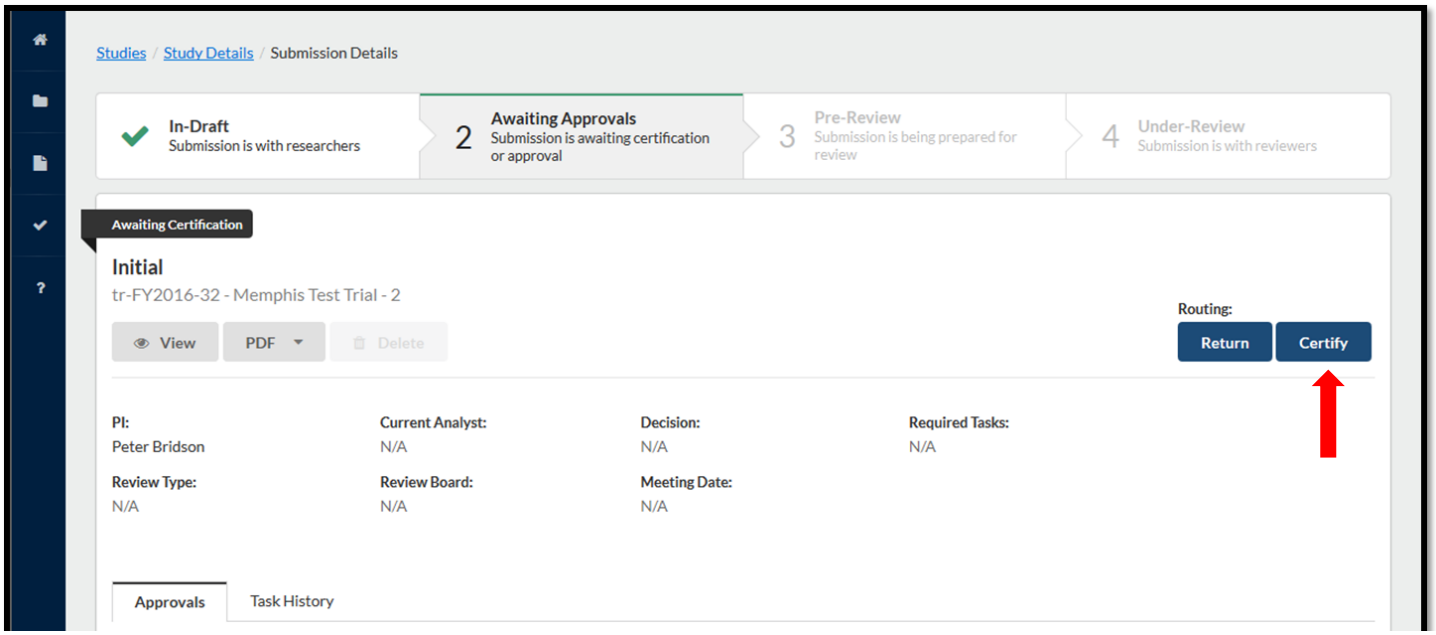


Once you have completed your submission and your section are marked with the checks, save your study, and select **"Complete Submission**." To route, your submission to the next step, select "Confirm."

