Cayuse IRB for Researchers

THE UNIVERSITY OF MEMPHIS

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What is CayuseIRB?

Cayuse IRB (memphis.cayuse424.com) provides visibility into the entire Institutional Review Board review and submission process while it simplifies the protocol creation process. Using your University of Memphis log in credentials, you will have 24/7 access to submission creation, IRB protocols, paperless electronic approvals – no waiting to receive approval docs - and management of IRB protocols from initial submission to close.

Cayuse IRB will be ready for use on August 1, 2016. Cayuse IRB will be ready for use on August 1, 2016. Investigators are requested to create new/initial protocols using

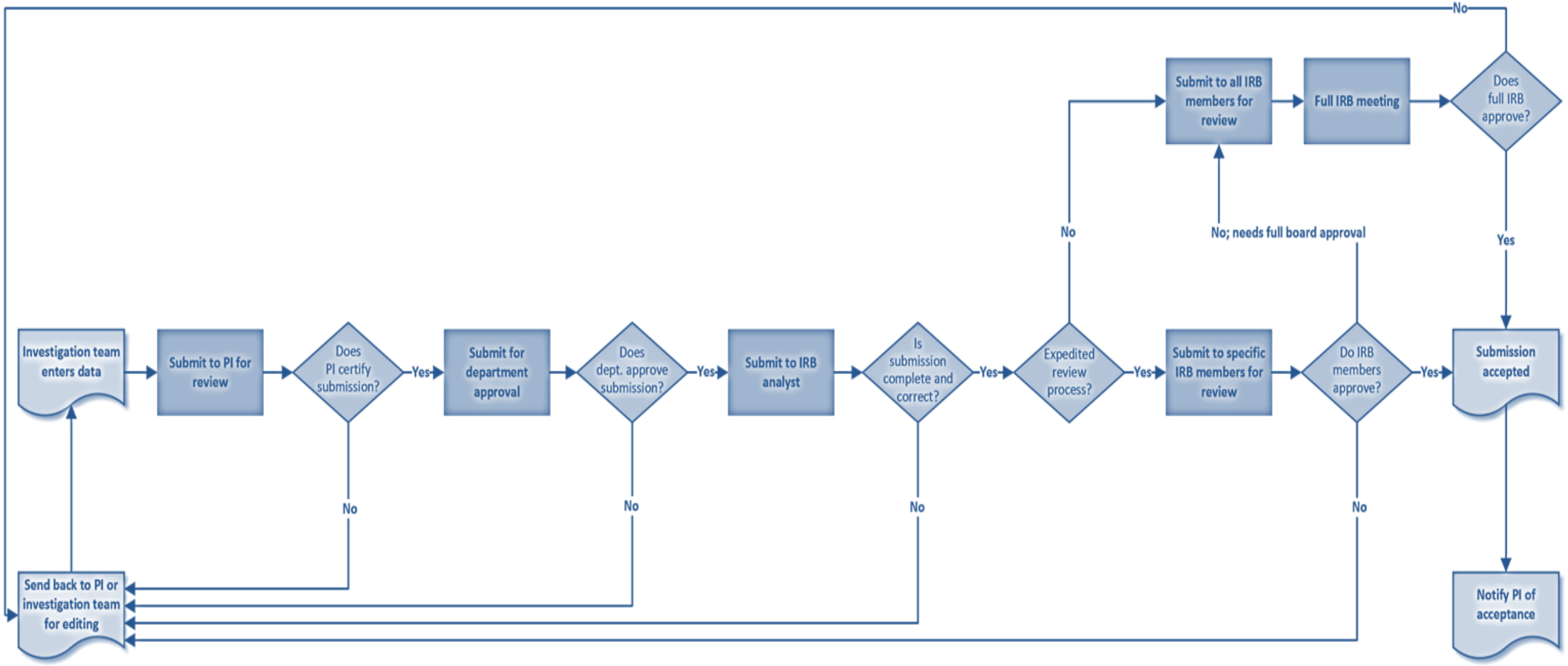
On September 1, 2016, it will be **REQUIRED** for all UofM researchers to use Cayuse IRB for all protocol submissions. If you have tried opening Cayuse IRB and are unable to access it or have any questions, please contact the IRB Administrator at irb@memphis.edu or (901) 678-2705.

For more information visit http://www.memphis.edu/rsp/compliance/cayuse_irb.php.

Your role as a UofM Researcher

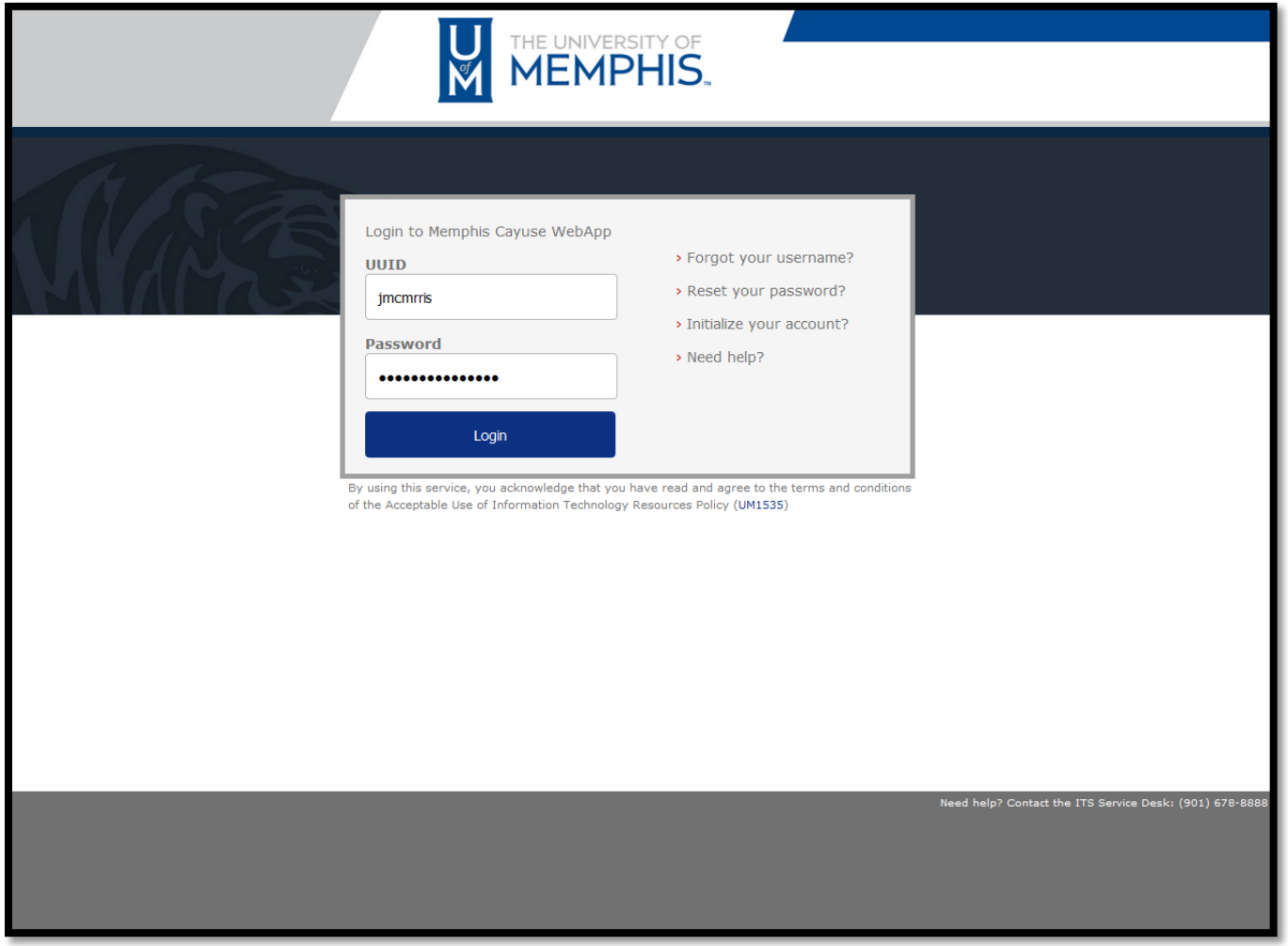
- ✓ **Submit, modify, renew, report adverse event or incident, close your study,**
- ✓ **Have 24/7 access to the your study and know exactly where your study is in the review process.**
- ✓ **Receive and correspond all communications and decisions regarding your study**

Submission Workflow



Logging Into Cayuse

Go to memphis.cayuse424.com and log to *MyMemphis* by using your UM Credentials (UM UUID and Password).

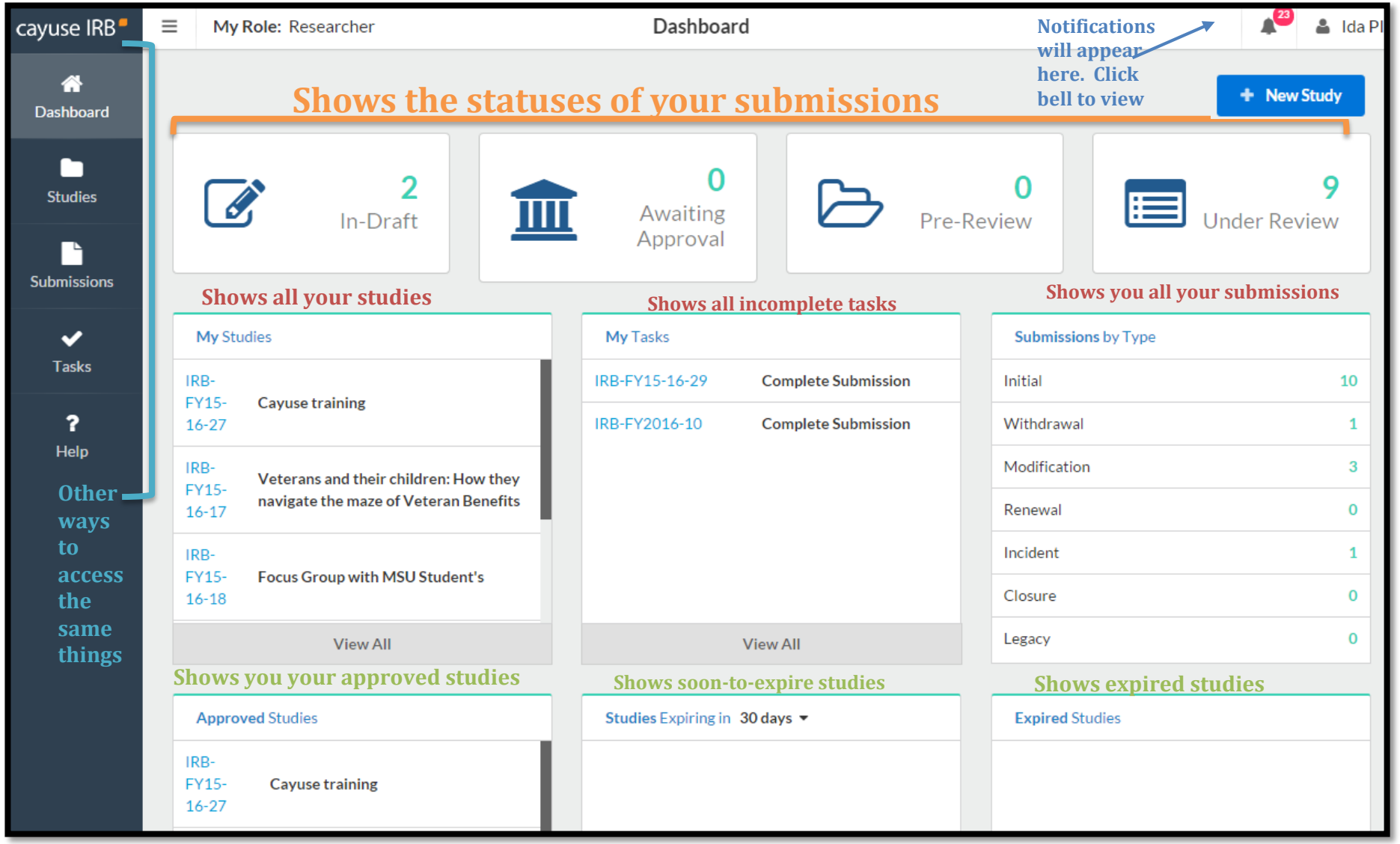


Study vs. Submission

STUDY refers to your entire research project

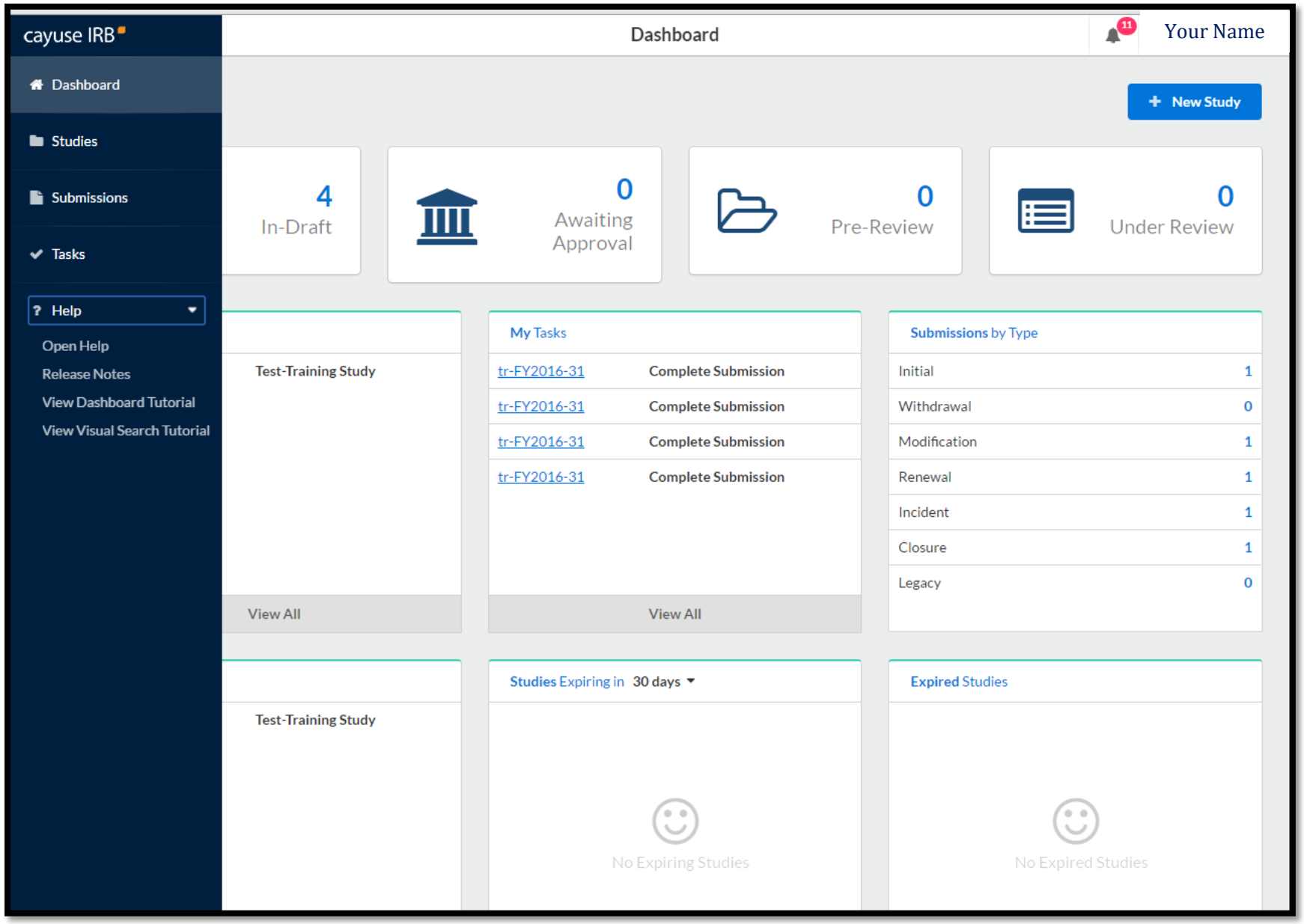
SUBMISSION refers to specific applications- e.g. initial application, modification, renewal, closure, etc.

CayuseIRB Dashboard Summary



Need Help?

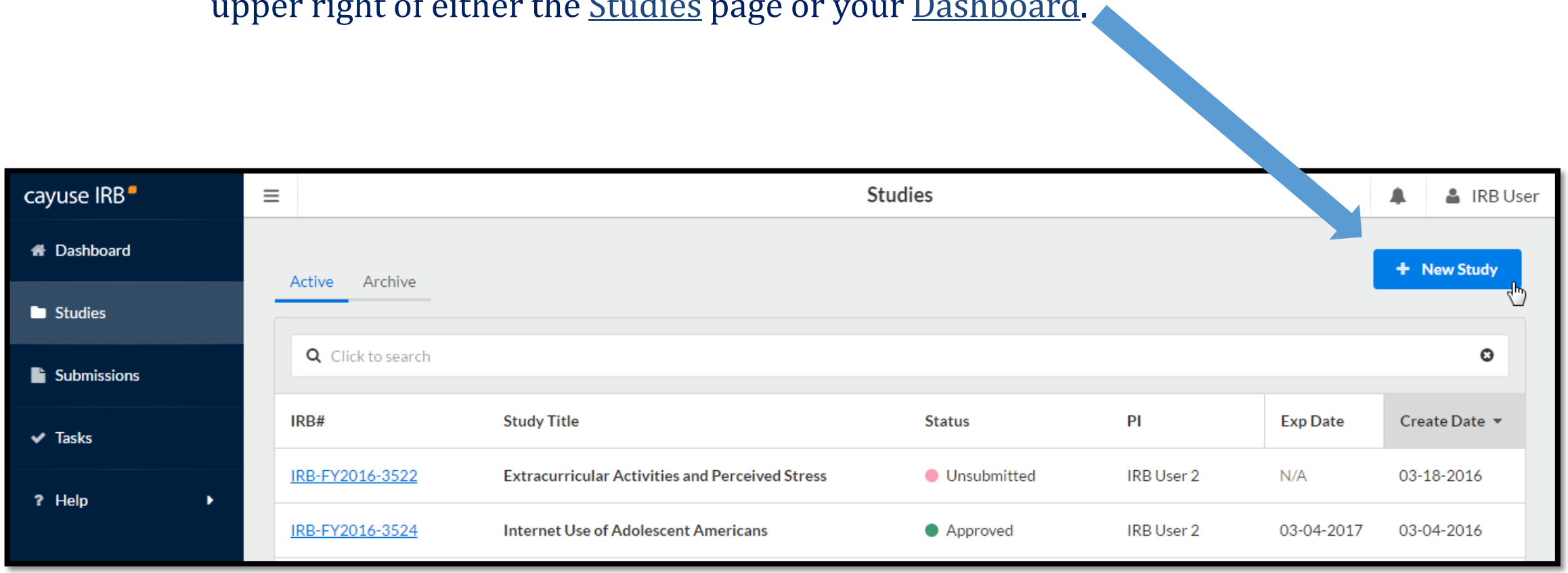
For additional help with CayuseIRB, in the left column, select **Help** to expand its drop-down menu. **Open Help** will take you to the main CayuseIRB Tutorial Page.



Creating an Initial Review Request

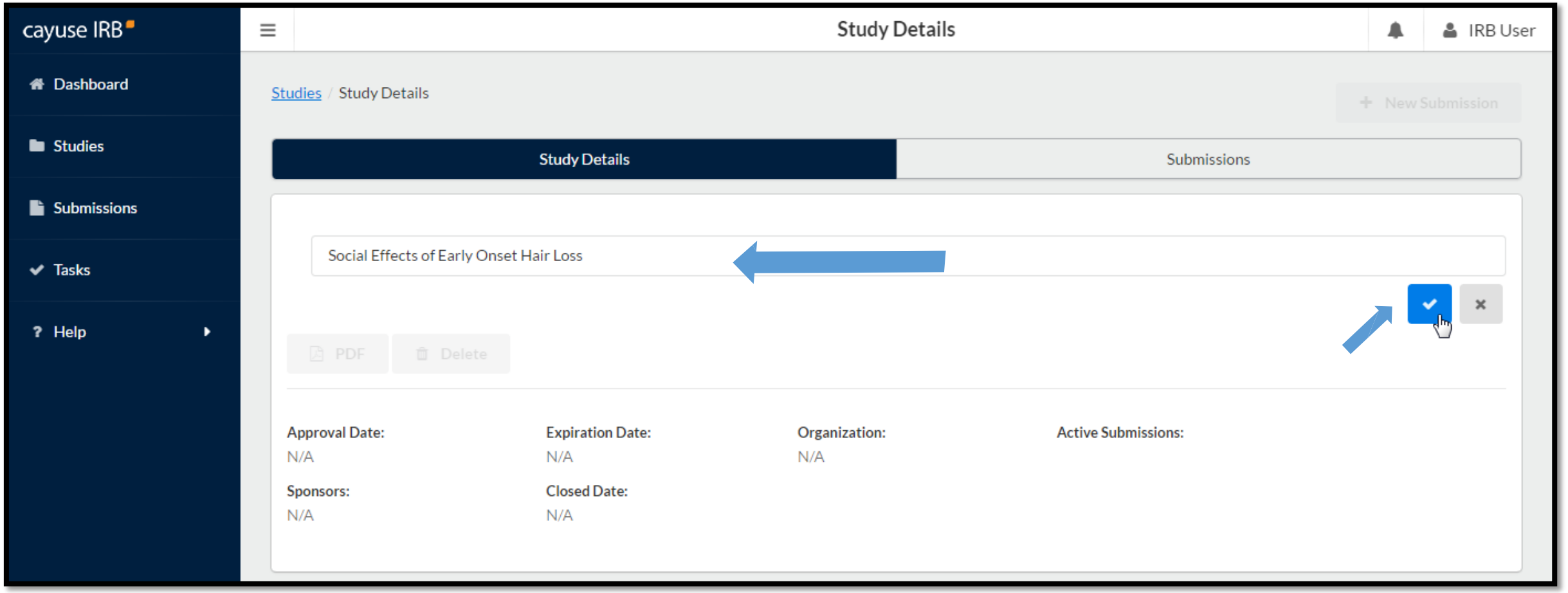
Create a New Study

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



Study Title

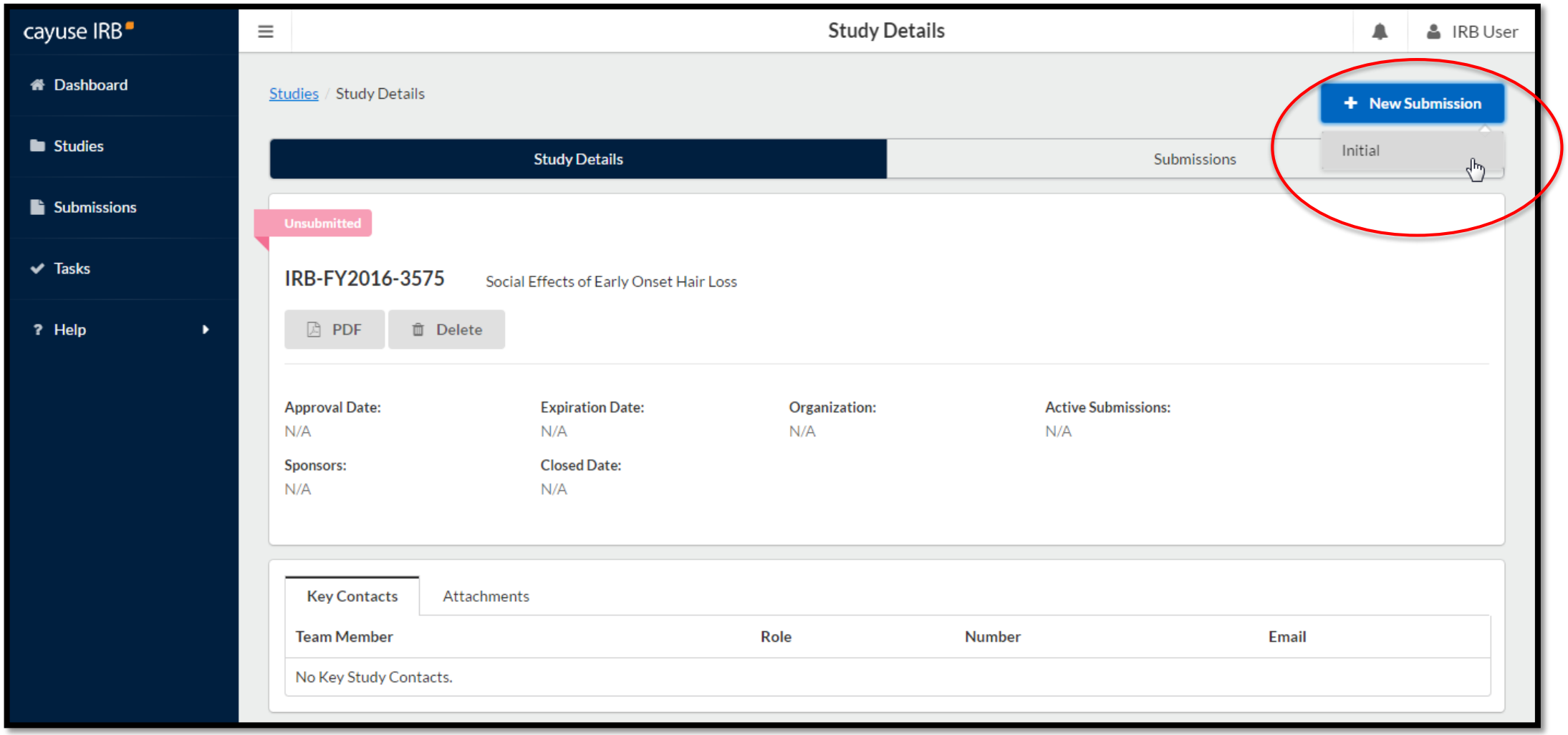
Enter a title for your study (up to 600 characters). Then, click the **Save** button.