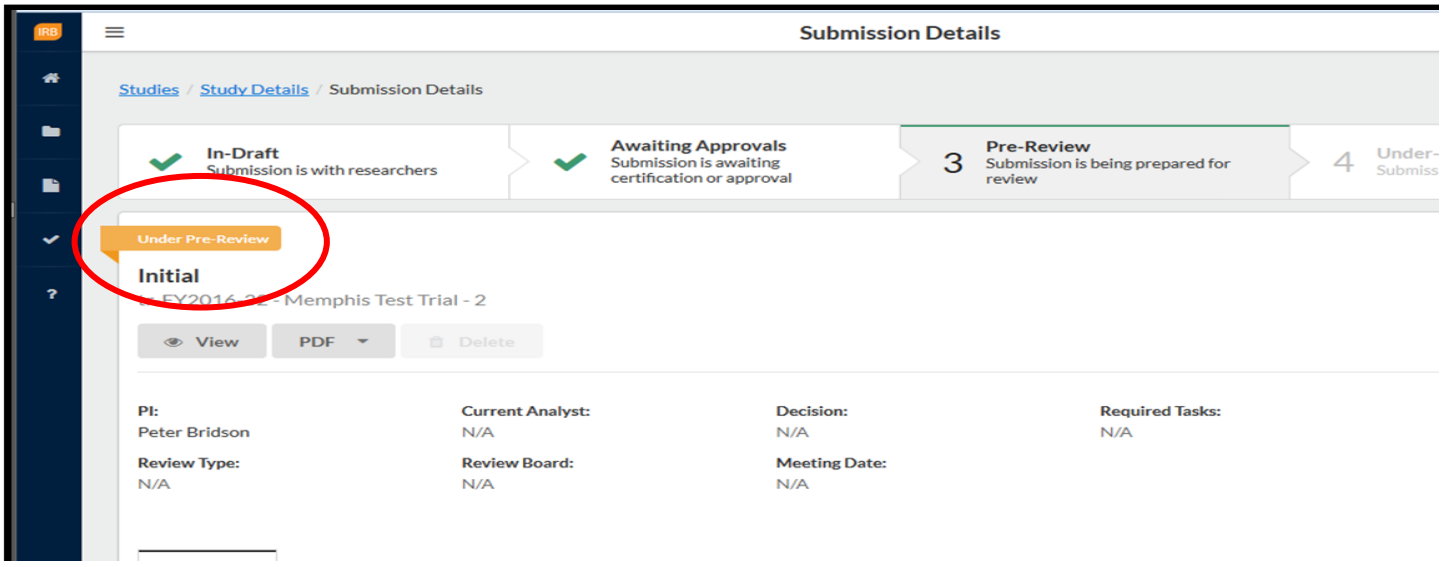


Certifying your Submission

You will be routed to back to your submission details page and the status will be Awaiting Certification. Select **"Certify**" to proceed. Your Co-PIs will be instructed to also certify the submission



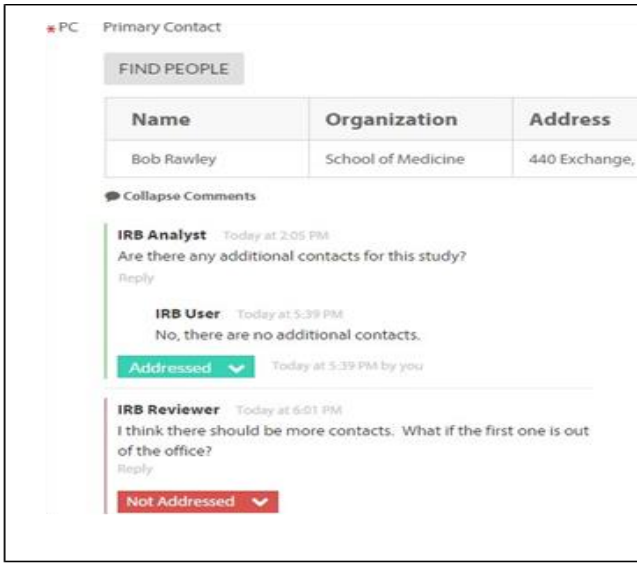
Once all members of the research team who are required to certify the submission have completed this task, your submission will move to **Pre-Review**. This means that the IRB analyst is reviewing your study to ensure your study is complete and ready for review.



Addressing Feedback and Contingencies

Addressing Comment from the IRB Analyst

When reviewing a submission, the IRB Analyst may have questions regarding some information provided in your submission. If the submission gets returned to you, you will see a comment icon in the sidebar next to each section that contains comments, and a similar icon underneath the questions that have comments on them. Click the 1 Expand Comments link to see and respond to these comments.



When you have responded to a comment, change the dropdown from Not Addressed to Addressed. Unaddressed comments have a red bar to their left and display the comment count in the comment bubble icon for that question. You can toggle comments between addressed and unaddressed as needed.

After you have addressed the feedback and made all necessary changes, click Complete Submission to proceed to route your submission back to the IRB Analyst. You will follow the same step described in **"Certifying your Submission**."

Addressing Contingencies from the Reviewer.

Carefully read the contingencies and the directions outlined in your contingency letter. Example below.

The contingencies are listed below:

1. Add (xxx) information to your consent document
2. Provide more detail regarding (xxx)

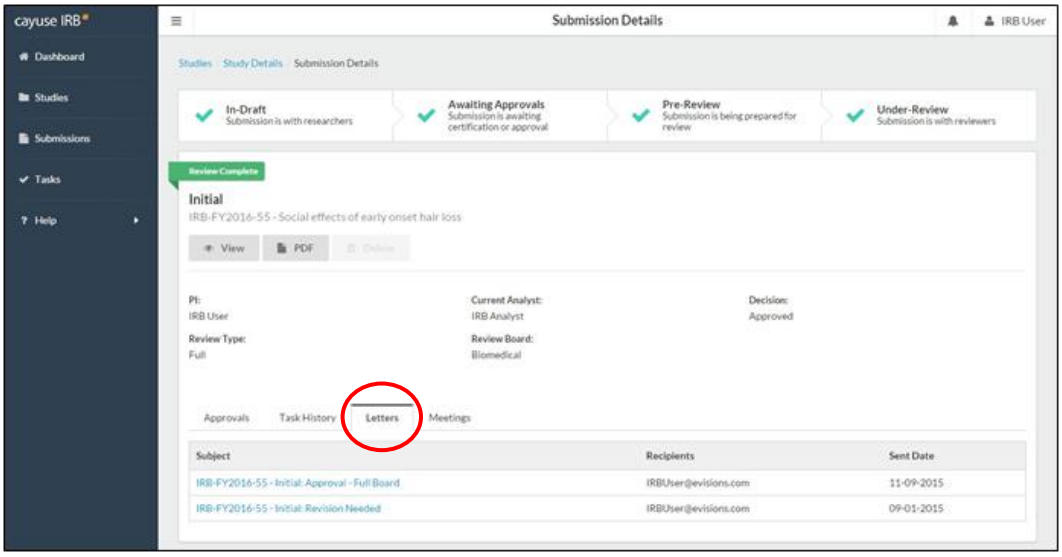
ALL changes made in your attached documents (consent, flyers, scripts, etc.) are to be highlighted. Once you have addressed the contingencies listed above in your protocol, please revise, edit, and resubmit your protocol. **In Cayuse, complete Section 6, "Investigator Response."** If you have any questions regarding the Board's contingencies, you can contact me via e-mail (irb@memphis.edu). If you have questions regarding how to submit your revised protocol or questions about the IRB process, please contact the Institutional Review Board at irb@memphis.edu or 901-678-2705.