Completing Forms

Begin Submitting Information & Documents

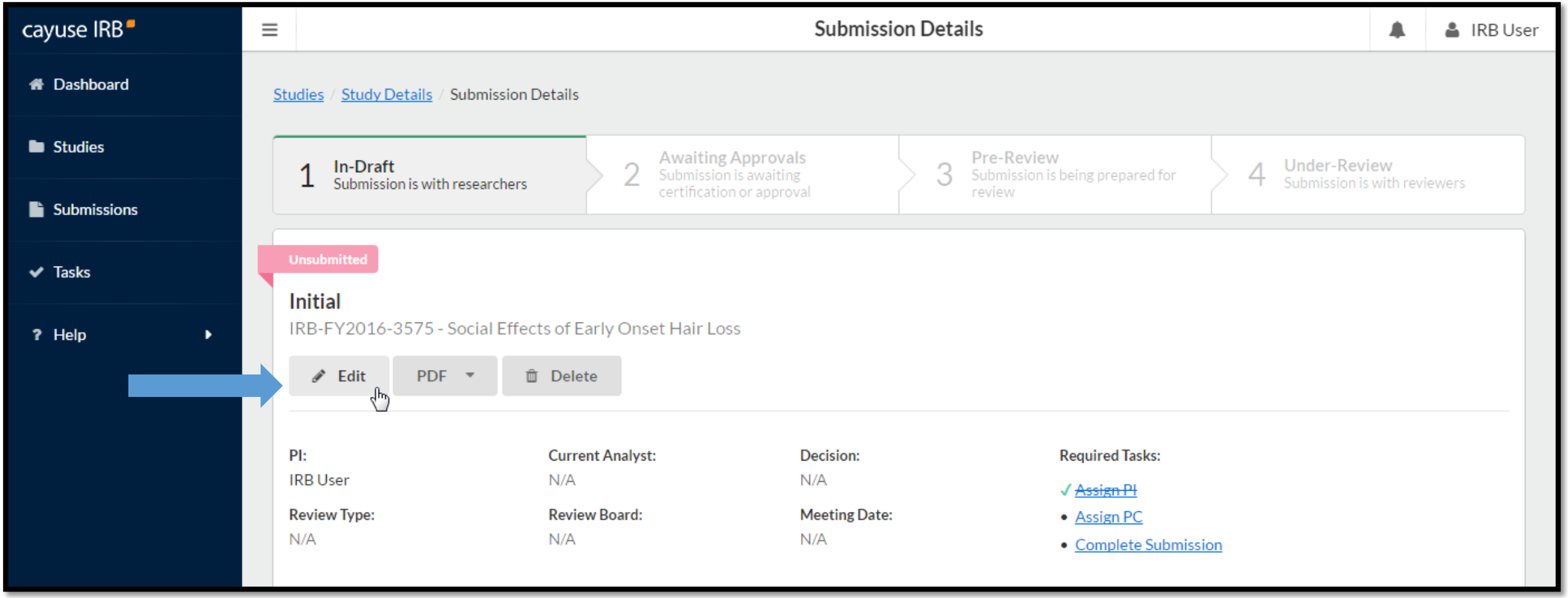
To begin working on your study, click **New Submission** to add the **Initial** submission for your study.



Study's Submission

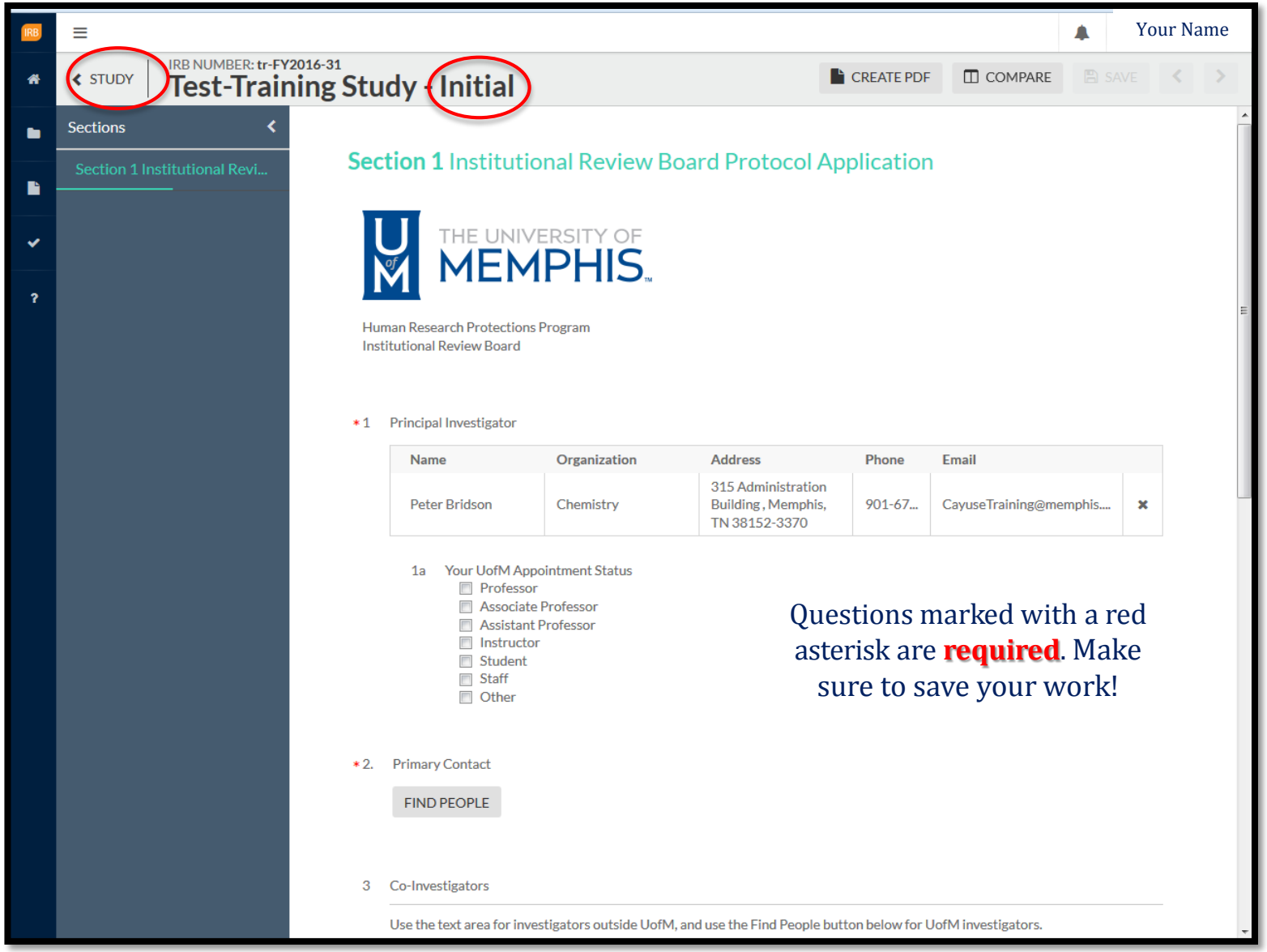
The initial submission appears below the study details. The person who creates the study is added as the PI by default. You can change this when editing the submission, if needed.

Click the **Edit** button to begin working on the initial submission.



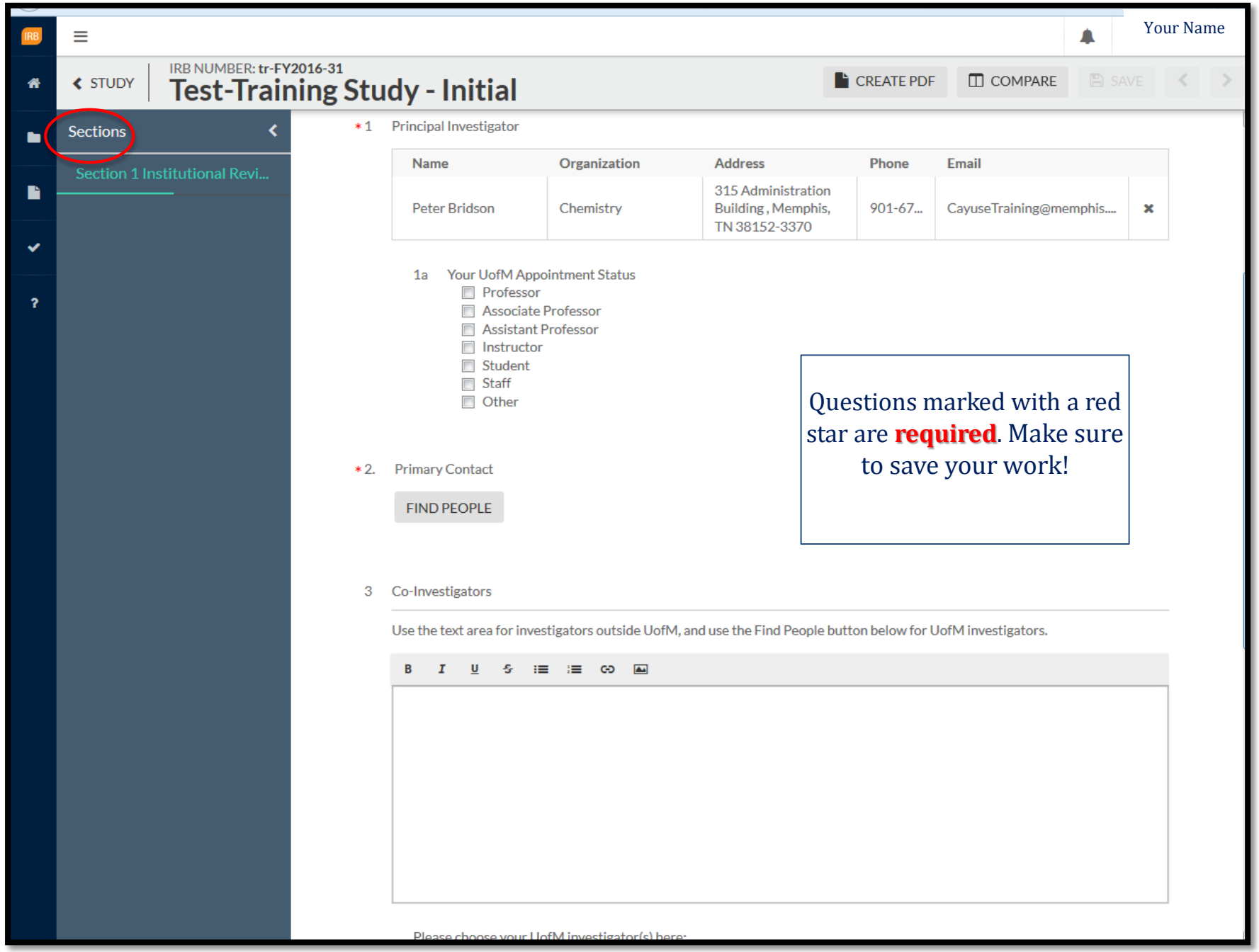
Initial Submission Form

You will now be taken to your institution's initial submission form, where you can begin filling out information. Your study is saved, and you can return to the Study Details page at any time by clicking on the **< STUDY** link in the upper left of the screen.



Section 1. General & Contact Information

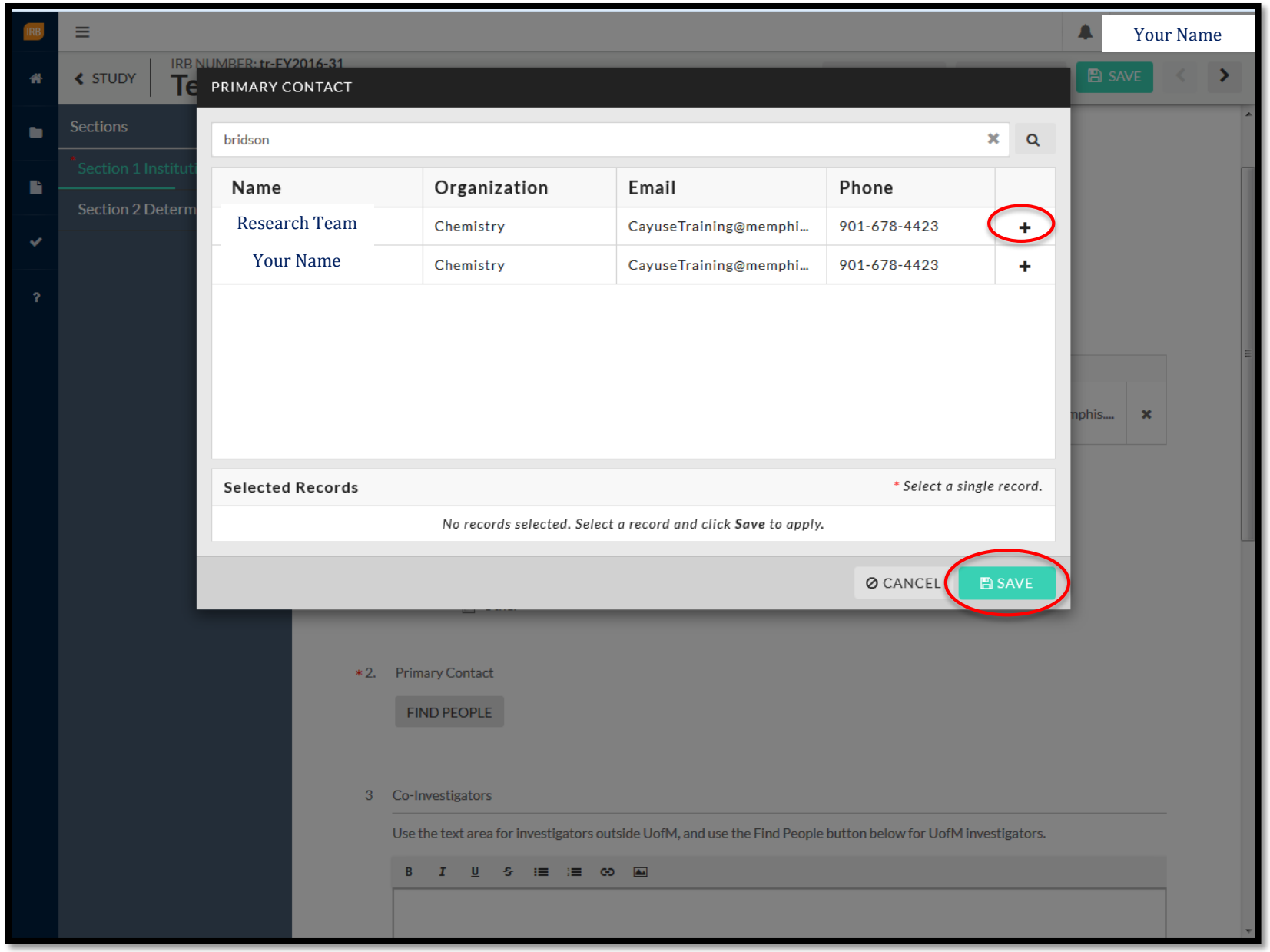
When you create a new submission for your study, the submission prompts you for the information required by IRB. The information of includes the Principal Investigator's contact, students' advisor(s), Primary Contact, Co-Investigators, and other prompted questions.



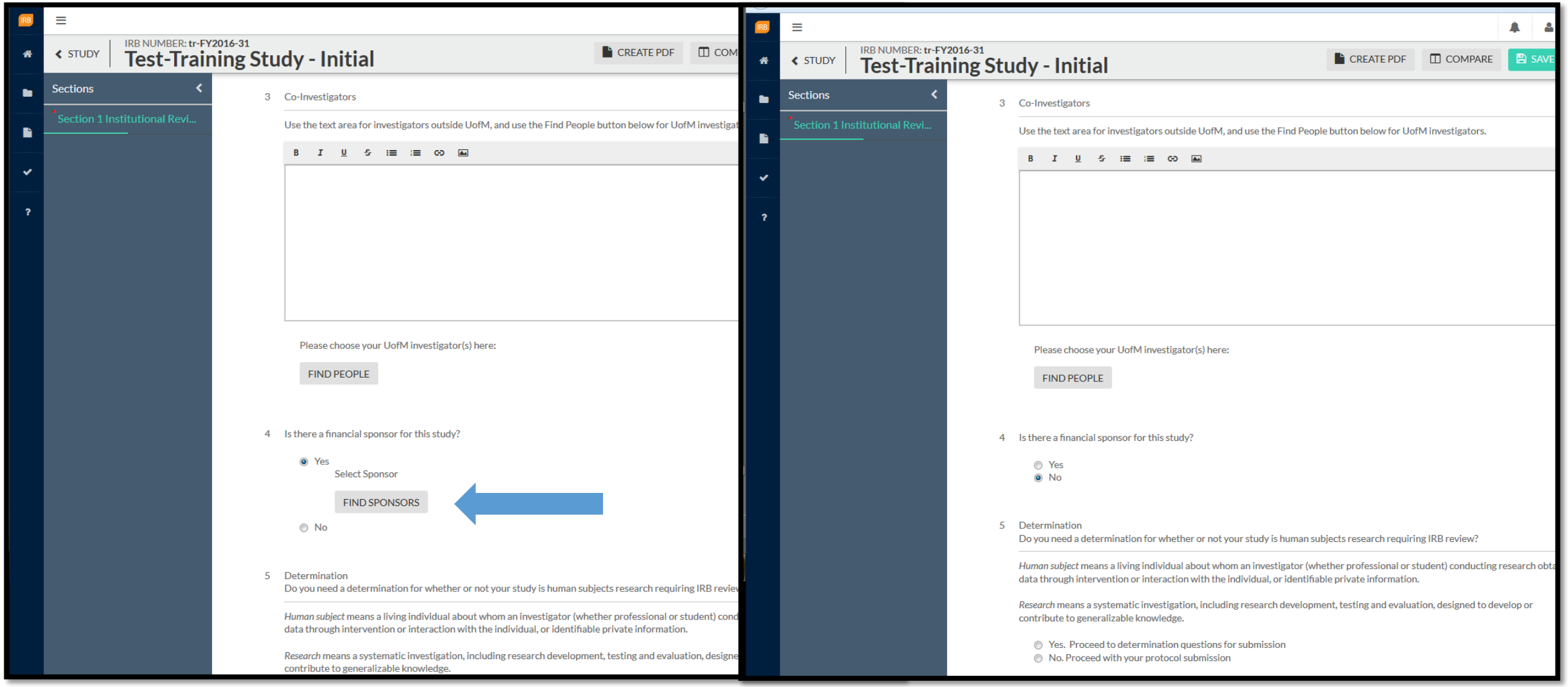
Primary Contact & Research Team

You must have a Primary Contact. Select **FIND PEOPLE**, enter the contact's name in the search bar and slick the search icon.

When individual appears, click the **(+)** symbol and then "**SAVE**". You will do this for ALL contact/ "**Find People**" questions.



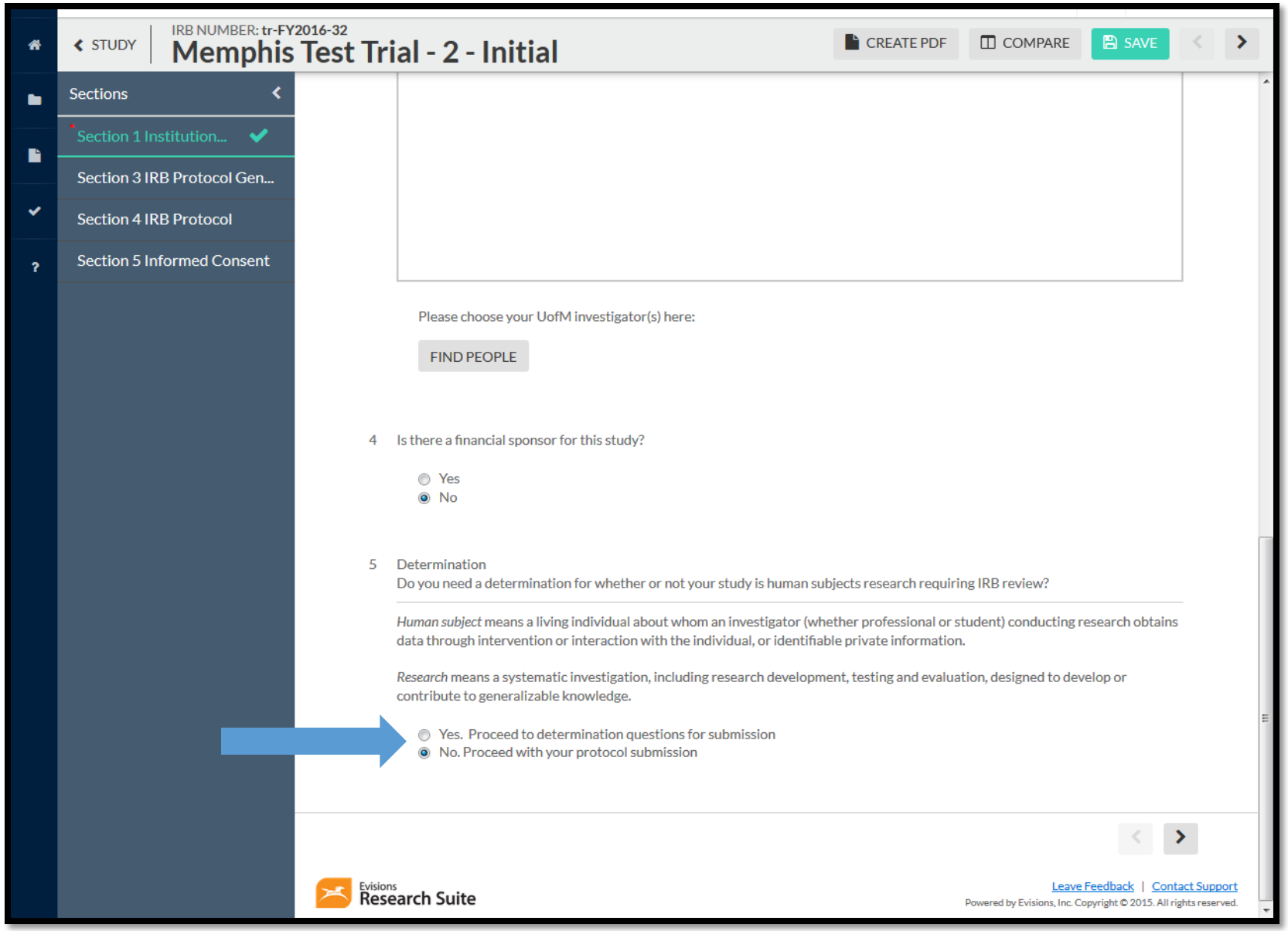
Section 1. Question 4 asks for Financial Sponsor(s). If you select Yes, click FIND SPONSORS to add the individual.



Determination

If you select *Yes. Proceed to determination questions for submission,* go to page **29**.