****Note your submission will be returned if you do not provide the request information**

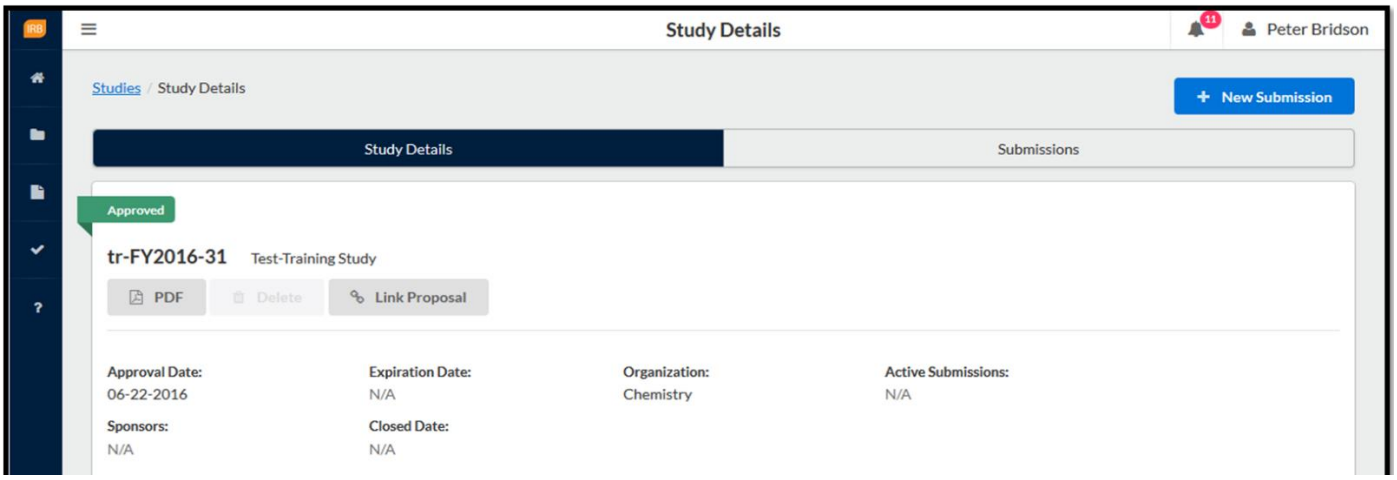
After you have addressed all contingencies and made all necessary changes, click Complete Submission to proceed to rerouting your submission back to the IRB Analyst. You will follow the same step described in “Certifying your Submission.”

Notification of Review Outcomes

All review outcomes will be communicated to you via email from irb@memphis.edu. You may also find outcome notification within the study in Cayuse under the "**Letters**" tab. The Letters tab appears for a submission when there is at least one letter associated with that submission. Click on the Letters tab to view the letters associated with the submission



When your study is approved, you will notice that the study status has changed from Under Review to Approved



Submission Types

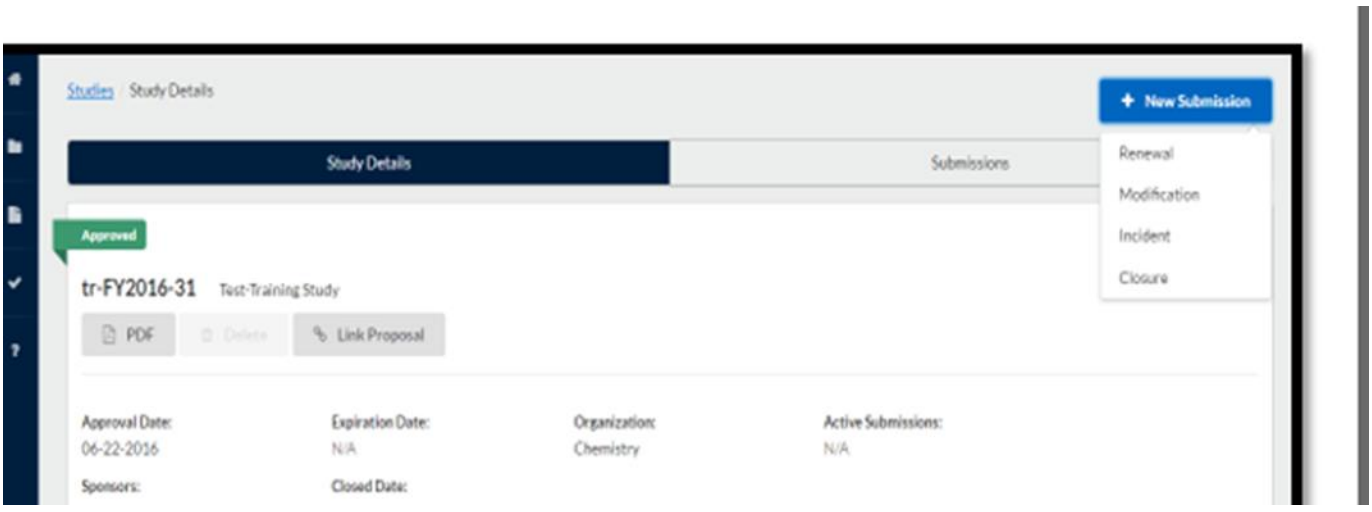
When you first create a study, you create the initial submission outlining the purpose of that study. In addition to this initial submission, there are five other types of submissions that may be submitted during the course of your research. The available submission types include:

- **Modification**: a change of any of the detail of the study after it has been approved. Before implementing any changes, the modification MUST be approved
- **Renewal:** Request to continue working with the research. The renewal must be approved to continue working on the research after the expiration date
- **Incident:** You must submit an incident report to inform the IRB of any adverse event as required by the University. Incident submission should occur in a timely manner.
- **Closure**: a closure submission indicated that the research is complete and will not continue. Closed studies are marked as finalized and can no longer be modified
- **Withdrawal:** notifies the IRB that you no longer wish to submit your initial submission and you want to withdraw the study. When the withdrawal is complete it will move into your archived submission

Each submission type has its own template to complete and route to the IRB analyst.

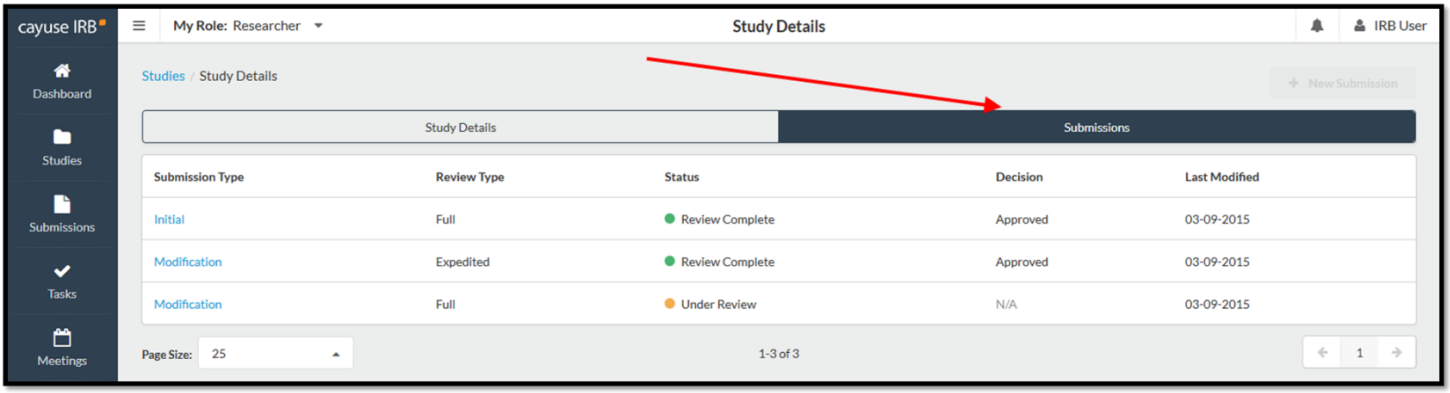
Submitting a Modification, Renewal, Incident, Closure or Withdrawal

First, you need to select the study you want to Modify, Renew, Close, or Withdraw. Click on "**New Submission**" in the upper right corner. This will provide you with a drop-down menu. Select the option that best meets your needs. After you have made your selection, you will be brought to the submission details page where you will have the option to edit your submission. When you select "**edit,**" you will be taken into the submission form where you can begin filling out the requested information.