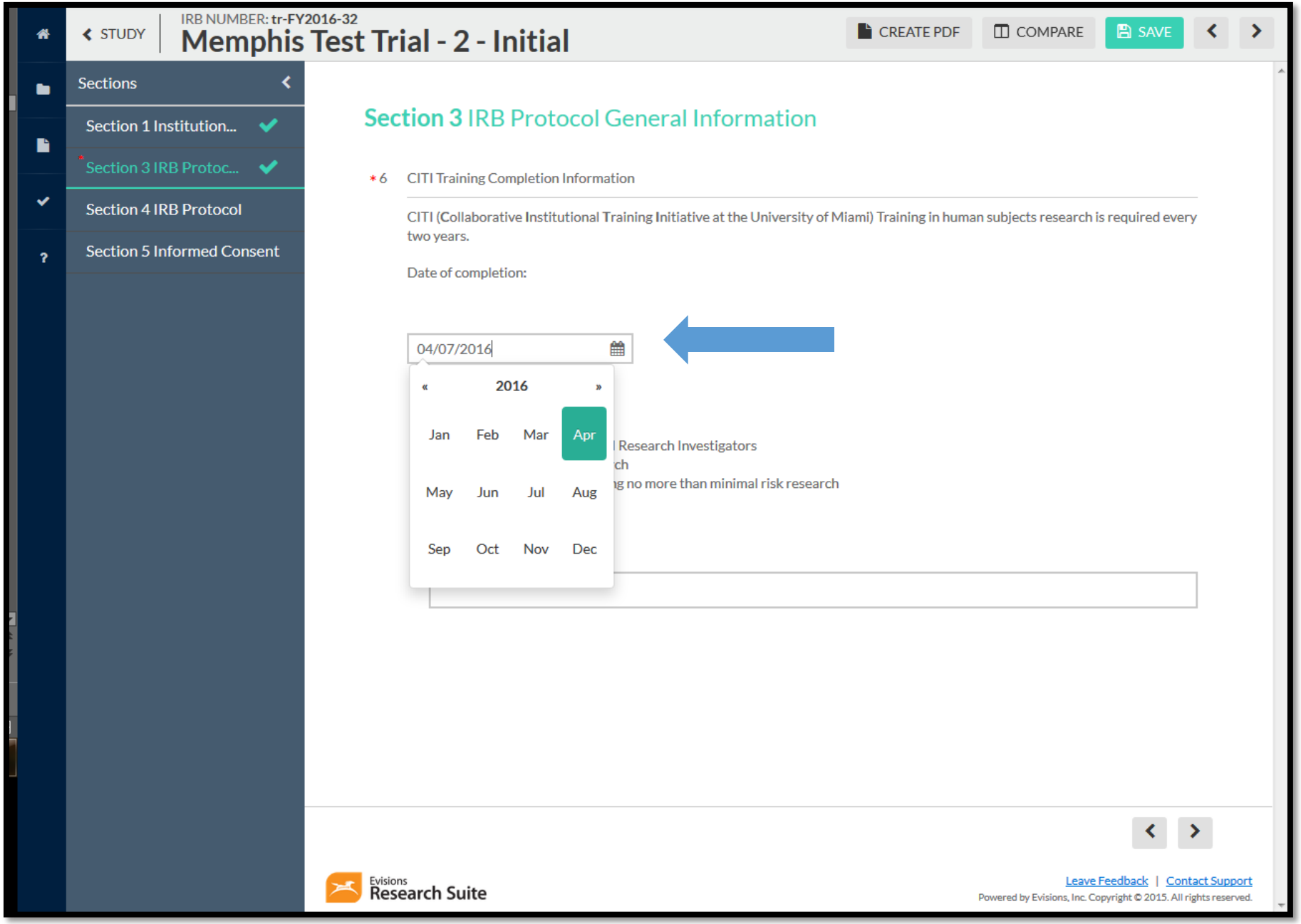
If you select *No. Proceed with your protocol submission*, you will begin submitting information on the next page.



IRB Protocol General Information

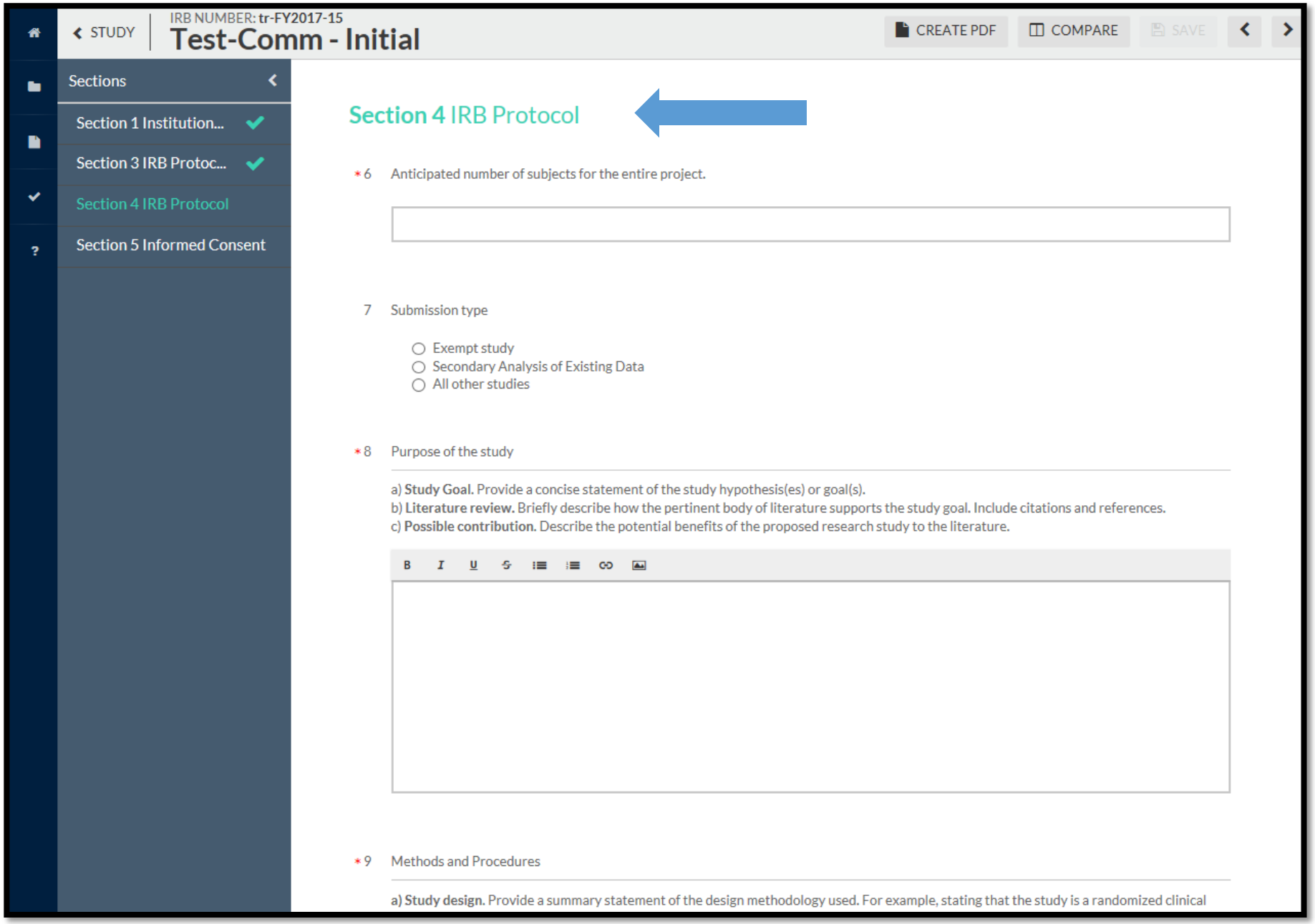
CITI Training

Enter your CITI training completion information including date of completion, modules taken, and CITI Training Cert. Number.



Your Protocol Information

Section 4 IRB Protocol is the most important section. This is where a majority of your required information will be entered.



Section 4 IRB 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.

Section 4 IRB Protocol Questions (continued…)

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

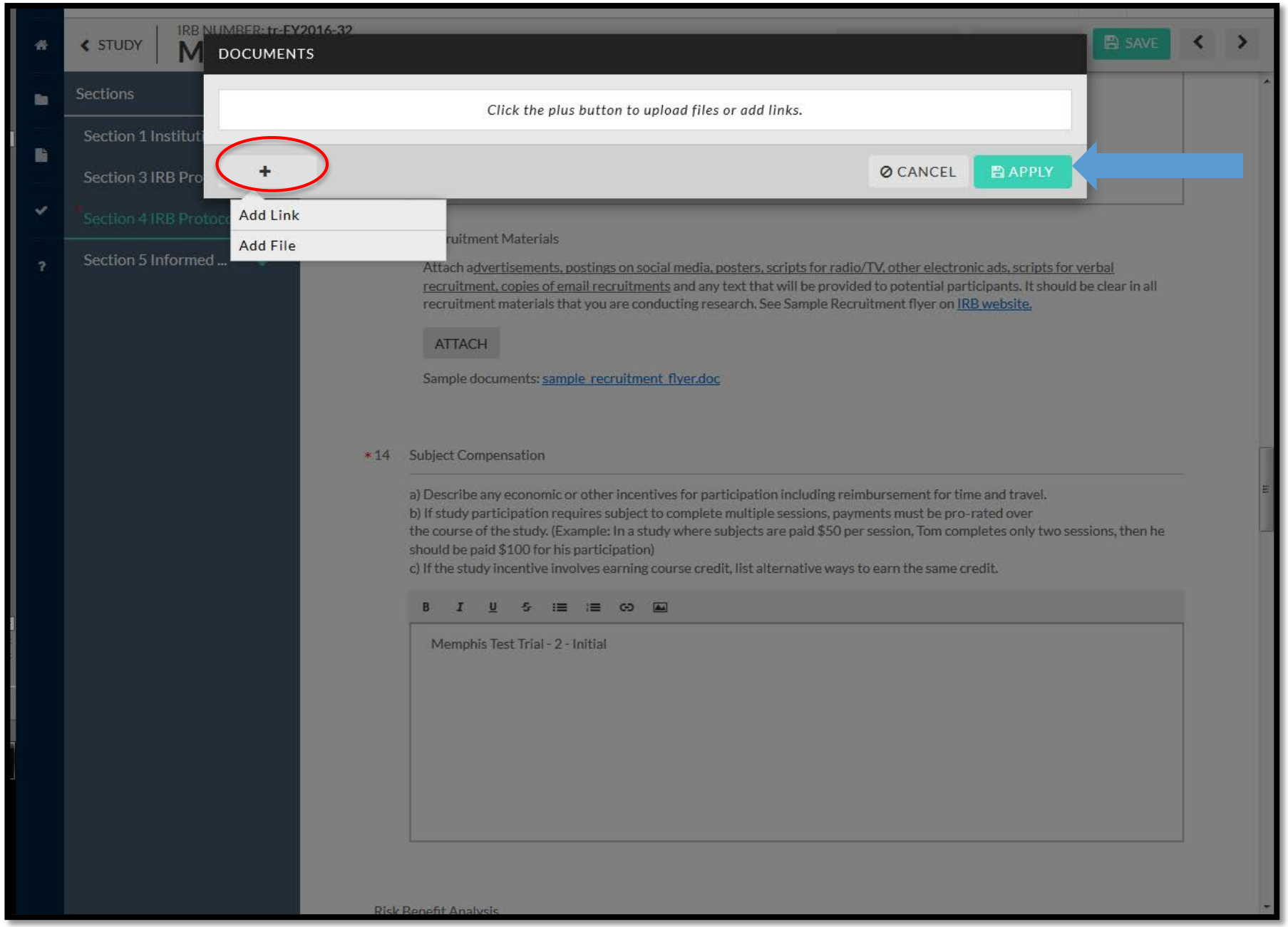
21. Proposal

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

Attachments & Links

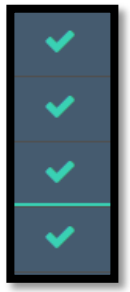
To add a document, link, or any supplemental files, select **ATTACH**. Once selected, click the plus sign (+) and **Add Link** and/or **Add File**.

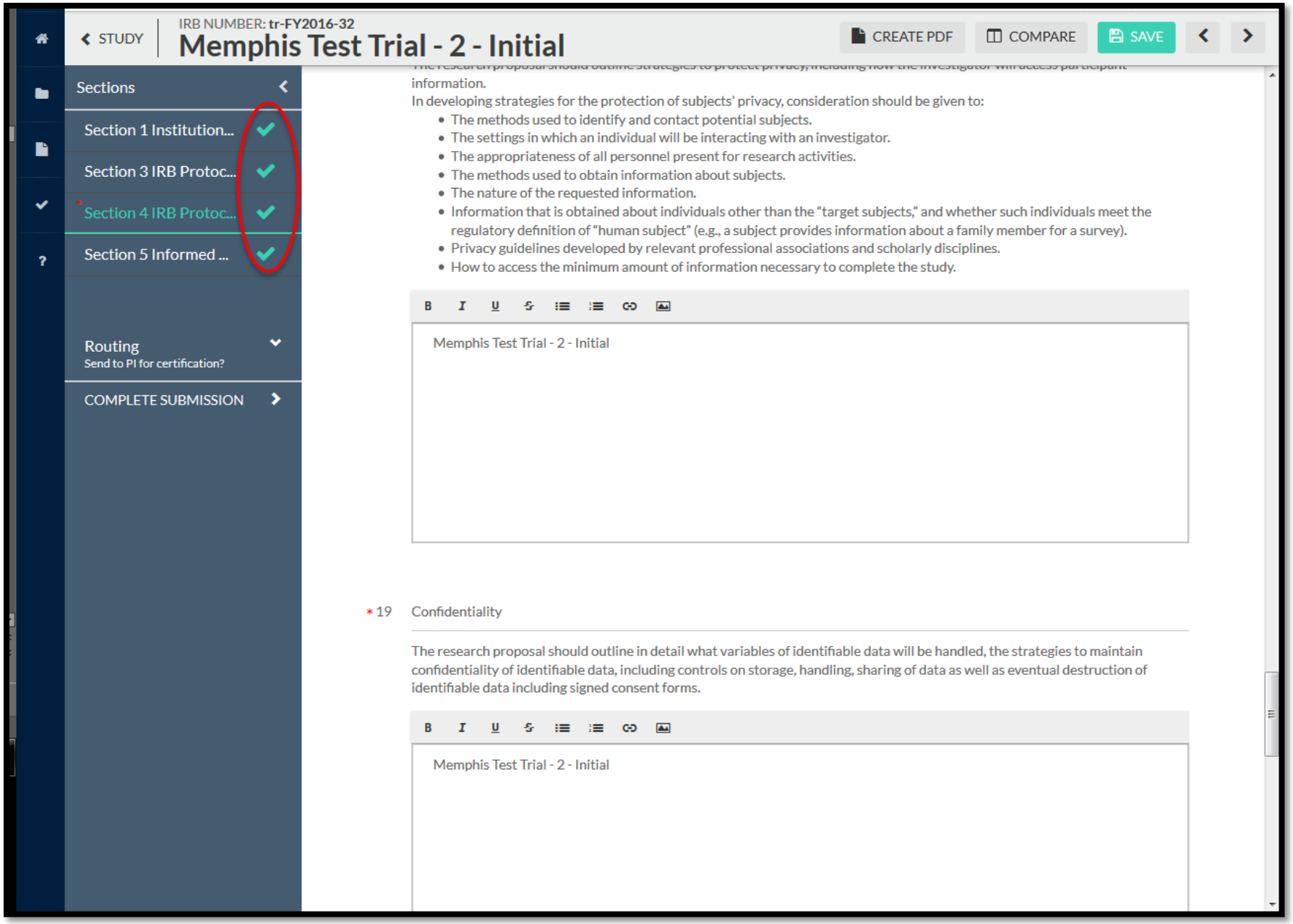
After, you have uploaded your file and/or added your link, select **APPLY** to proceed.



26 Completion

All of your sections must have the checkmarks before you can proceed to COMPLETE SUBMISSION.

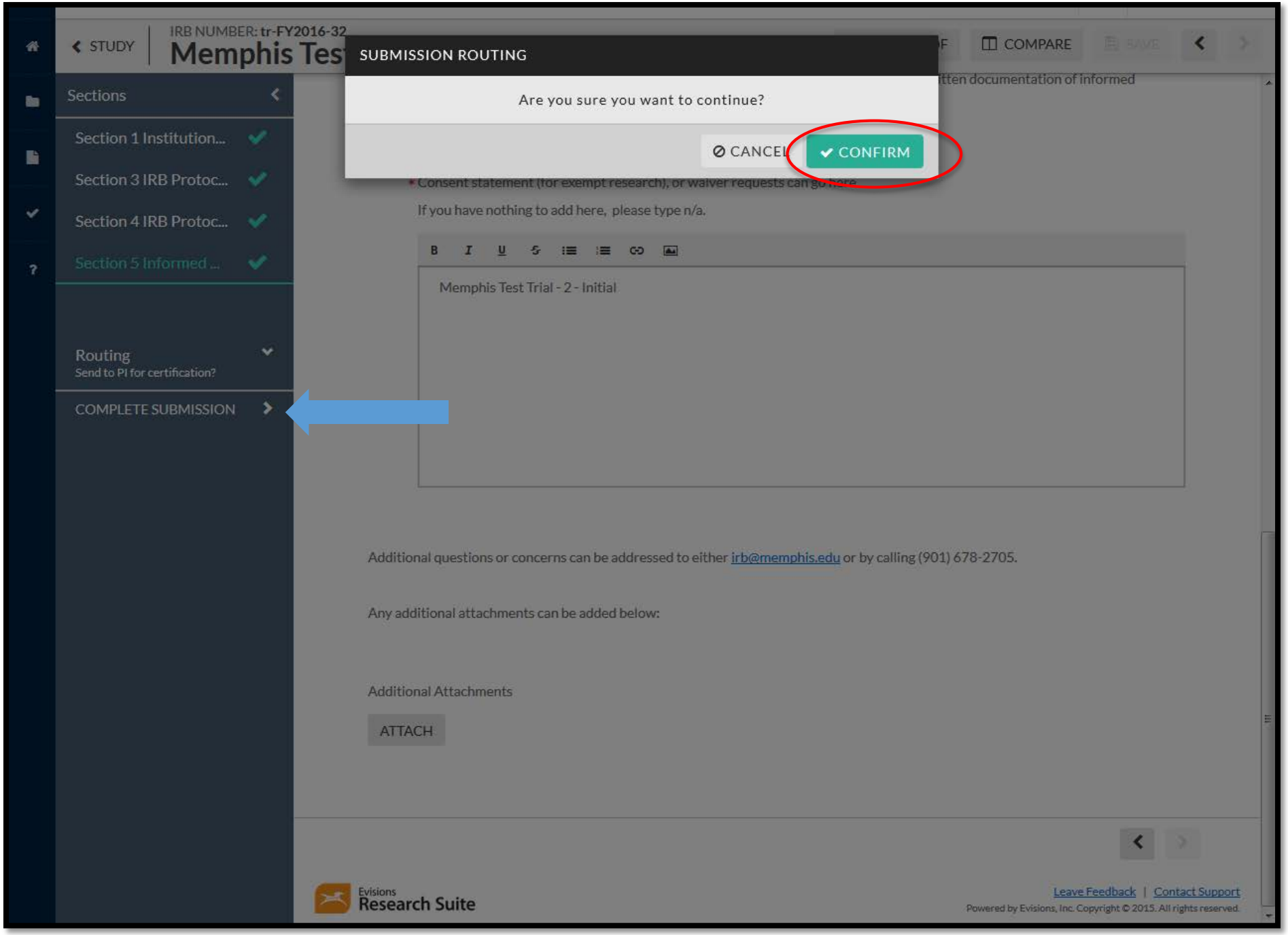




COMPLETE SUBMISSION

Once you have completed your submission and your sections are marked with the checks, SAVE your study and select COMPLETE SUBMISSION.

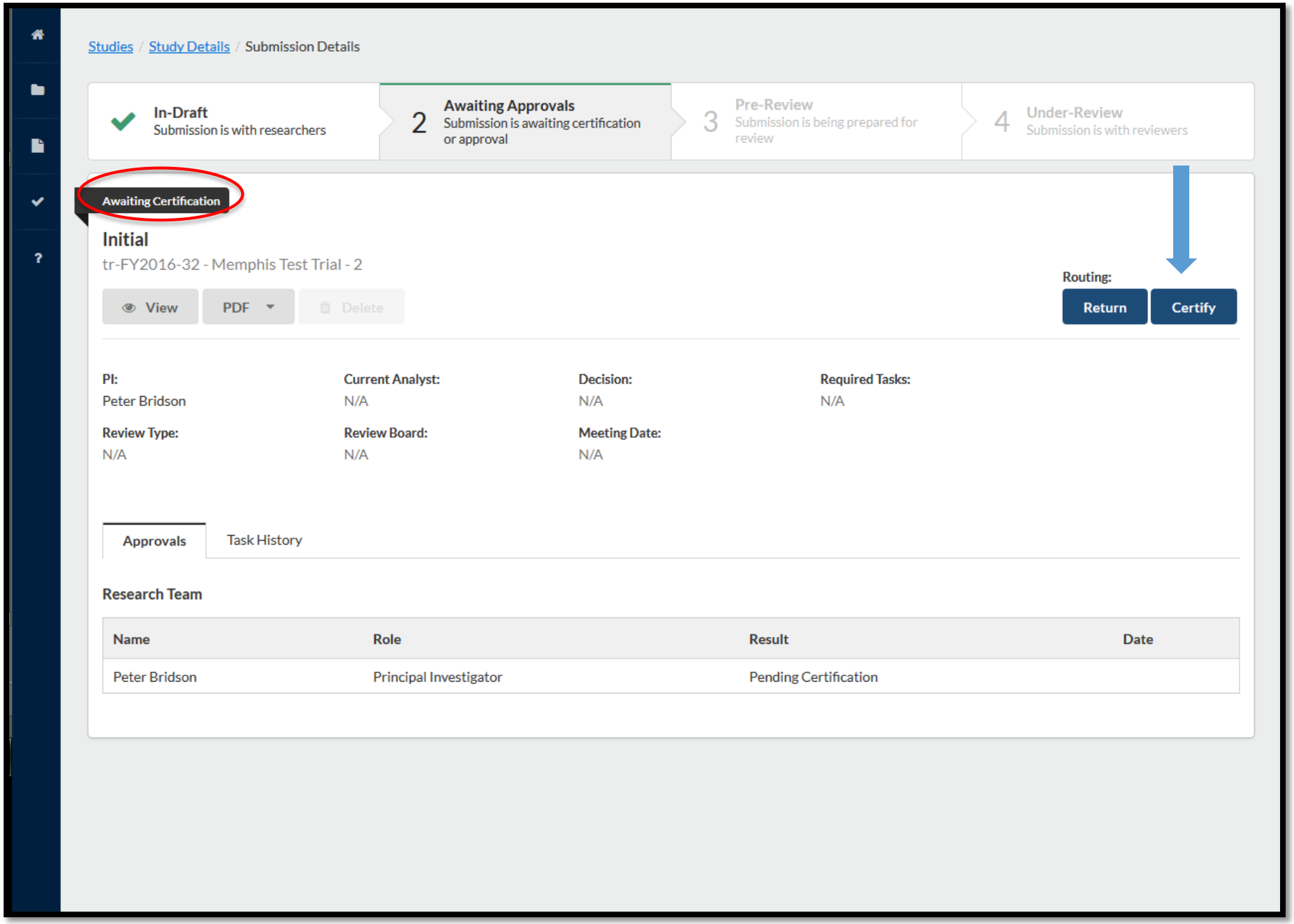
To route your submission to its next step, select CONFIRM under SUBMISSION ROUTING, after you have clicked COMPLETE SUBMISSION.