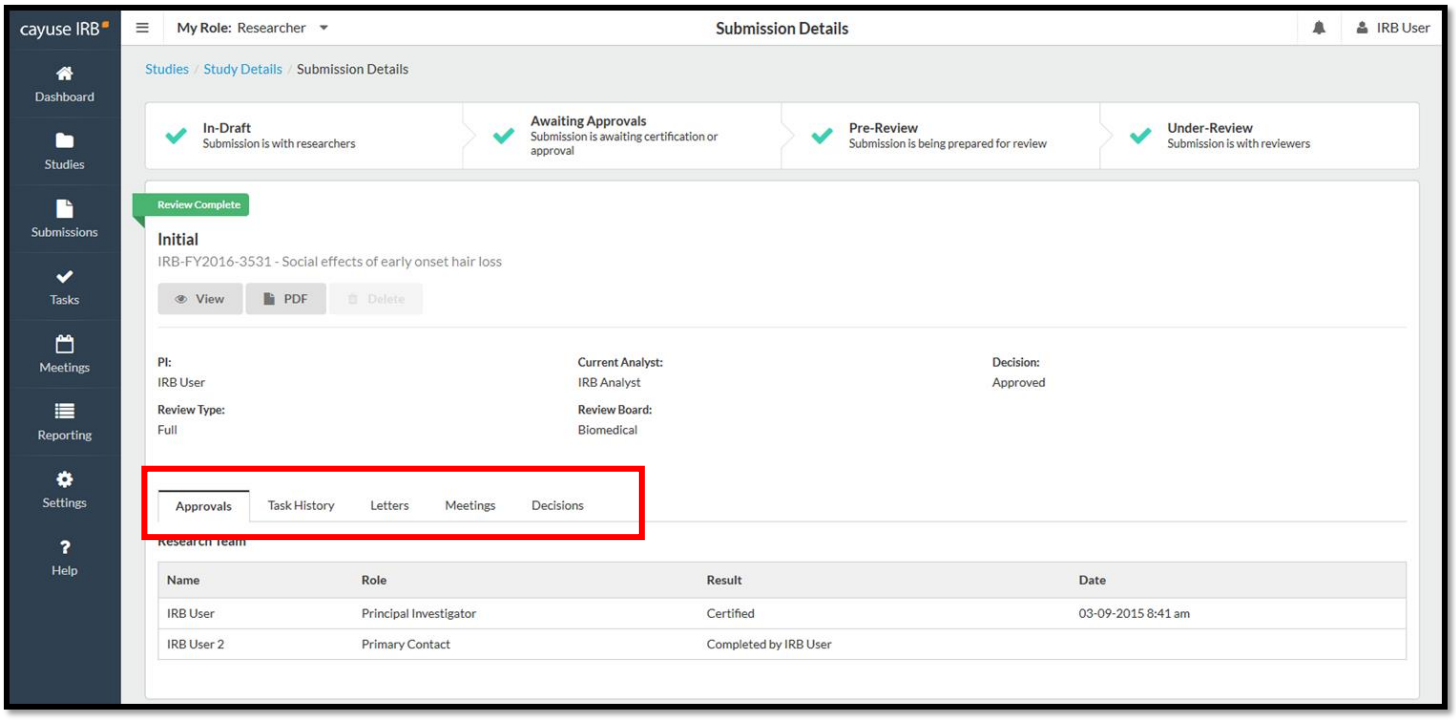


Viewing Submission History

To view the submission History for a study, go to the Study Details page and click on the "**Submissions**" tab.