Certifying Your Submission

You will be routed to back to your submission details page and the status will be Awaiting Certification. If you are NOT a student, select Certify to proceed. Your Co-PIs will be instructed to also certify the submission

If you are a student you will certify your submission as well as your Advisor. Students, Your Co-PIs will be instructed to also certify the submission

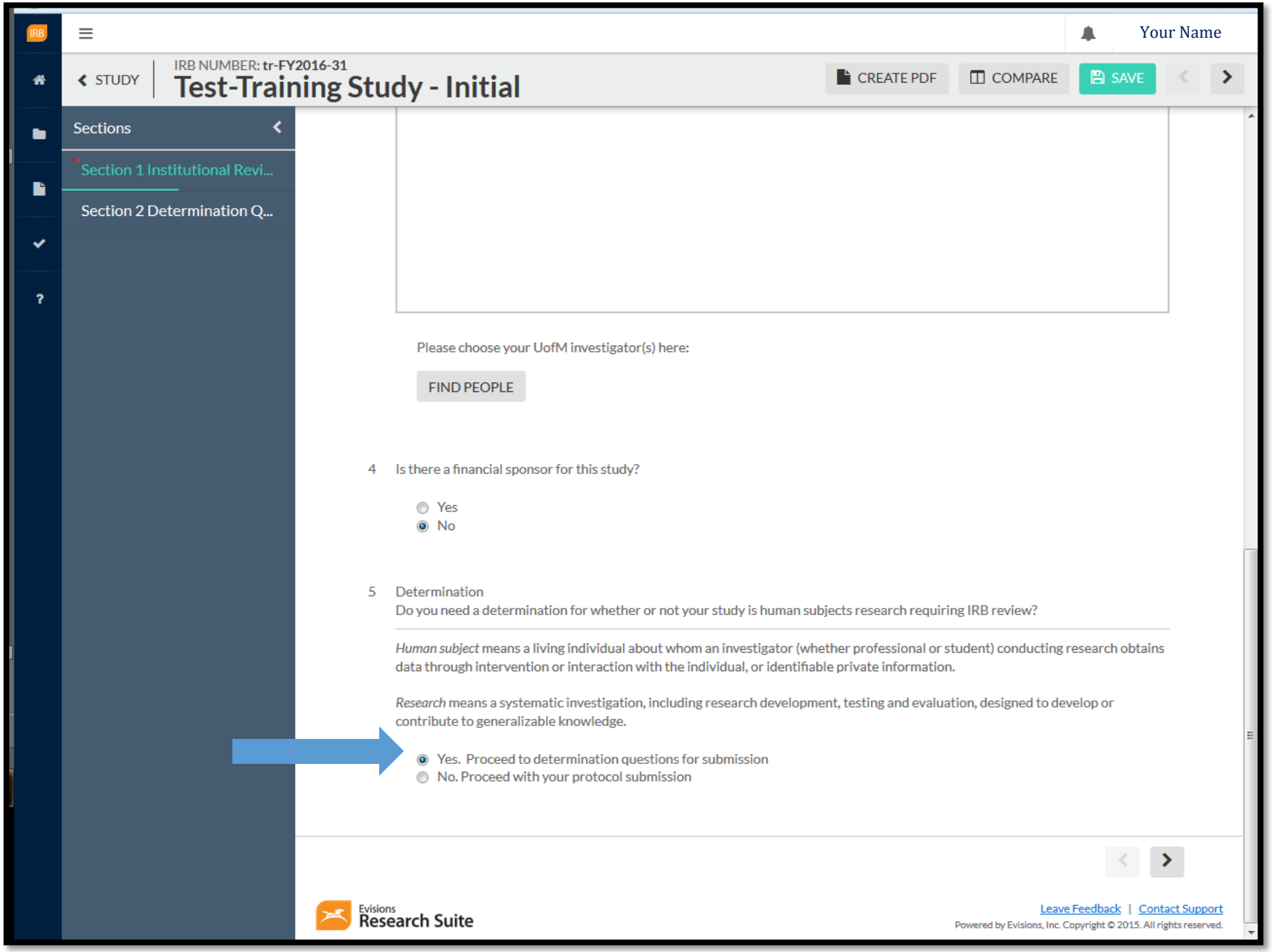


Determinations

Determination

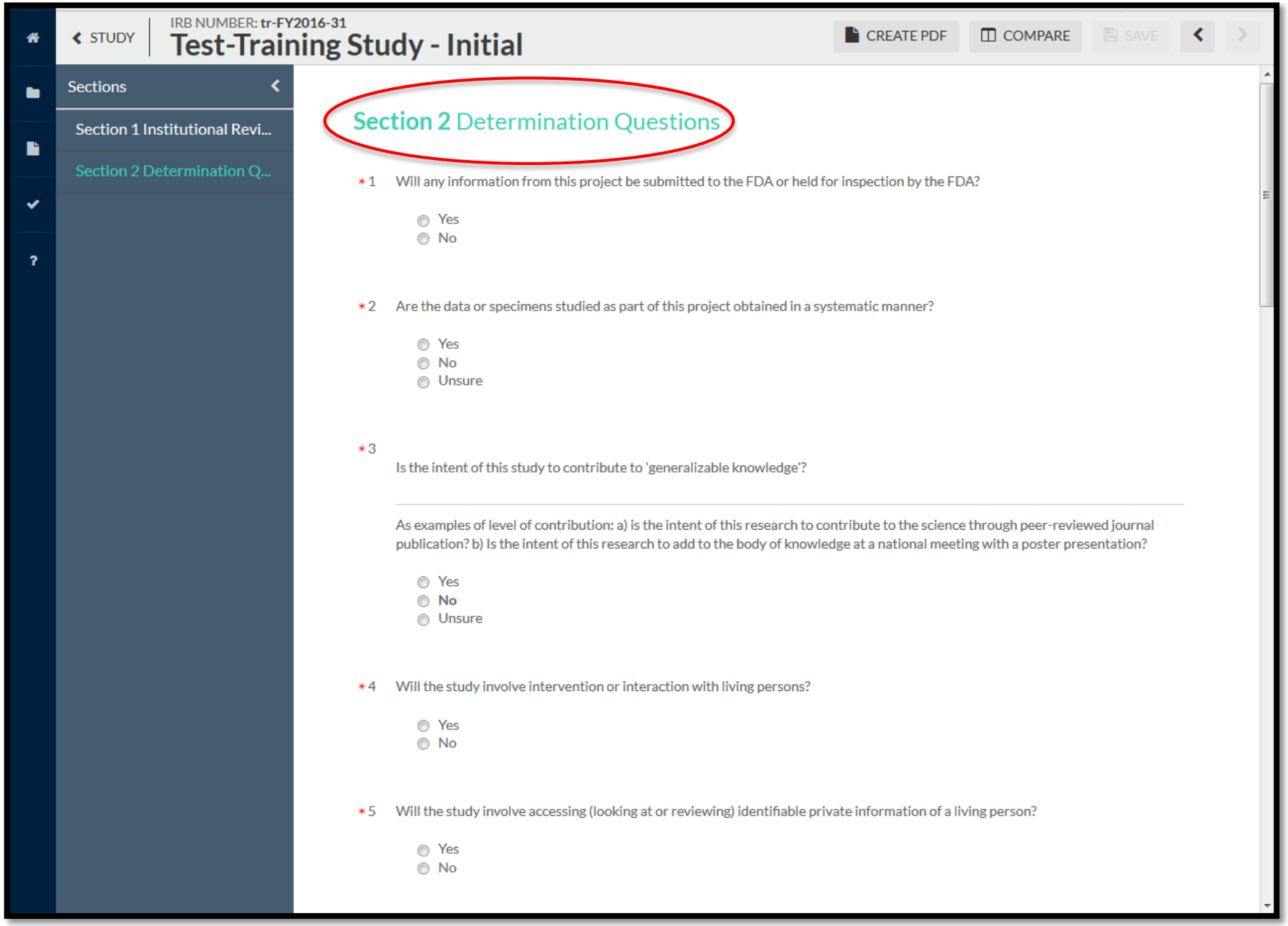
(continued from page 22)

If you have selected Yes. Proceed to Determination questions for submission. Your next step will be completing Section 2: Determination Questions.



Section 2 Determination Questions

All questions listed under <u>Section 2: Determination Questions</u> are required in order for IRB Analysts to determine whether your study is Human Subject Research or not.



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?

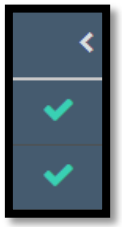
10. **Study Design and Methods**
How will the study be conducted? How will the results be analyzed to determine that study aims have been met?

11. Additional information or comments for the reviewer.

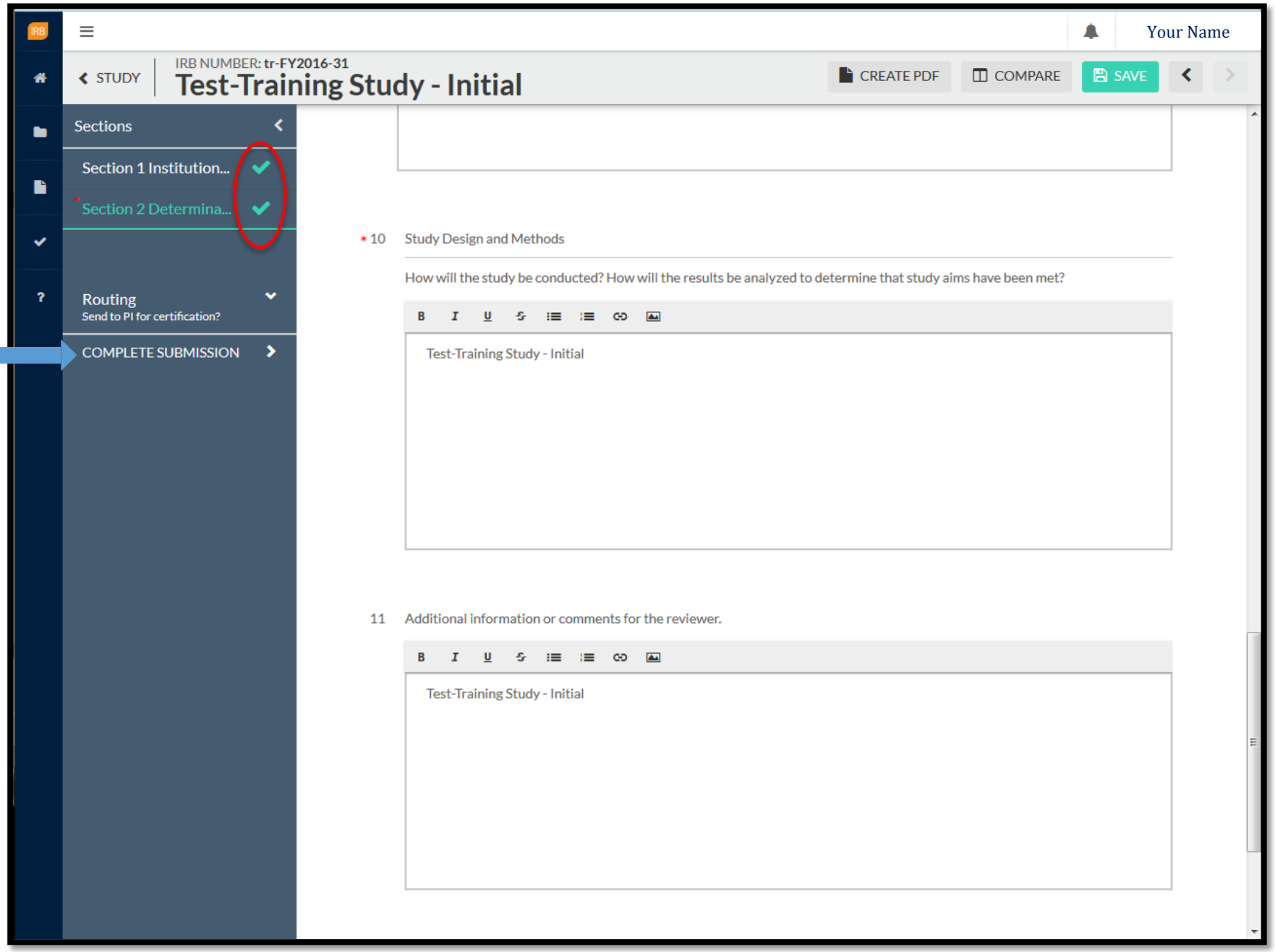
12. Attach any additional materials required to make a determination including any surveys or assessment materials to be used.

Completing Determination Submission

After successfully completing all of your determination questions, ensure your sections are checked as complete.

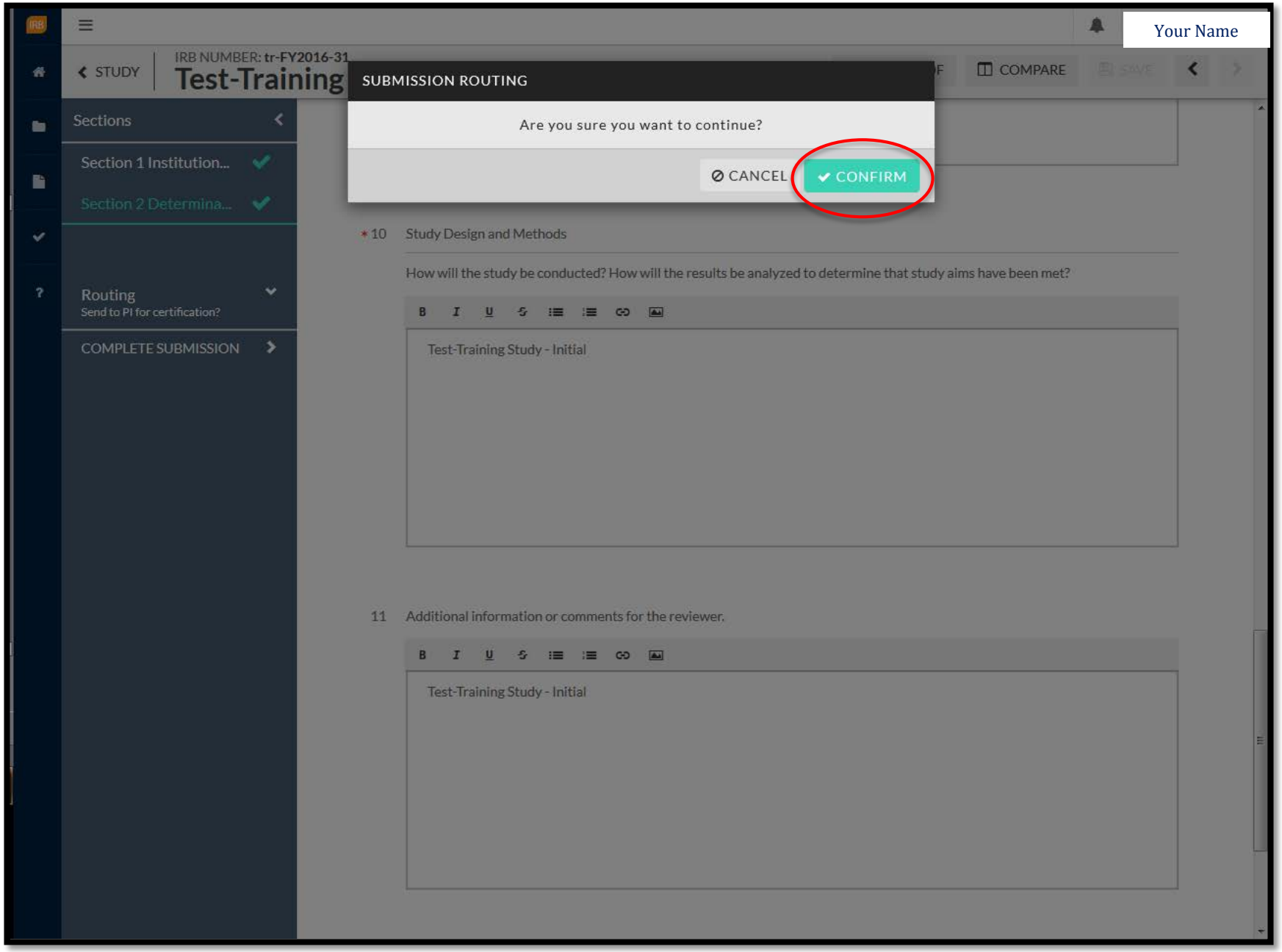


If so, select COMPLETE SUBMISSION.



Completing Determination Submission (continued)

Select CONFIRM to continue submitting your determination.

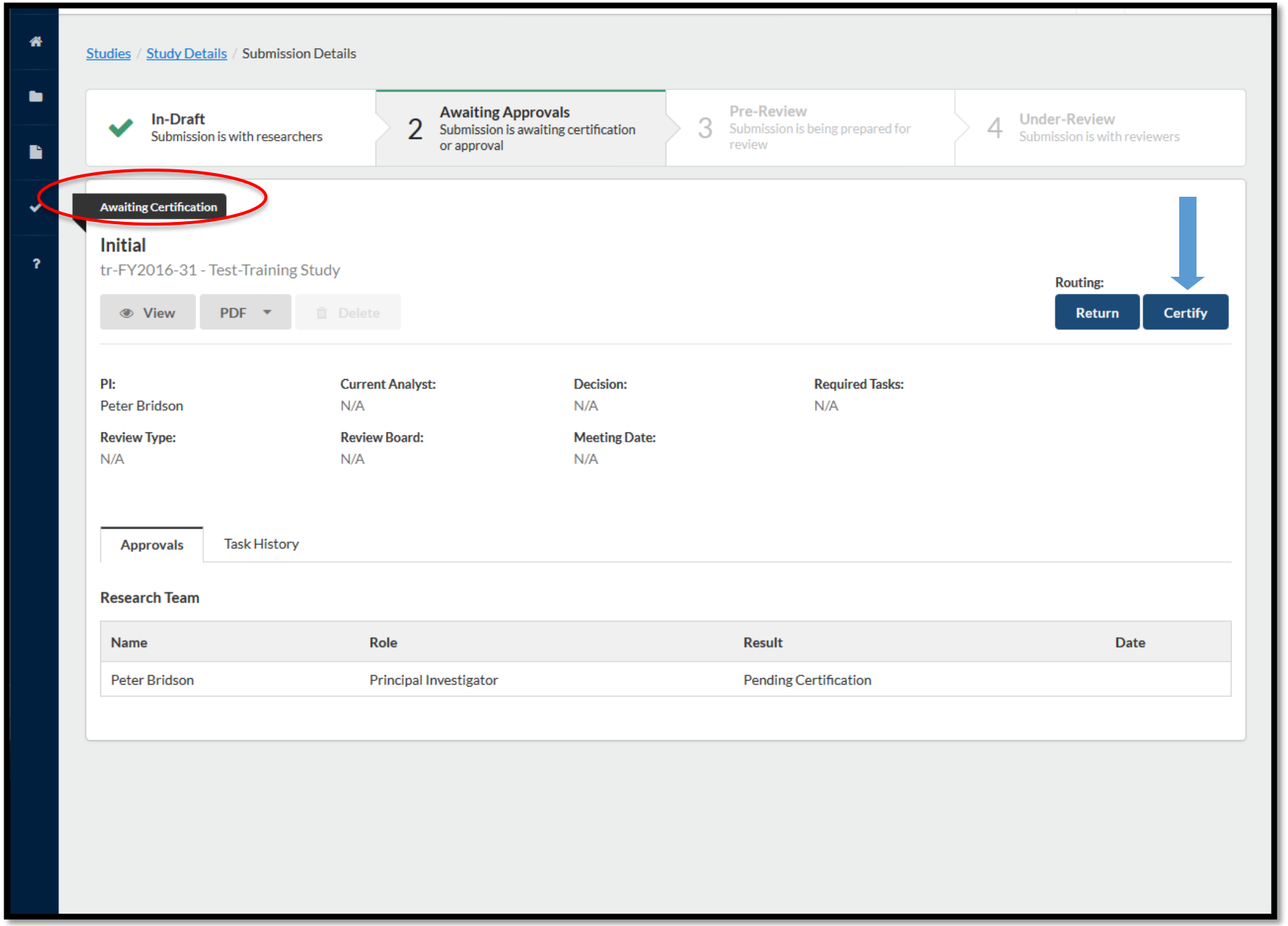


Certifying Your Determination Submission

After you have successfully submitted your determination, you will be returned to your Study's submission details page.

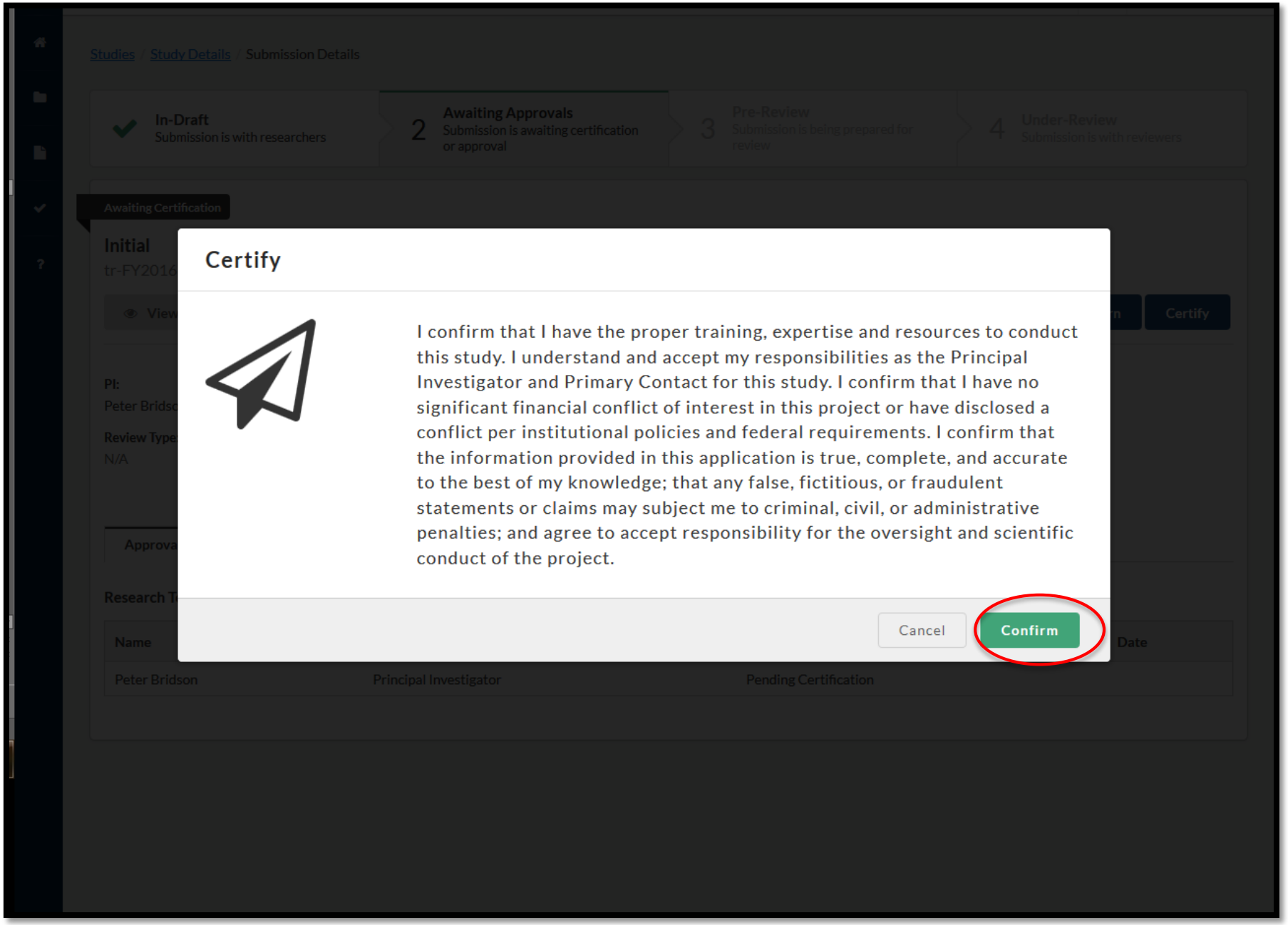
If you are NOT a student, select Certify to proceed. Your Co-PIs will be instructed to also certify the submission

If you are a student you will certify your submission as well as your Faculty Advisor/Co-PIs.



Certifying Your Determination Submission (continued)

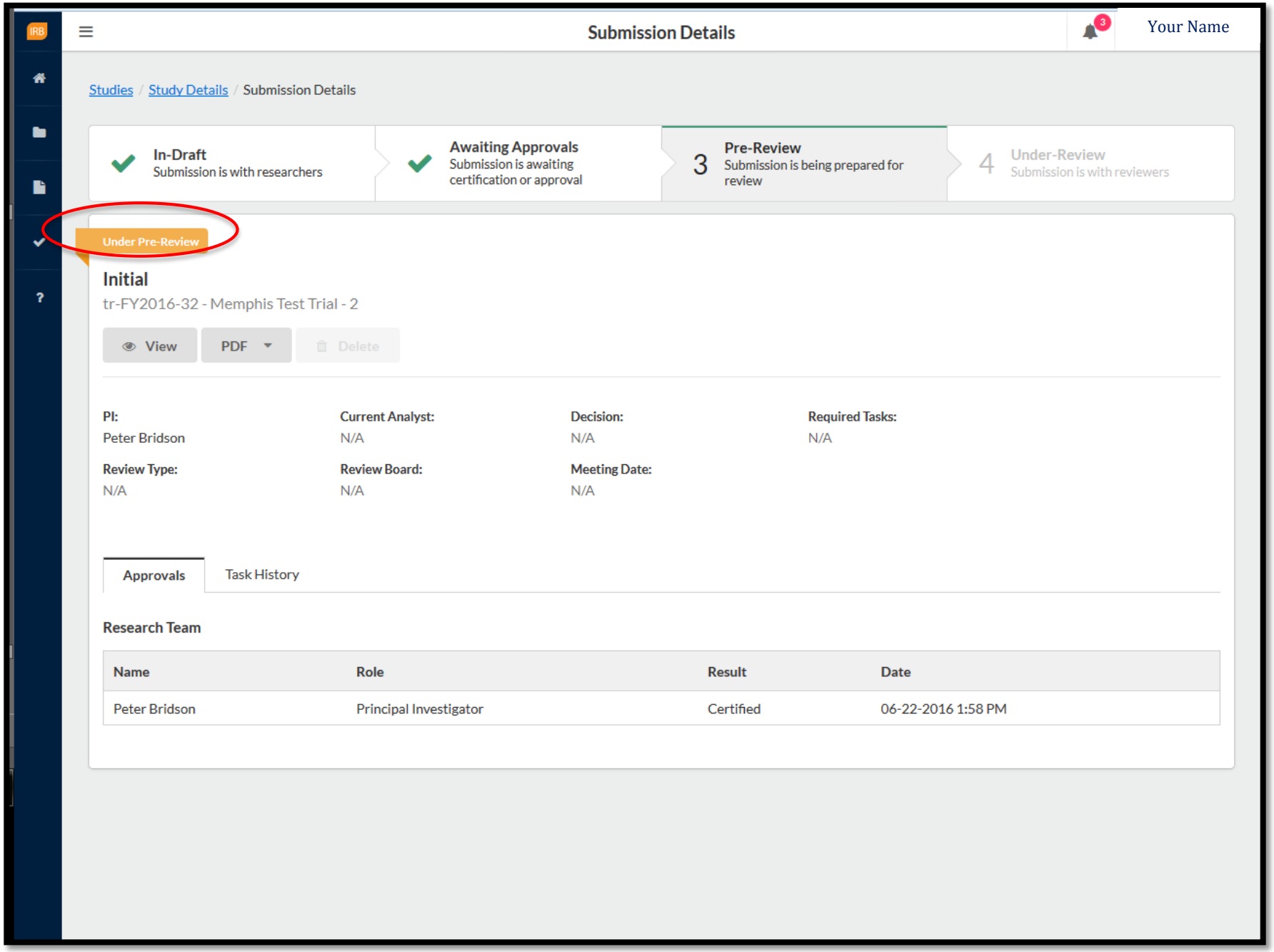
Read the entire **Certify** statement before selecting **Confirm** to go to the next step.



Under Pre-Review

At this point in the submission process, your Study's Submission is **Under Pre-Review.**

This means that the IRB Analyst is reviewing your study, ensuring your completed all necessary steps so it can be determined as Human Subject Research or not.



Study Statuses

There are 11 different statuses that a study can be in:

Approved - Study has been approved by the Compliance Office and/or Review Board.

Closed - Study is no longer in progress.

Disapproved - After being reviewed, the study was not approved by the Compliance Office/review board.

Expired - The study has passed its expiration date without being renewed.

Legacy - Optional status that can be used when importing legacy submissions, in place of "Approved".

Requires Changes - The Compliance Office has requested modifications to the study in order for it to be approved.

Submitted - The PI has sent a submission to the Compliance Office and it is awaiting review.

Suspended - Used when an incident has occurred to place the study on hold until further notice. The research team must submit a modification in order to remove the suspension.

Under Review - The Compliance Office and/or Review Board is currently reviewing the study.

Unsubmitted - The study has not yet been sent to the Compliance Office for review.

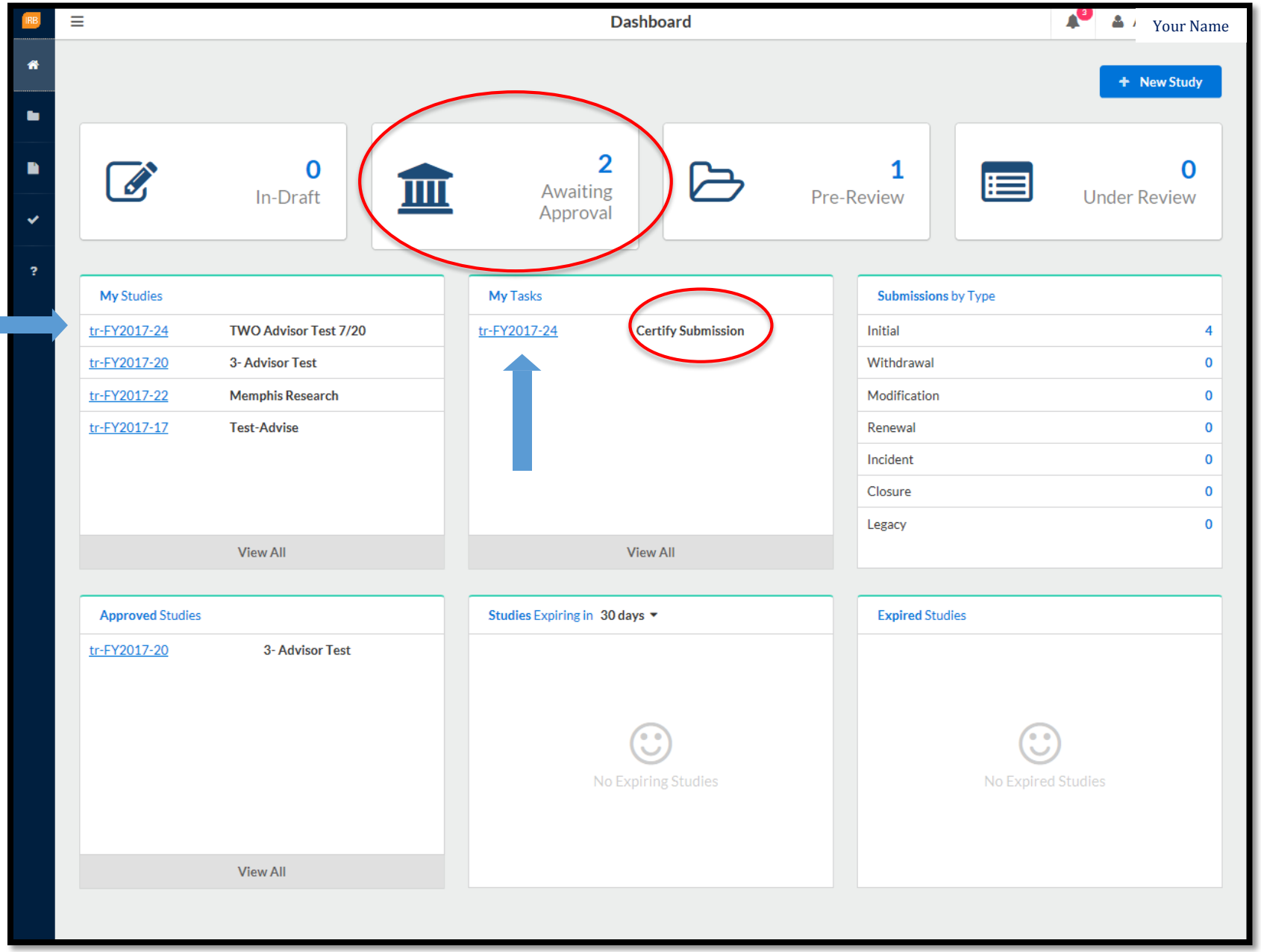
Withdrawn - The research team has submitted a withdrawal for this study and no longer wishes to pursue it.

Reviewing & Certifying the Submission (Advisor)

Reviewing & Certifying the Submission (Advisor)

Advisors and Co-PIs, when you log in, you may have the responsibility of reviewing and CERTIFYING your students' submission.

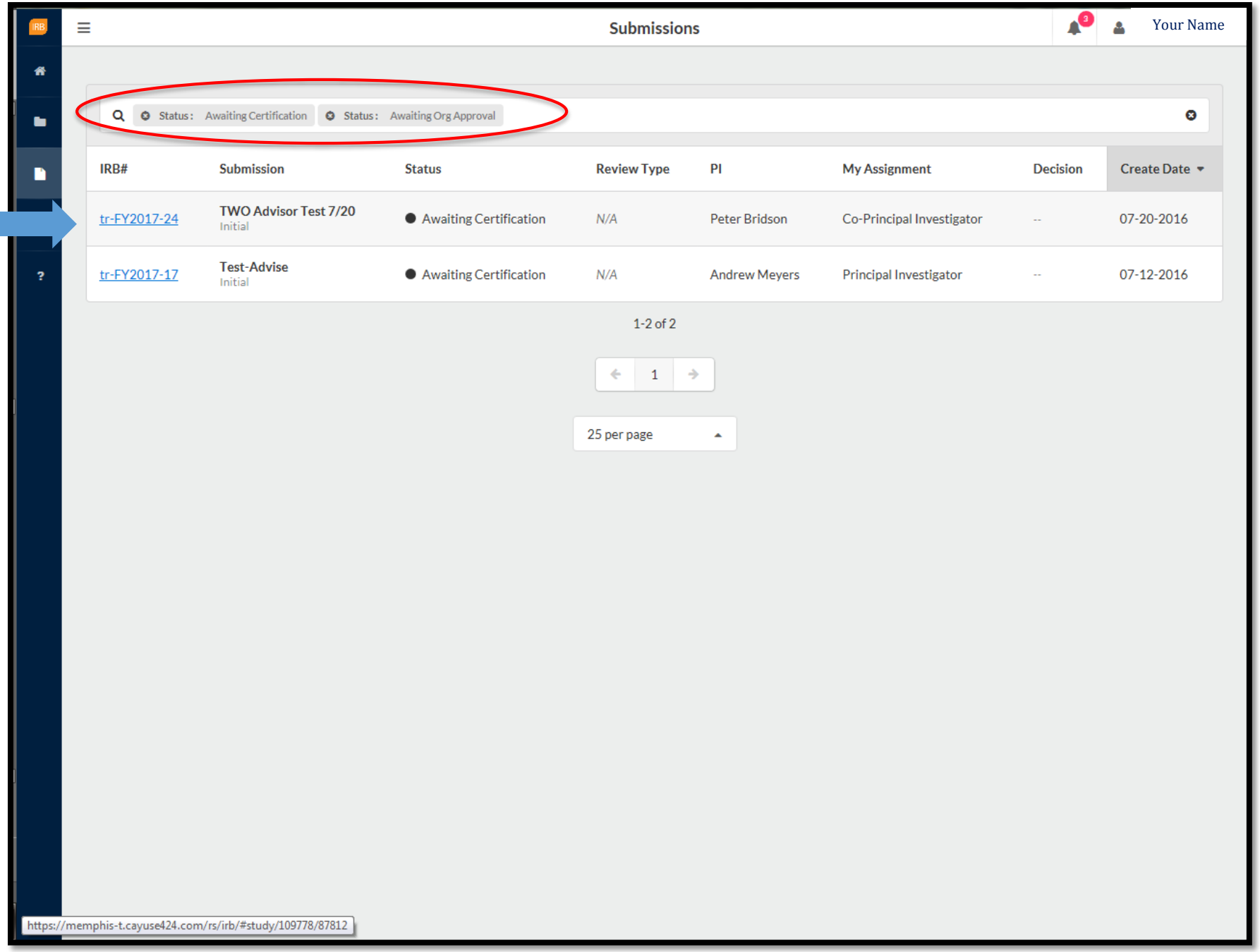
Submissions will be under Awaiting Approval. You will also see the study, awaiting certification, under My Tasks and My Studies.



Reviewing & Certifying the Submission (Advisor) continued

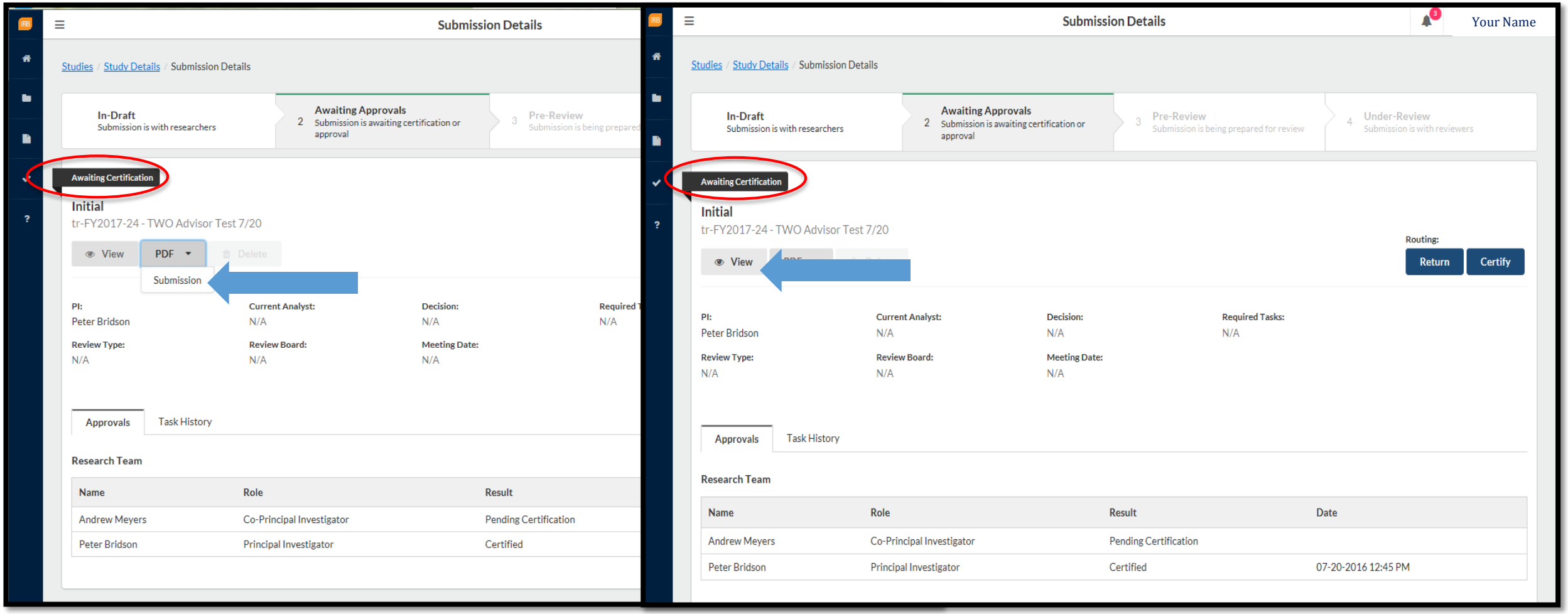
If you selected Awaiting Approval, you arrive to the page where all of the submissions listed are awaiting your review and certification.

Click on the study/submission.



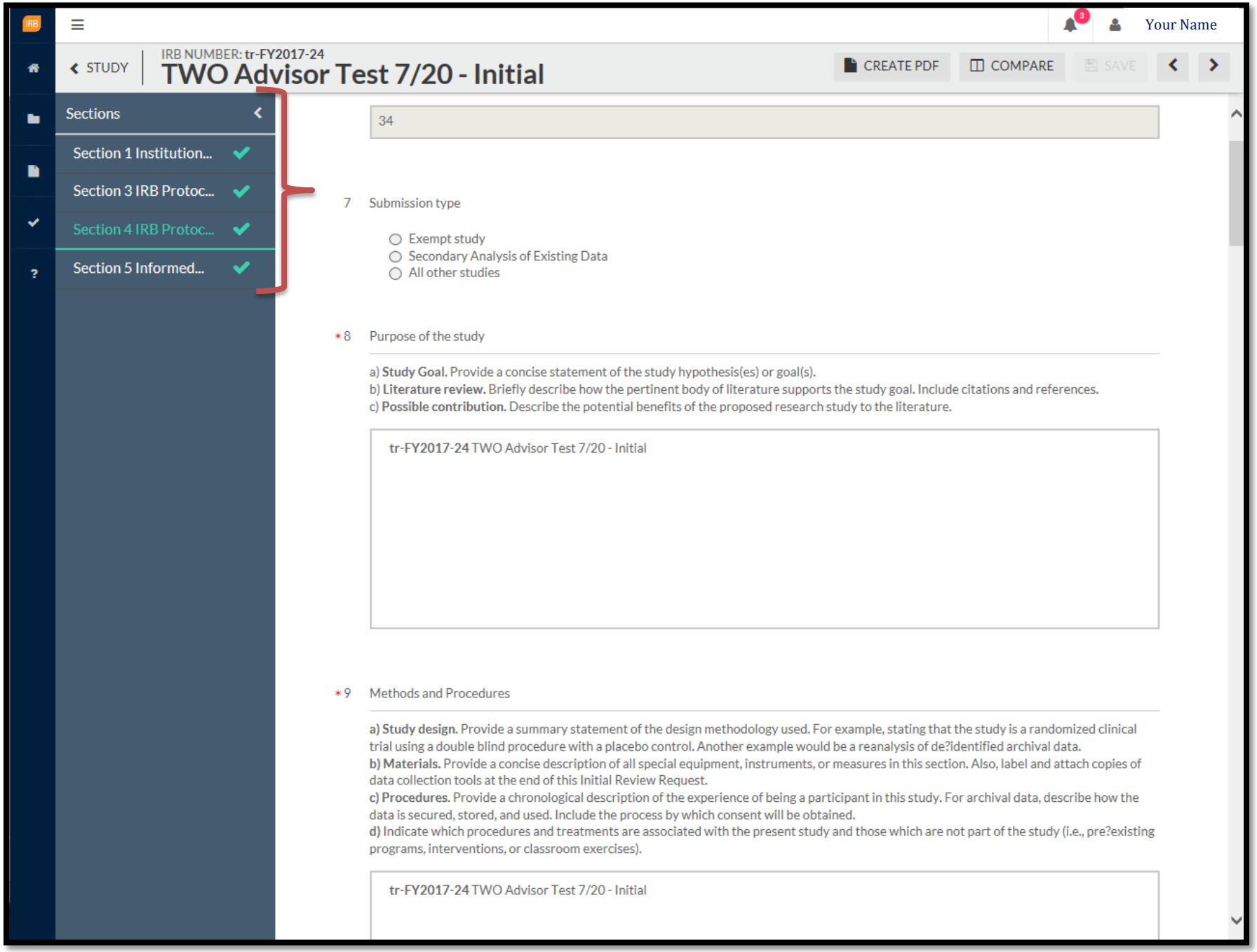
Reviewing & Certifying the Submission (Advisor) continued

As you can see, the status of the submission is Awaiting Certification. To begin reviewing students' study submission, you can either click on View or review a PDF version of the Submission.



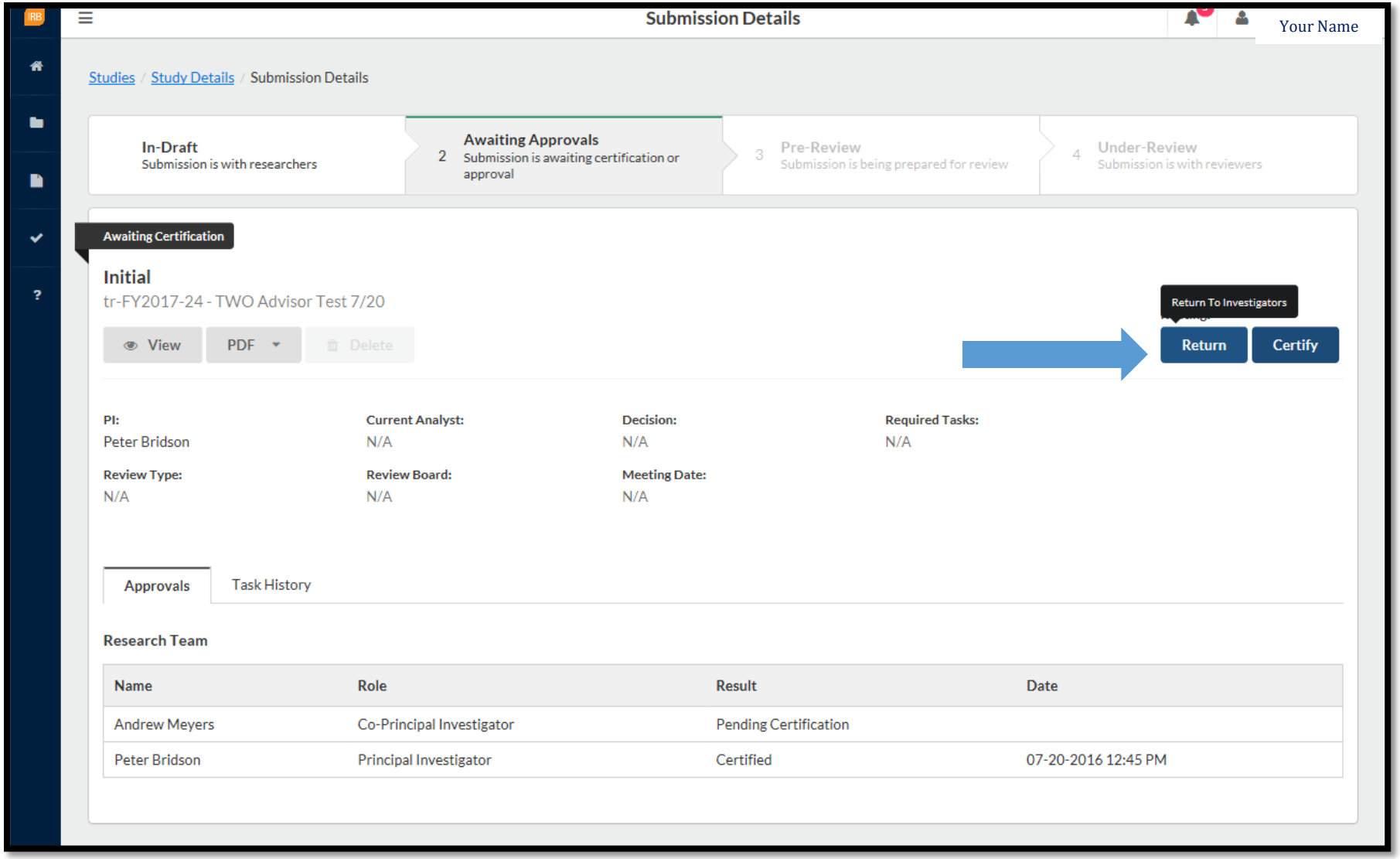
Reviewing & Certifying the Submission (Advisor) continued

Please thoroughly review students' study by clicking on each section. Take any notes regarding discrepancies and/or issues that you have found, so you can discuss this with your student(s) later.



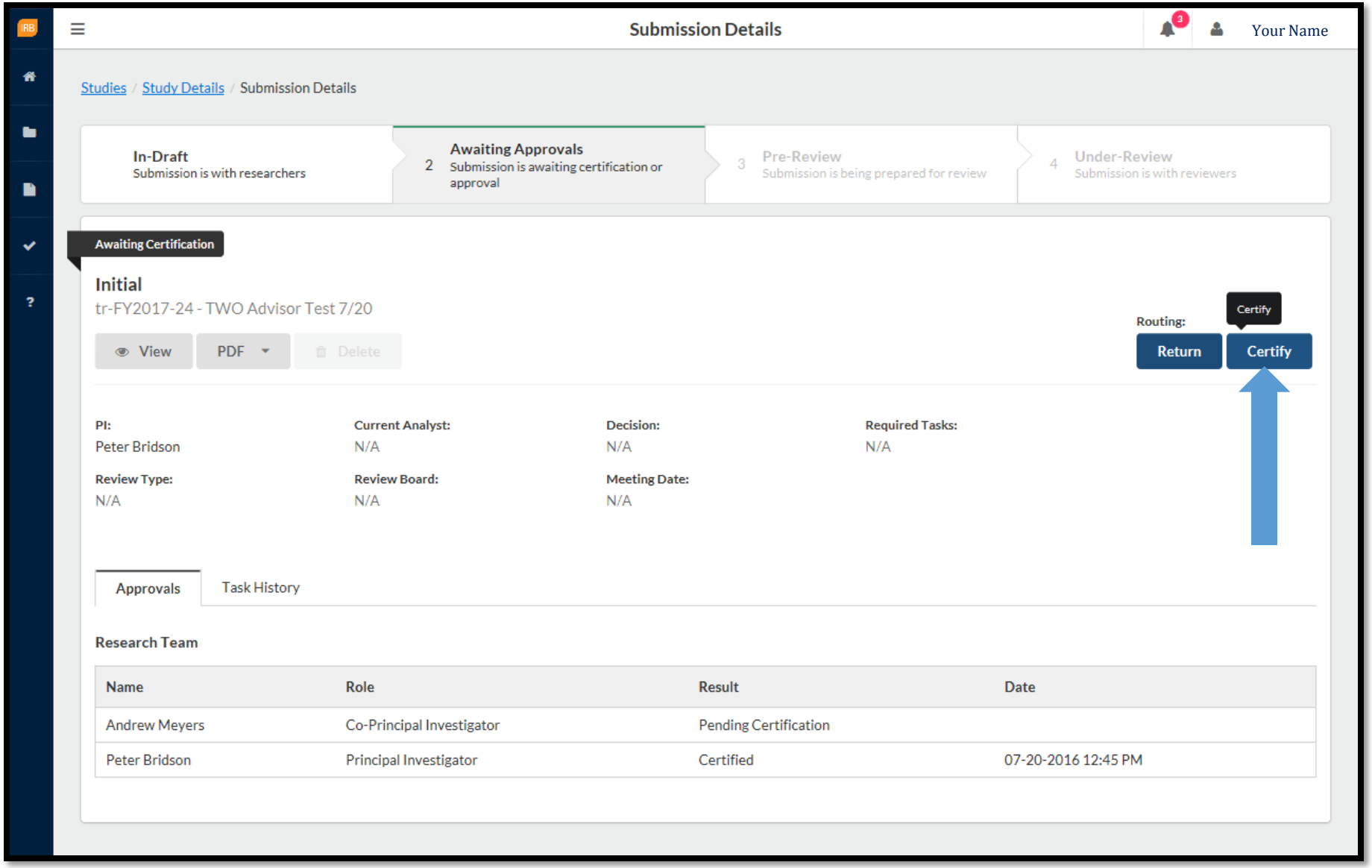
Reviewing & Certifying the Submission (Advisor) continued

If you have found discrepancies and/or issues with the students' study submission, you can Return to that student and discuss your issues with them so they can correct any issues. When the student correct those issues, it will be rerouted to you again, where you will have to review it and certify it, if the submission is satisfactory.