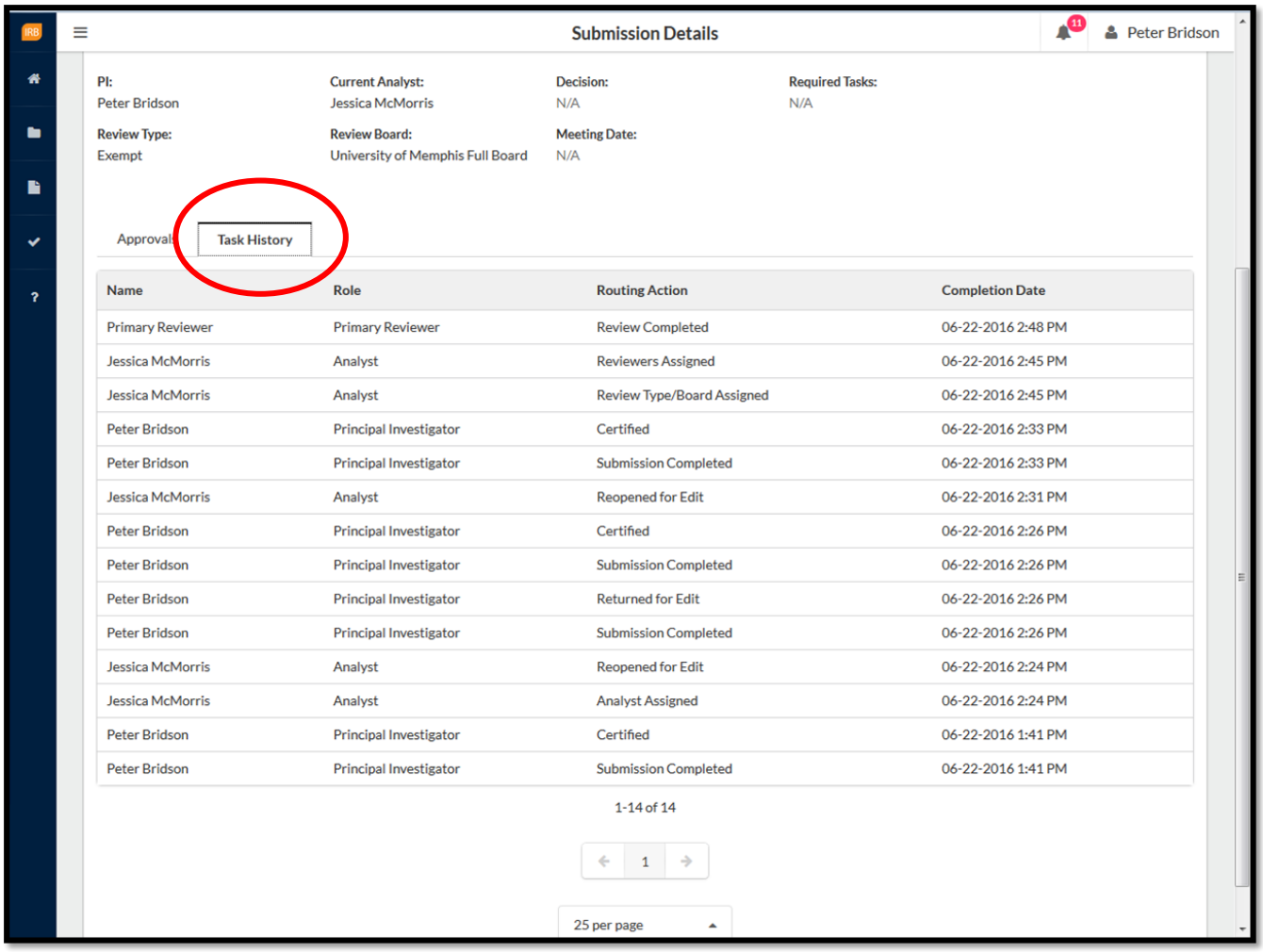


The Submission tab shows the list of submission associated with the study, including the submission type, review type, and status, decision. Click on any submission in the list to go to the Submission Details Screen. Notice the Approvals, Task History, Letter, Meeting, and Decisions tabs showing for this submission. Select the appropriate tab to obtain information you are seeking.



Task History

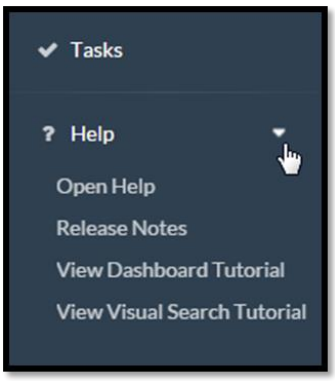
Using Cayuse IRB electronic system, all you 24/7 access and the ability to see exactly what is going on with your submission. To do this, select the "**Task History**" tab to view submission history.



Additional Assistance

You can click on the **Help** menu at any time to launch this in-product Help, or to view the release notes for this and all previous versions of Cayuse IRB. The Help menu also contains tutorials that explain the Dashboard screen, and how to search for studies and submissions

Clicking the small  icon throughout Cayuse IRB open the Help to the page with information relating to that part of the application



In-Person Training

If you would like to receive in-person training with Cayuse IRB please email irb@memphis.edu or Kellie Watson at kwtson10@memphis.edu or 901.678.2705 to discuss setting up an in-person training session. Sessions can be one-on-one or group sessions utilizing the test environment of Cayuse IRB.