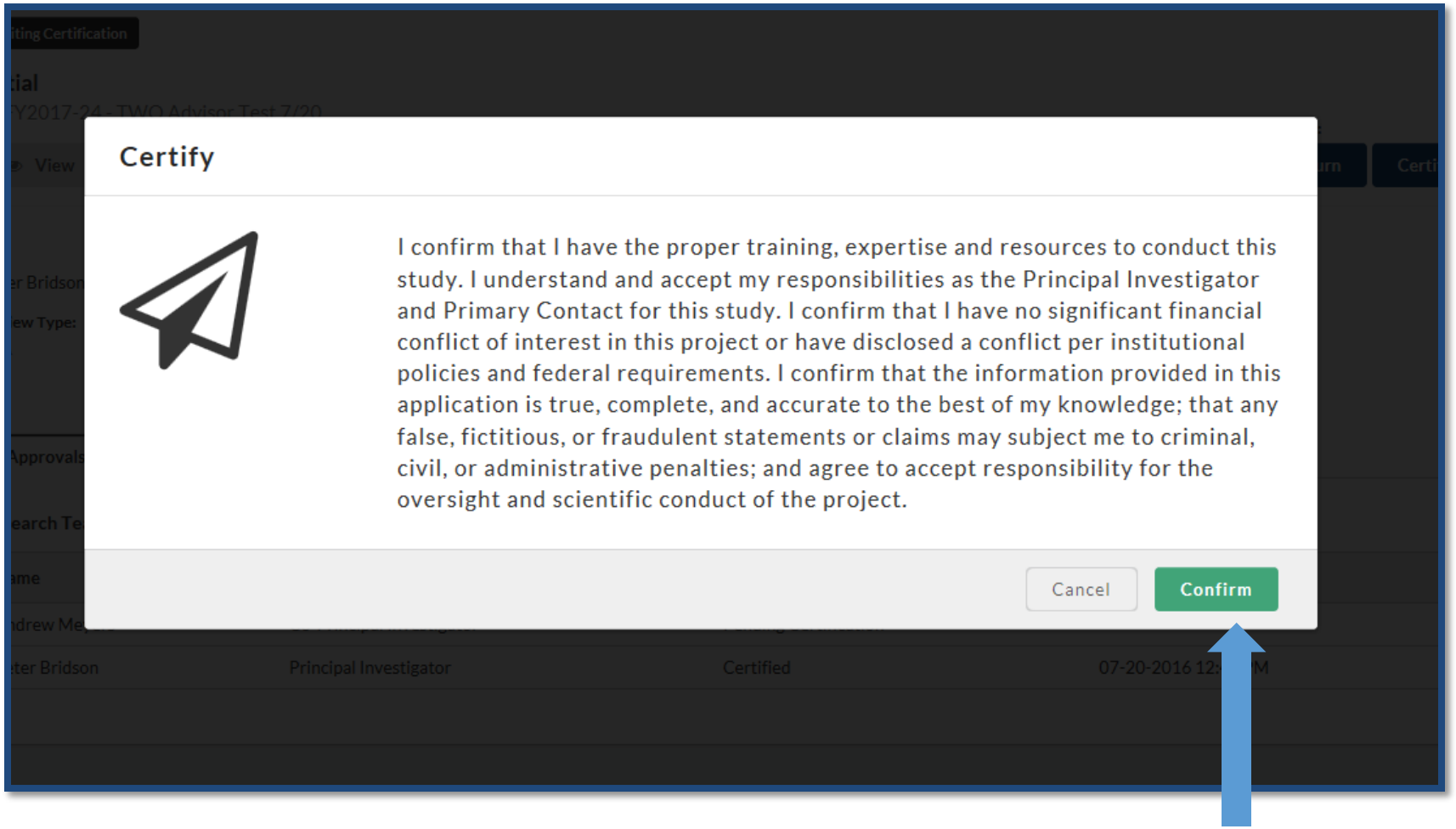
Reviewing & Certifying the Submission (Advisor) continued

If you found the submission satisfactory and feel that is read to proceed to the IRB Analyst, select Certify.



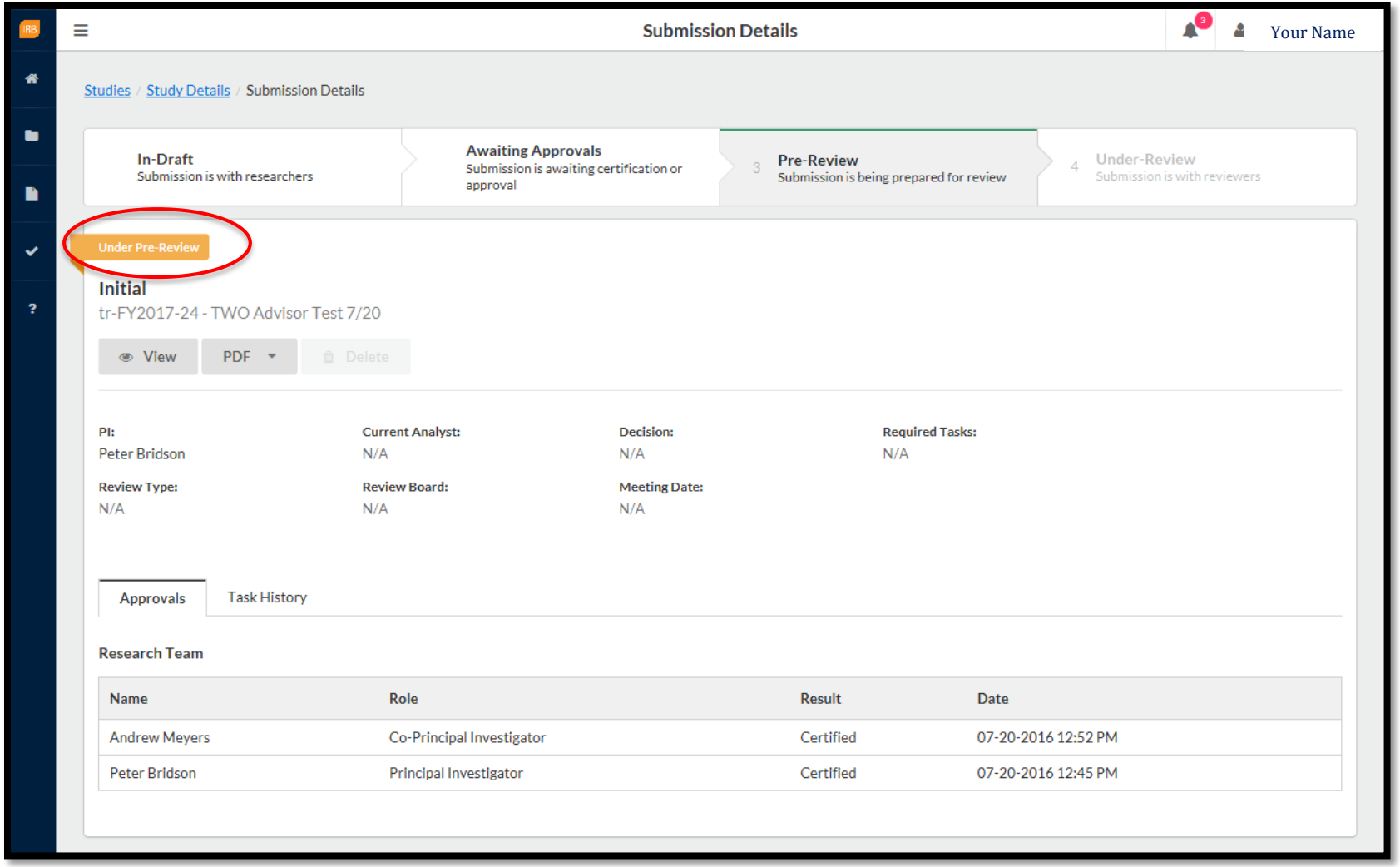
Reviewing & Certifying the Submission (Advisor) continued

Select read the Certify statement and Confirm to proceed.



Reviewing & Certifying the Submission (Advisor) continued

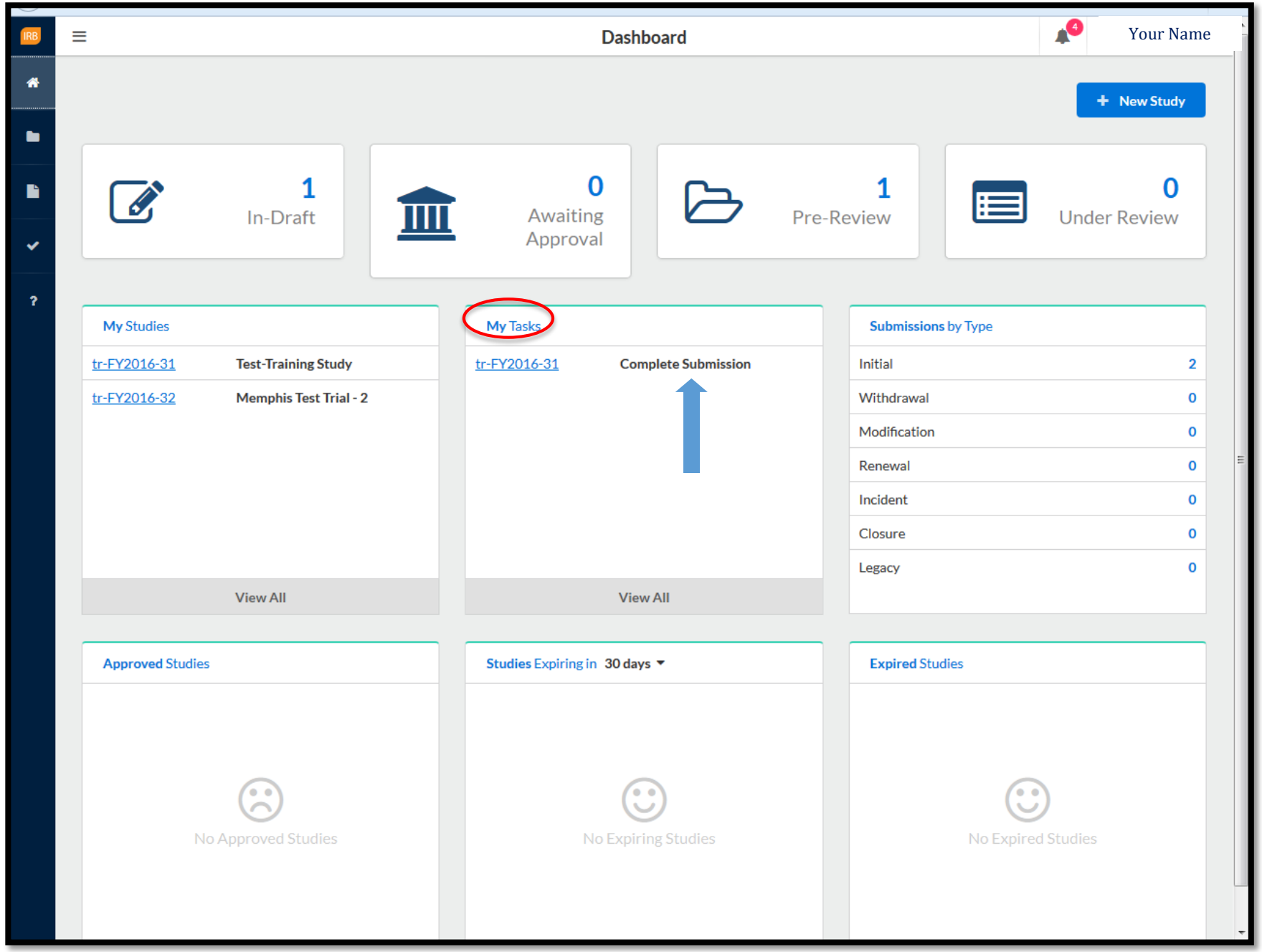
Once you have successfully certified the students' study submission, it is now Under Pre-Review, meaning it is with the IRB Analyst.



Addressing Feedback & Contingencies

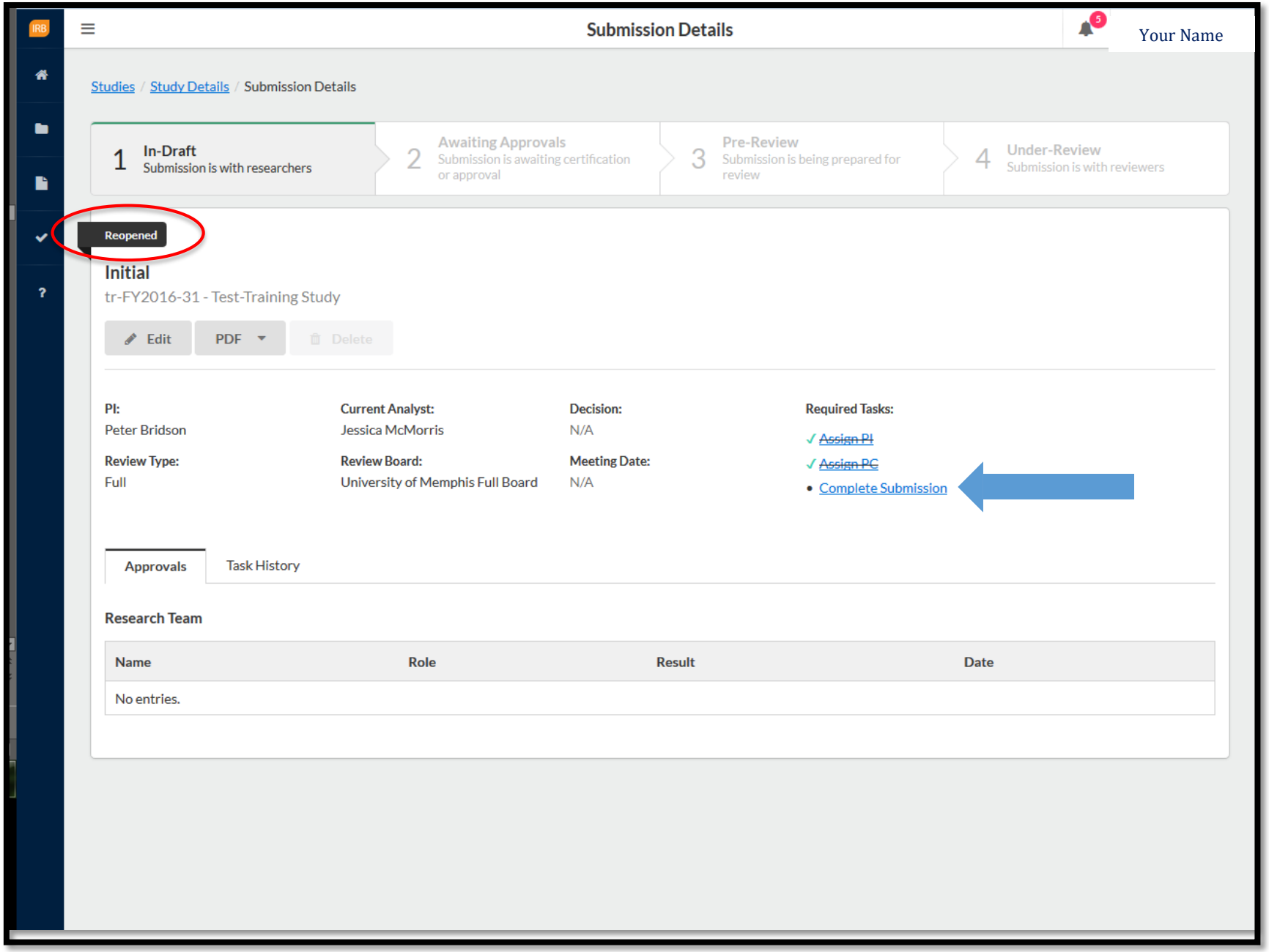
Your submission has been reviewed by an analyst and/or the reviewer and they either need more information so they can make a decision regarding your study.

Go to your dashboard to and you will see the feedback, if any, under My Tasks. Select the study.



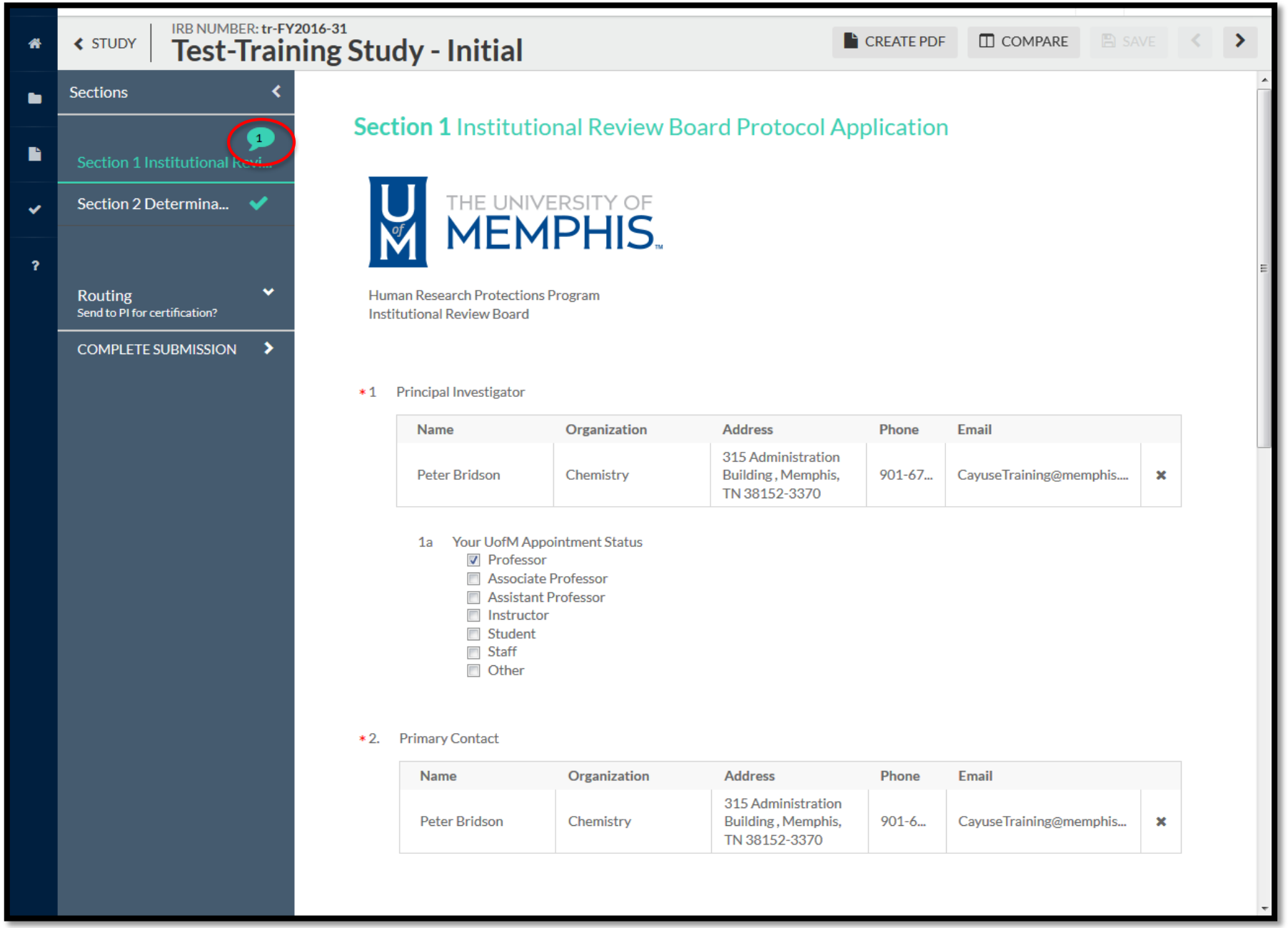
Once you click on the study, you will arrive to the Study's **Submission Details**. As you can see the current status of the submission is **Reopened**.

To begin editing your protocol/submission, select **Complete Submission**.



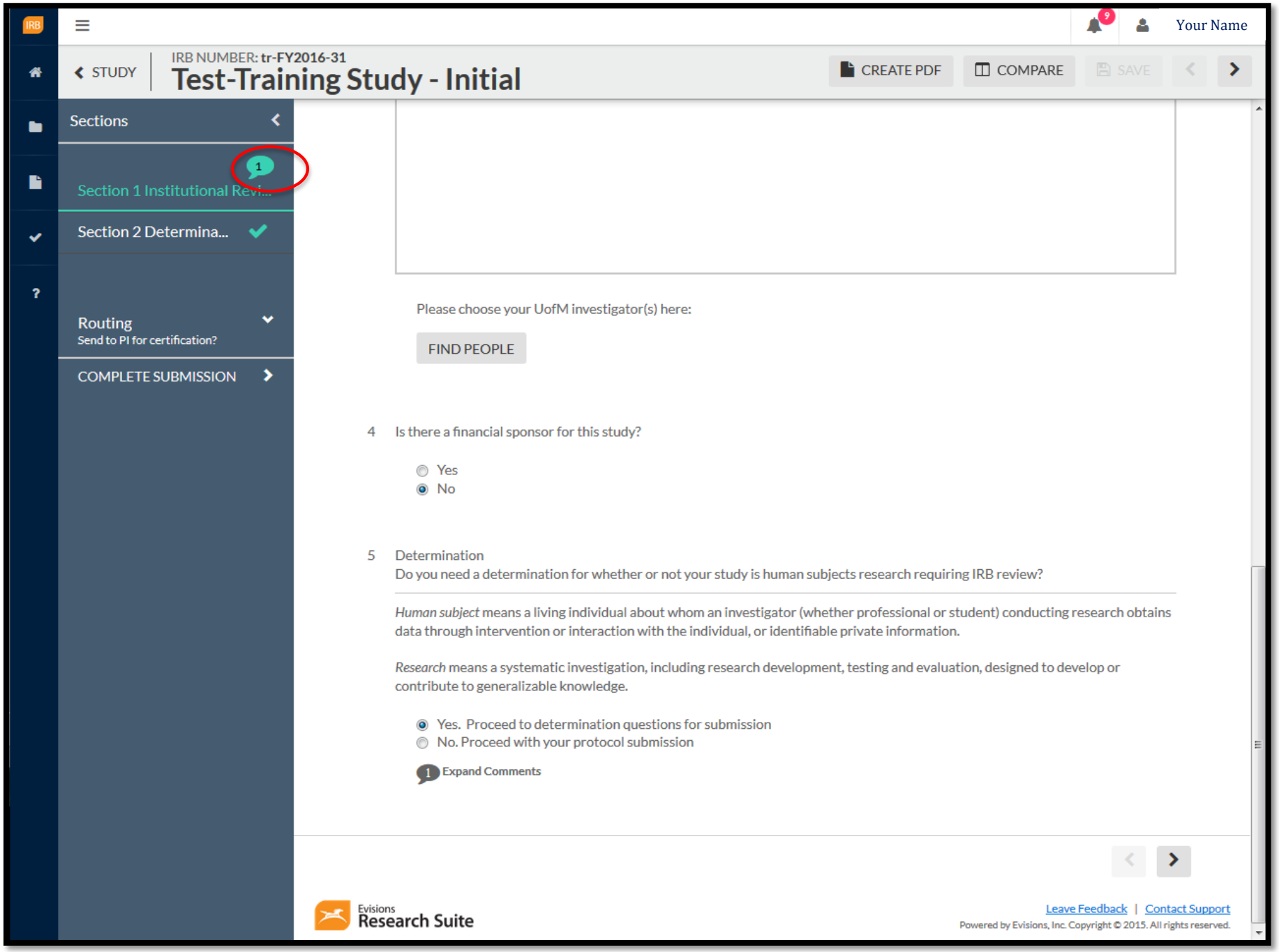
Reading/Addressing Feedback & Comments

You will arrive to your Initial submission. You will see the comment bubble in the Sections tab. Go to the section where the bubble is located.



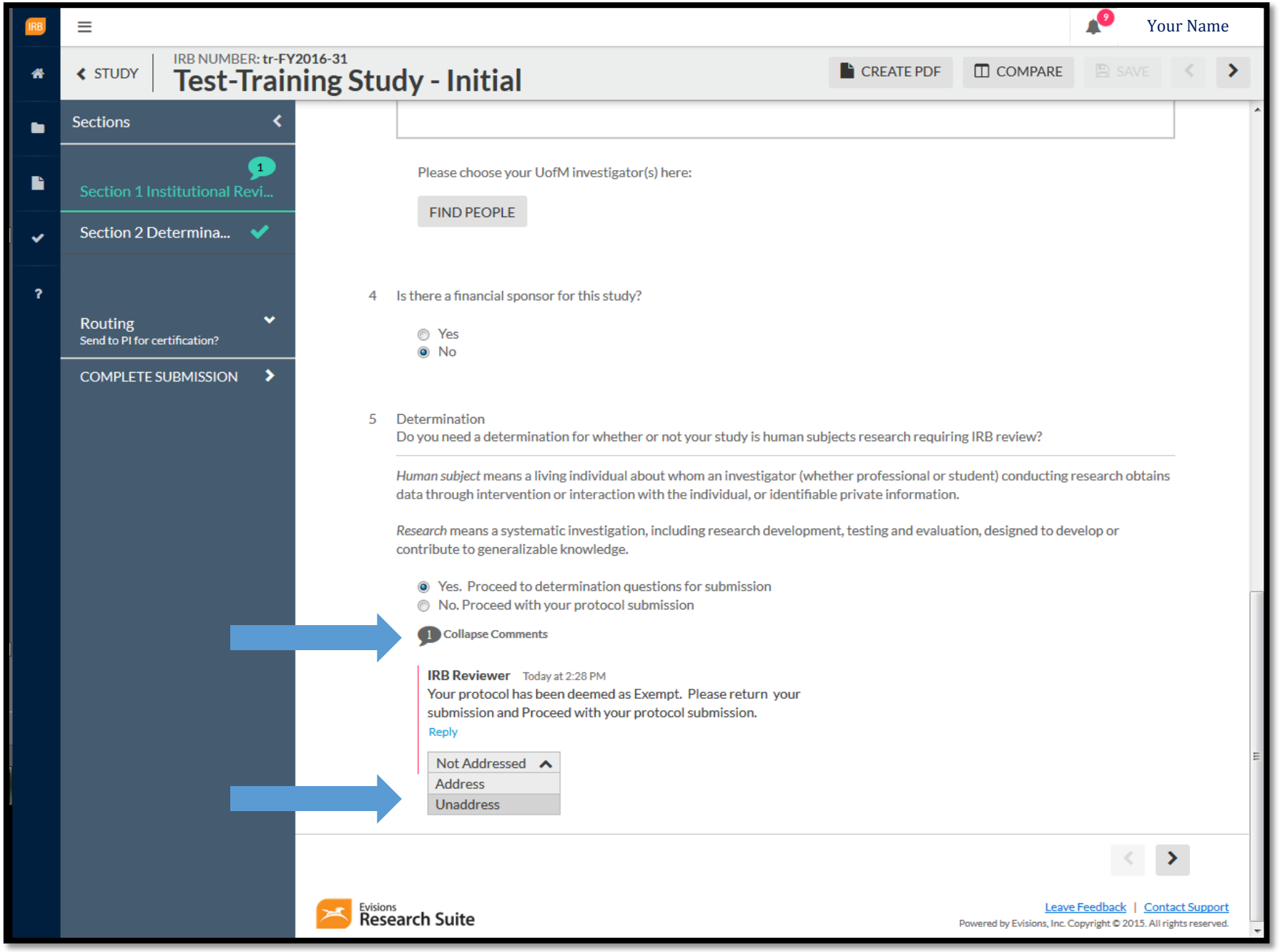
Addressing Comments

Once there, you will see where the feedback comment is located. Click Expand Comments.



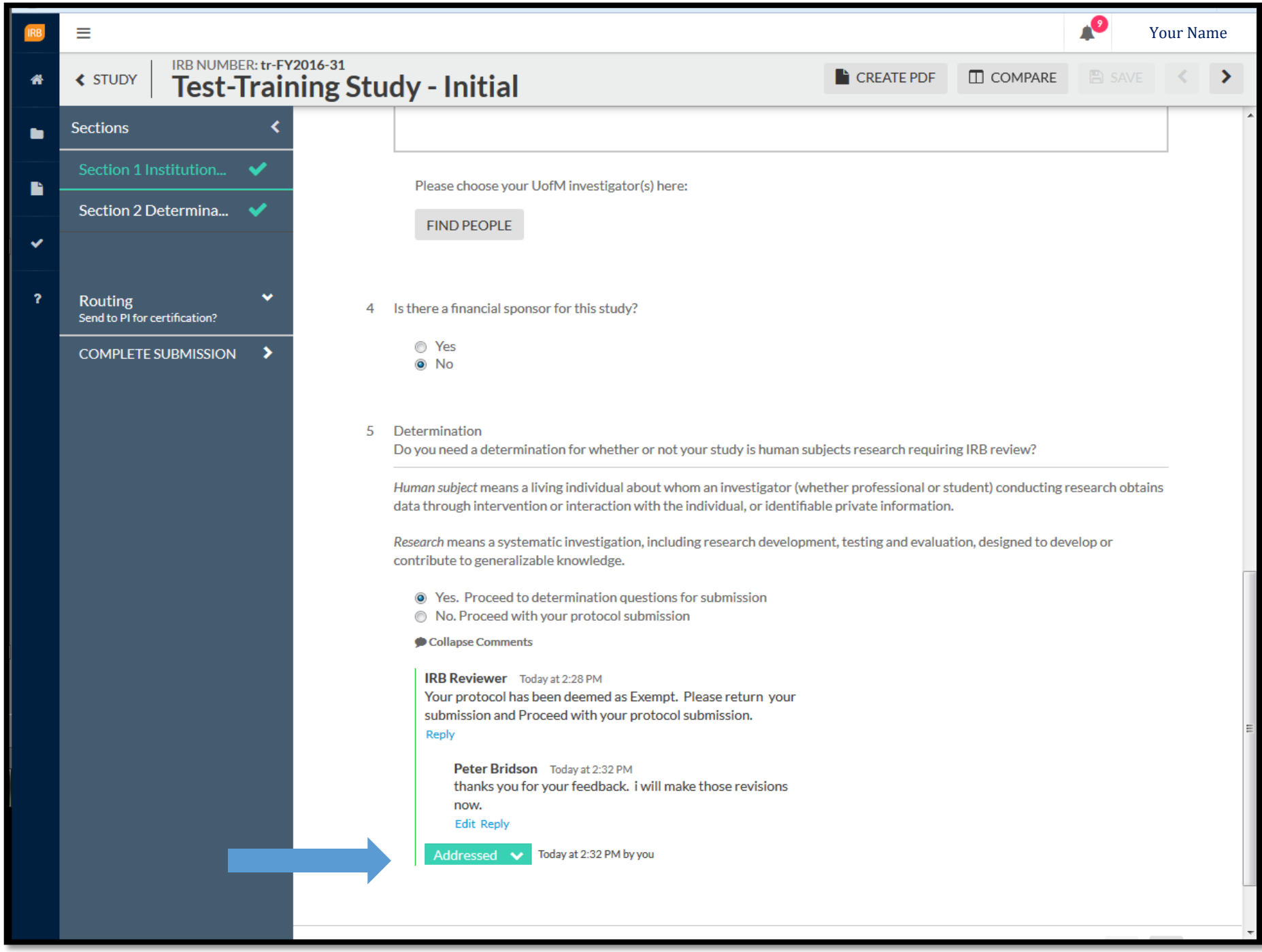
Addressing Comments (continued)

Once you have expanded the feedback comment, you will be able to address it, including making any changes asked of you.

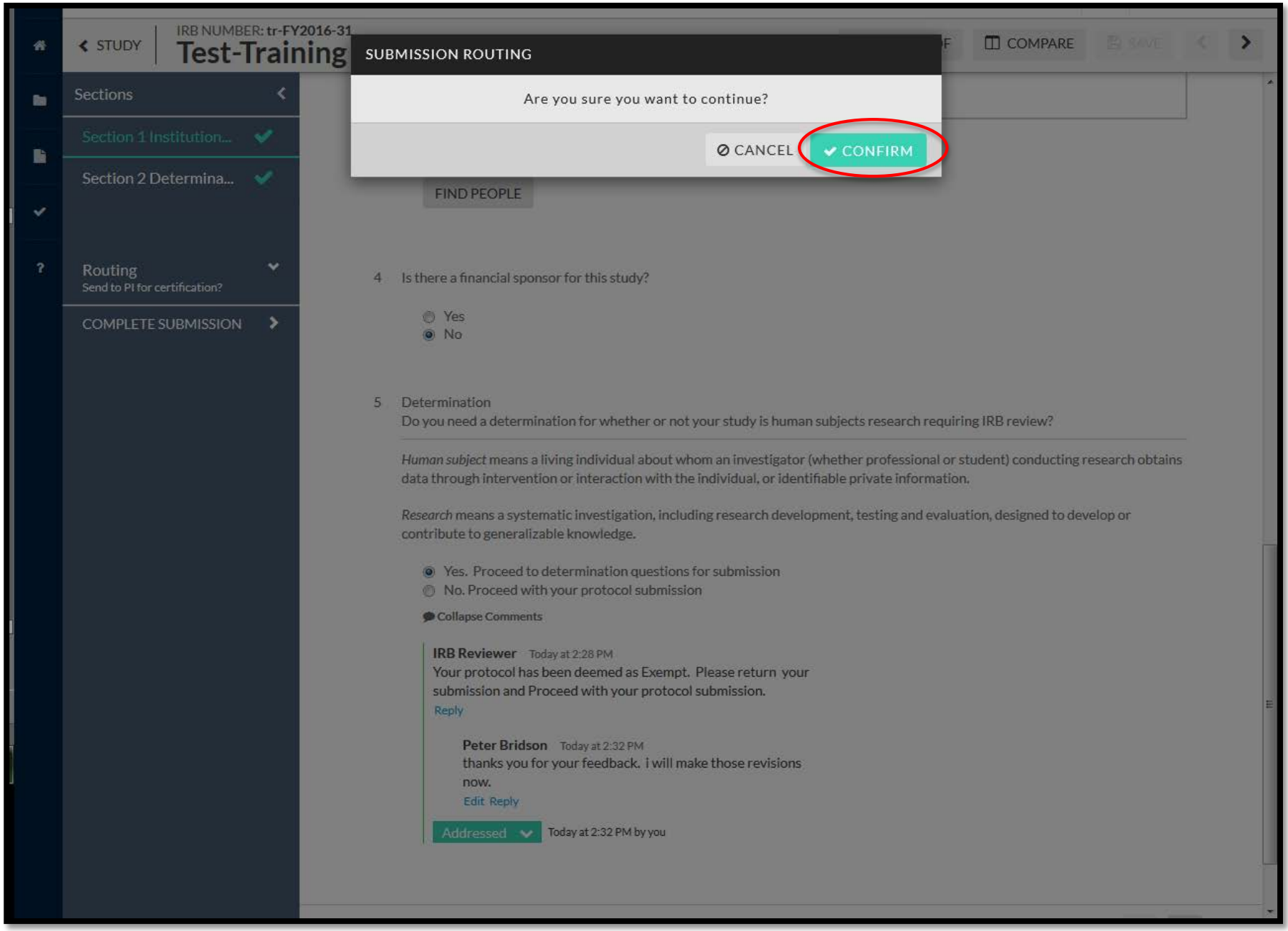


Addressing Comments (continued)

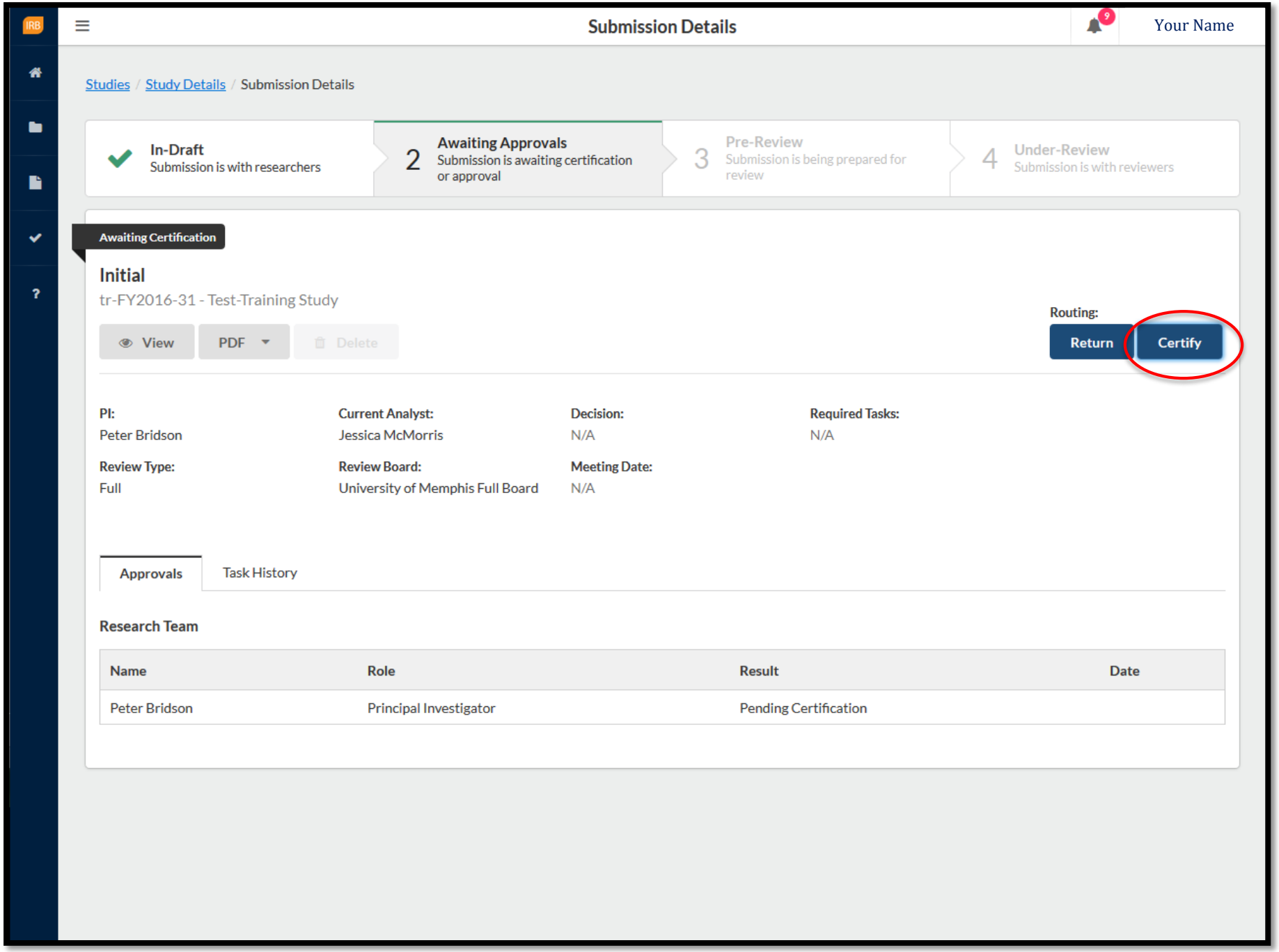
Once you have made your edits and addressed the feedback comment, the comment status will be changed to **Addressed**.



After you have addressed the feedback and made all necessary changes, click **COMPLETE SUBMISSION** and **CONFIRM** to proceed to rerouting your submission back to the IRB Analyst and Reviewer.

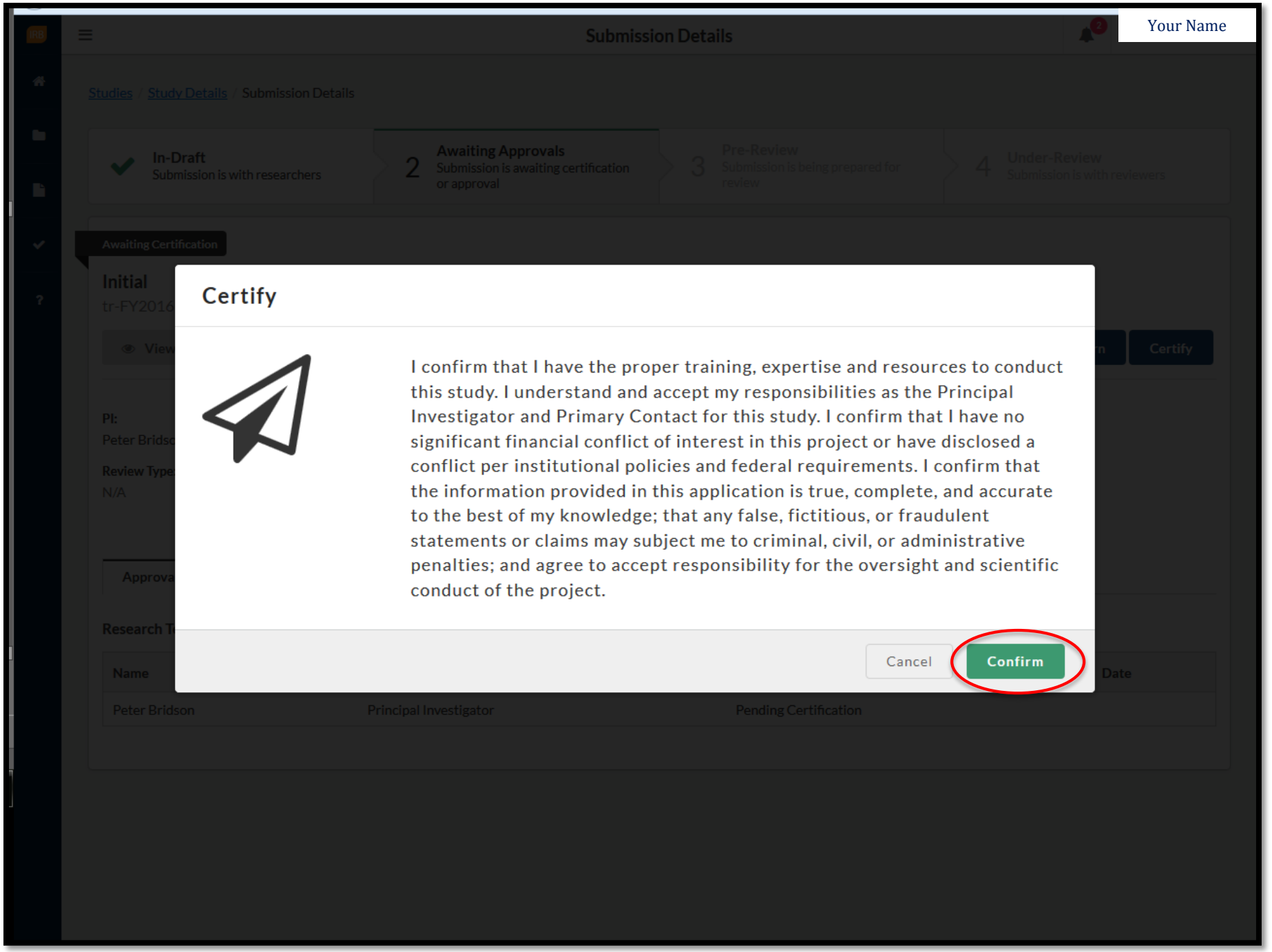


Once again, you will arrived to your study's **Submission Details** page. Select **Certify** to certify your changes. Remember, all individuals involved with this study, including your Advisor/Co-PIs, must also certify the study before it proceeds to the IRB Analyst.



Certifying Your Submission (continued)

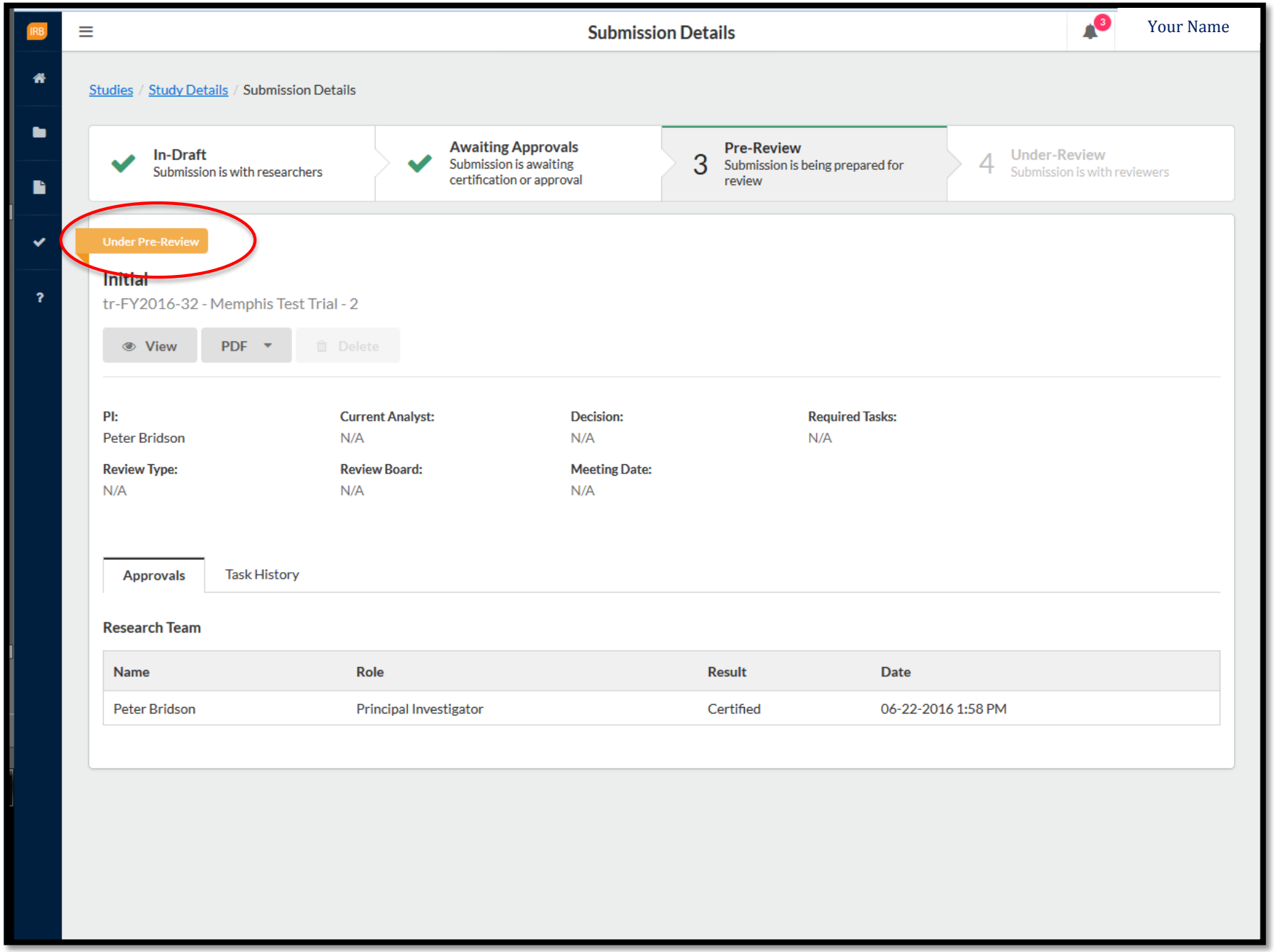
Read the entire **Certify** statement before selecting Confirm to go to the next step.



Under Pre-Review

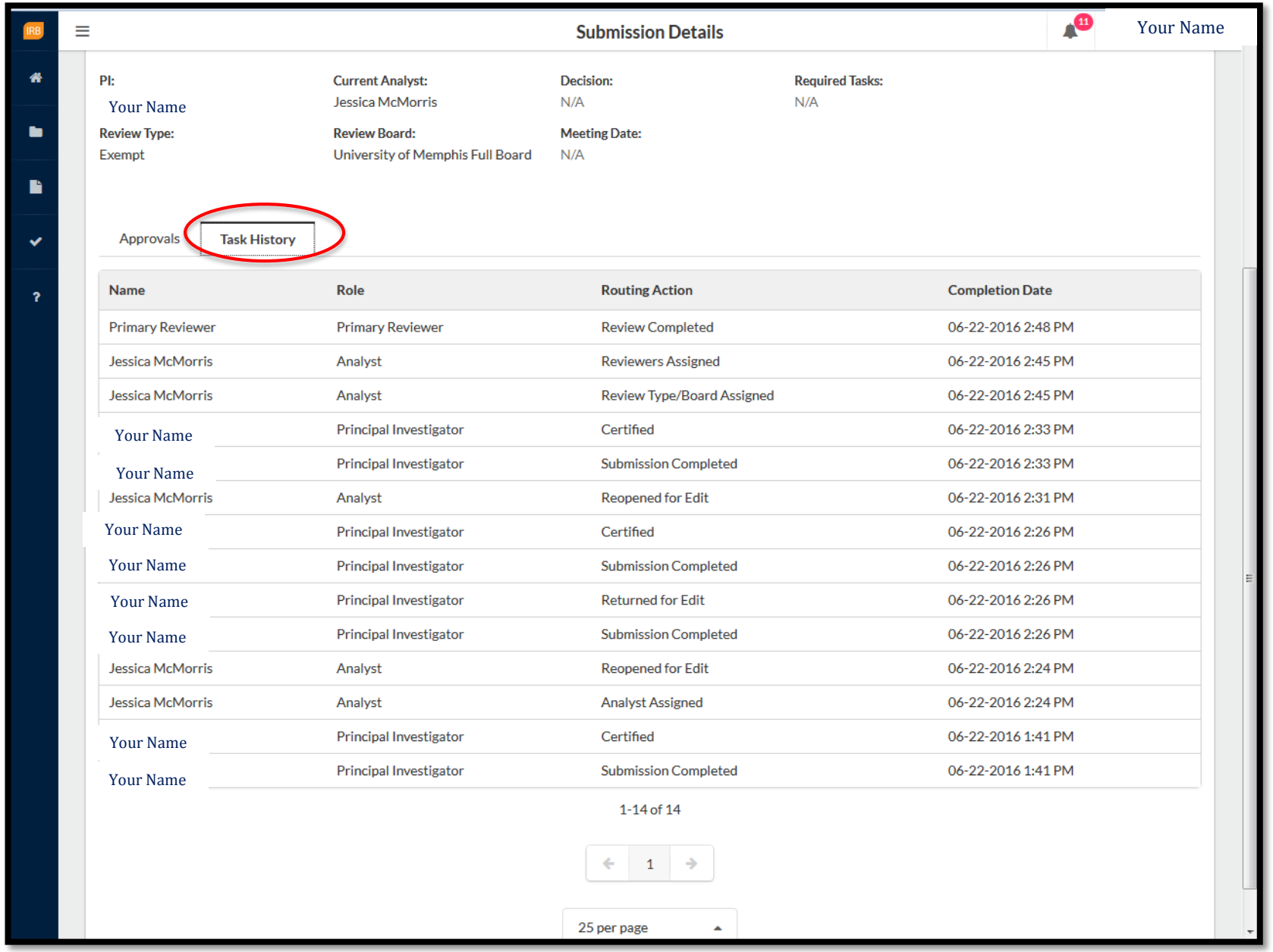
At this point in the submission process, your Study's Submission is **Under Pre-Review.**

This means that the IRB Analyst is reviewing your study, ensuring your completed all necessary steps so it can be determined as Human Subject Research or not.



Task History

Remember, you have 24/7 access to CayuseIRB and are able to see exactly what is going on with your Submission under **Task History** within your Study's Submission Details page.



Approval Letter

Once your study has been approved, you will receive a letter, emailed to you. The approval letter will include any details needed for your to begin your research.

THE UNIVERSITY OF MEMPHIS

Institutional Review Board
Office of Sponsored Programs
University of Memphis
315 Admin Bldg
Memphis, TN 38152-3370

Jun 22, 2016

PI Name: Your Name
Co-Investigators:
Advisor:
Submission Type: Initial
Title: Test-Training Study

Exempt Approval: Jun 22, 2016

Approval of this project is given with the following obligations:

1. When the project is finished or terminated, a completion form must be submitted.

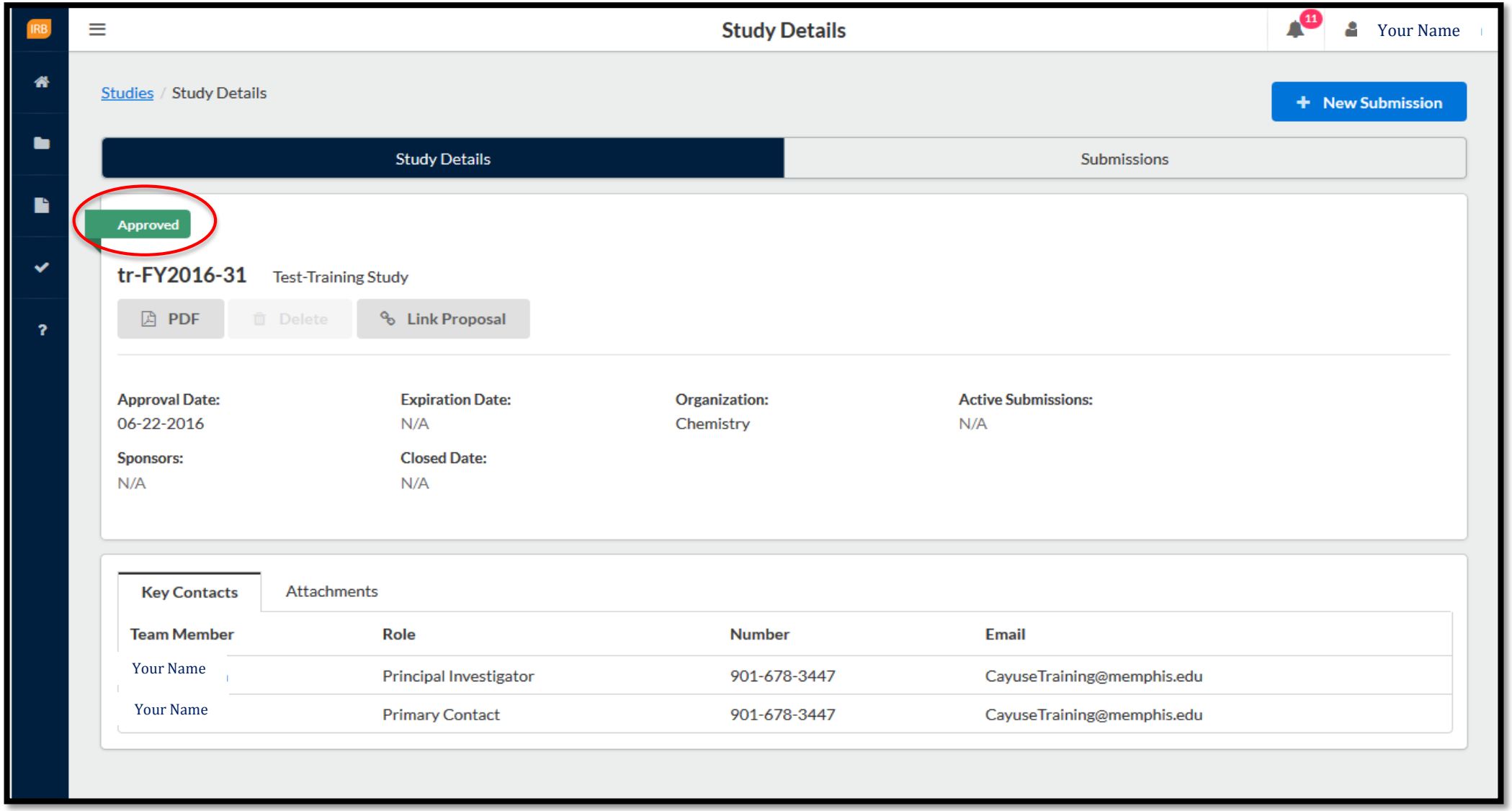
2. No change may be made in the approved protocol without prior board approval.

3. Exempt approval are considered to have no expiration date and no further review is necessary unless the protocol needs modification.

Thank you,

James P. Whelan, Ph.D.
Institutional Review Board Chair
The University of Memphis.

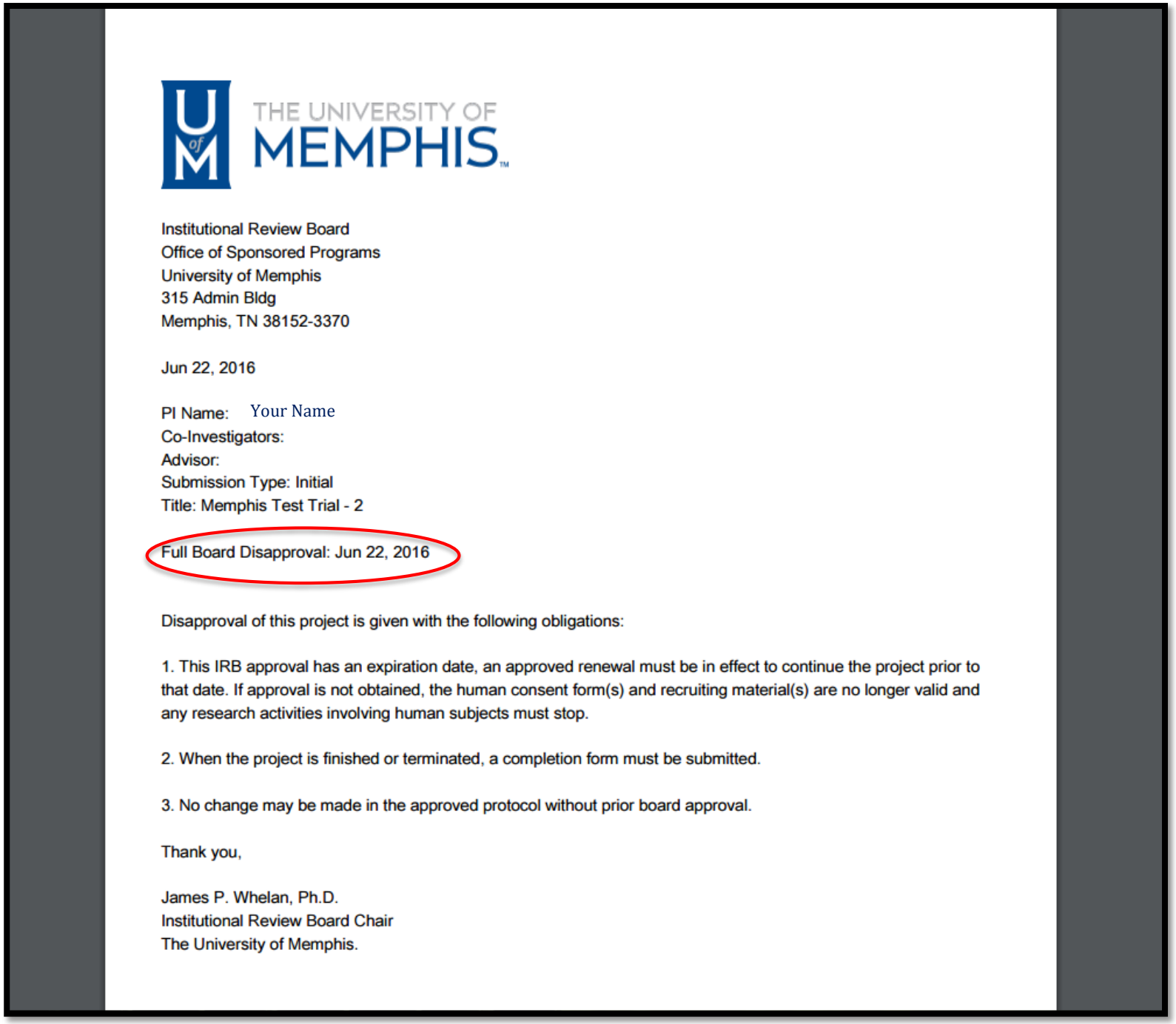
When you log back in to CayuseIRB, you will notice that the study's status has changed from **Under Review** to **Approved**.



Disapproval

Disapproval Letter

If your study has been disapproved, you will receive a letter, emailed to you. The disapproval letter will include all details as to why your study was disapproved.



THE UNIVERSITY OF MEMPHIS

Institutional Review Board
Office of Sponsored Programs
University of Memphis
315 Admin Bldg
Memphis, TN 38152-3370

Jun 22, 2016

PI Name: Your Name
Co-Investigators:
Advisor:
Submission Type: Initial
Title: Memphis Test Trial - 2

Full Board Disapproval: Jun 22, 2016

Disapproval of this project is given with the following obligations:

1. This IRB approval has an expiration date, an approved renewal must be in effect to continue the project prior to that date. If approval is not obtained, the human consent form(s) and recruiting material(s) are no longer valid and any research activities involving human subjects must stop.

2. When the project is finished or terminated, a completion form must be submitted.

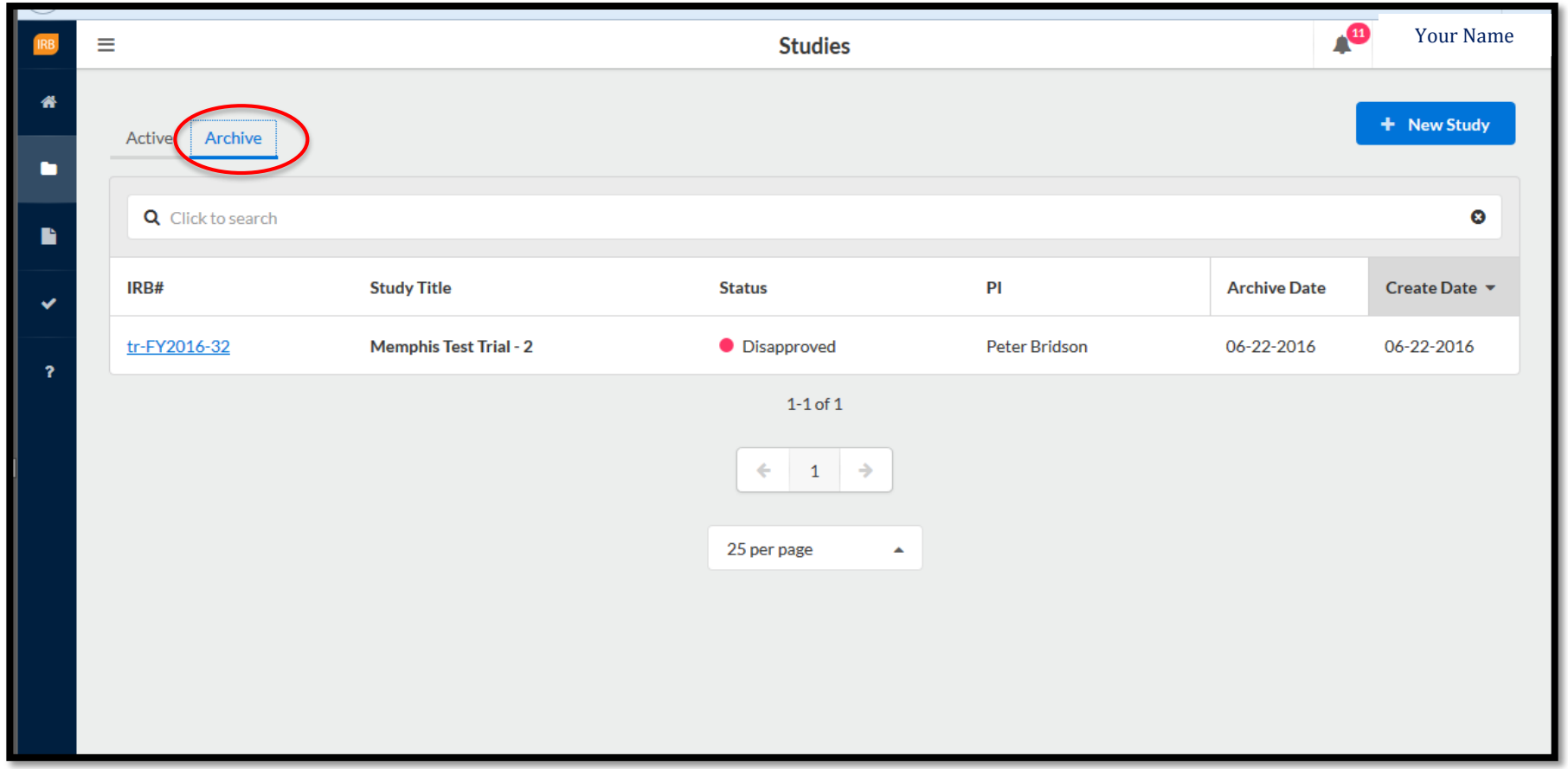
3. No change may be made in the approved protocol without prior board approval.

Thank you,

James P. Whelan, Ph.D.
Institutional Review Board Chair
The University of Memphis.

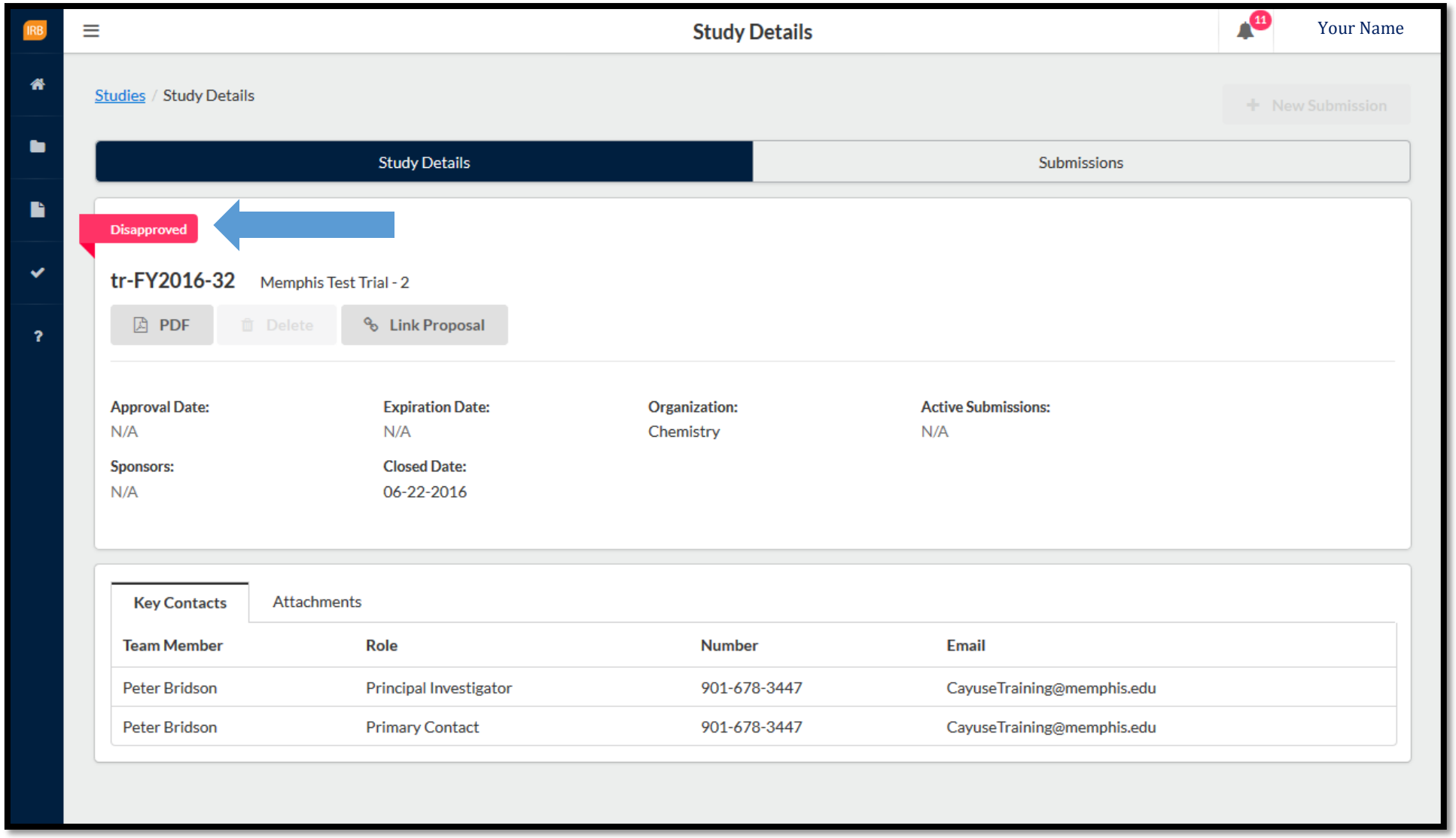
Disapproved Studies

When you log into CayuseIRB, your study's submission has been Disapproved, it will be located in the **Archive** section of Studies. Click the Folder Icon (Studies). Next, select Archive to see your Study. Click on the Study.



Disapproved Studies (continued)

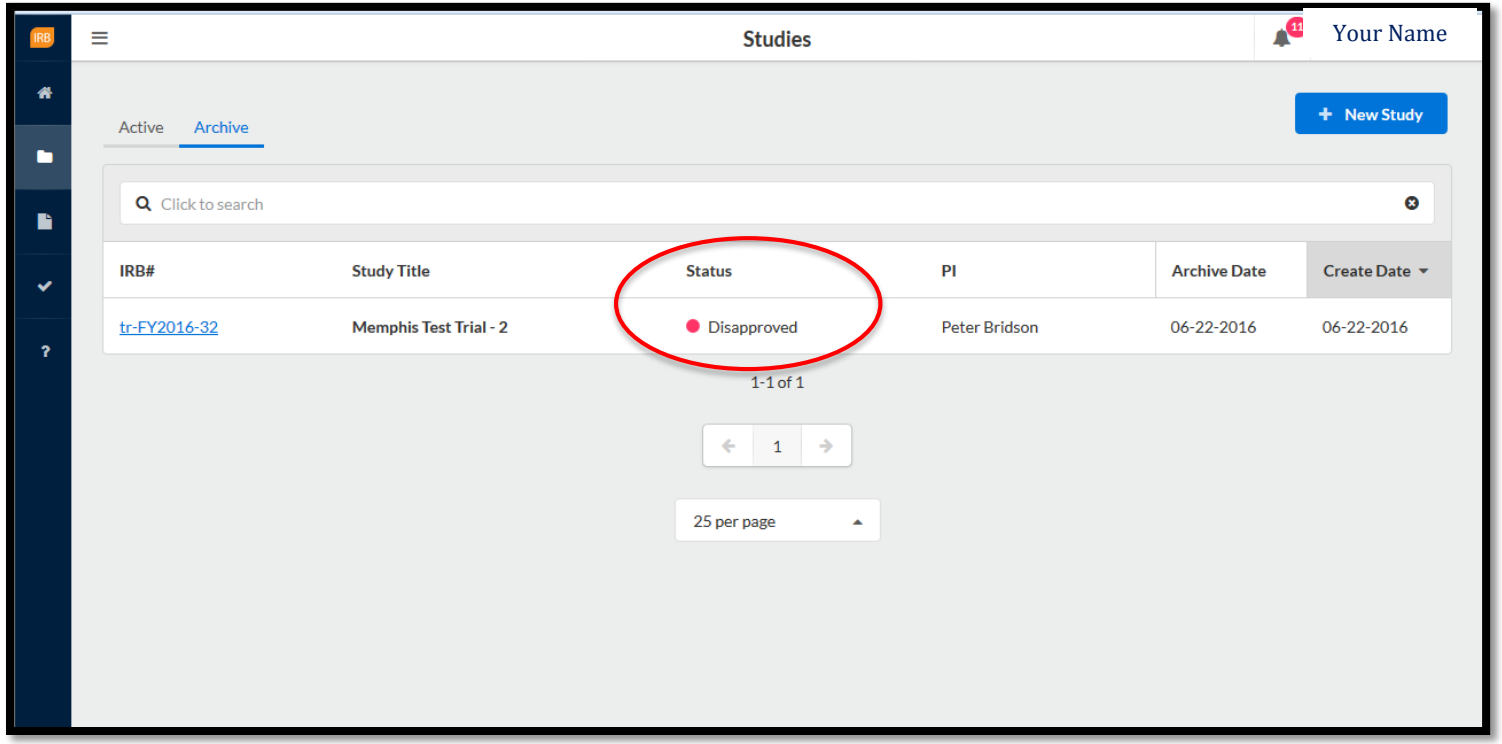
Your study, you will be able to see all the details of the Disapproved submission.



NOTE:

If you are planning to resubmit a disapproved study, you must submit the study as an original, **initial** submission.

The full board identified major issues with the study or submission and disapproved the research. In the case of a disapproved initial study, a new study and submission will need to be created. For disapproved renewal, modification, etc. submissions, the research team will need to create a new submission if they wish to proceed. The submission and/or study are disapproved and no longer editable. Disapproving an initial submission archives the study.



Renewals, Modifications, Incidents, & Closures

If your study has been approved, you have the option to do the following,

Initial - This is the first submission that you create when you enter a new study in the system. The initial submission describes the research you intend to do and the methodology you intend to use. The initial submission must be approved before any research can begin.

Modification - If you wish to change any of the details of the study after it has been approved, you must submit a modification which must be approved before you can proceed with the changes.

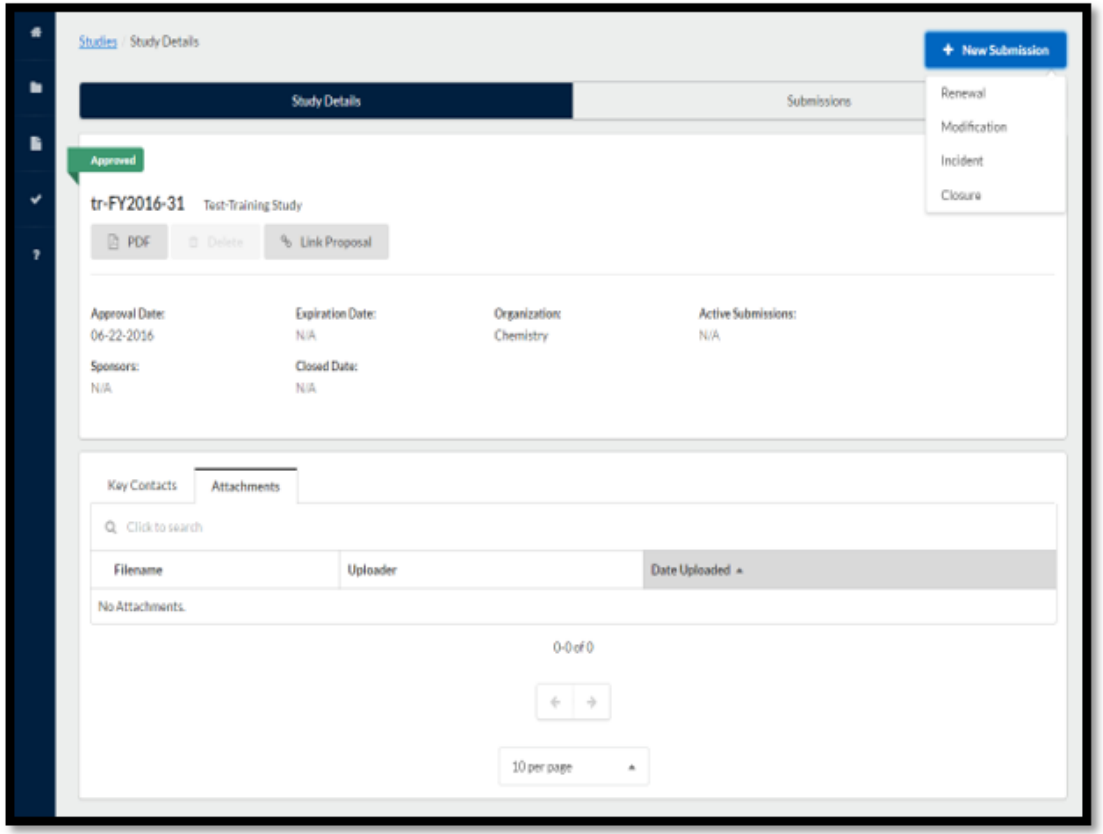
Renewal - When a study is nearing its expiration date, you must submit a renewal request in order to continue with the research. The renewal will need to be approved before you can continue with the study.

Incident - You must submit an incident report to inform the Compliance Office of any adverse incidents, as required by your institution. Incident reports may be submitted at any time after a study has been approved, including after it has been closed. More than one incident report may be created for a given study, as needed.

Withdrawal - A withdrawal submission notifies the Compliance Office that you no longer wish to submit your initial submission and want to withdraw the study. Withdrawn studies are marked as finalized and can no longer be modified. You may create a withdrawal submission at any point once an initial submission has been created, until it has been approved. If the initial submission has been approved, you must create a closure submission in order to close the study if you no longer wish to conduct the research.

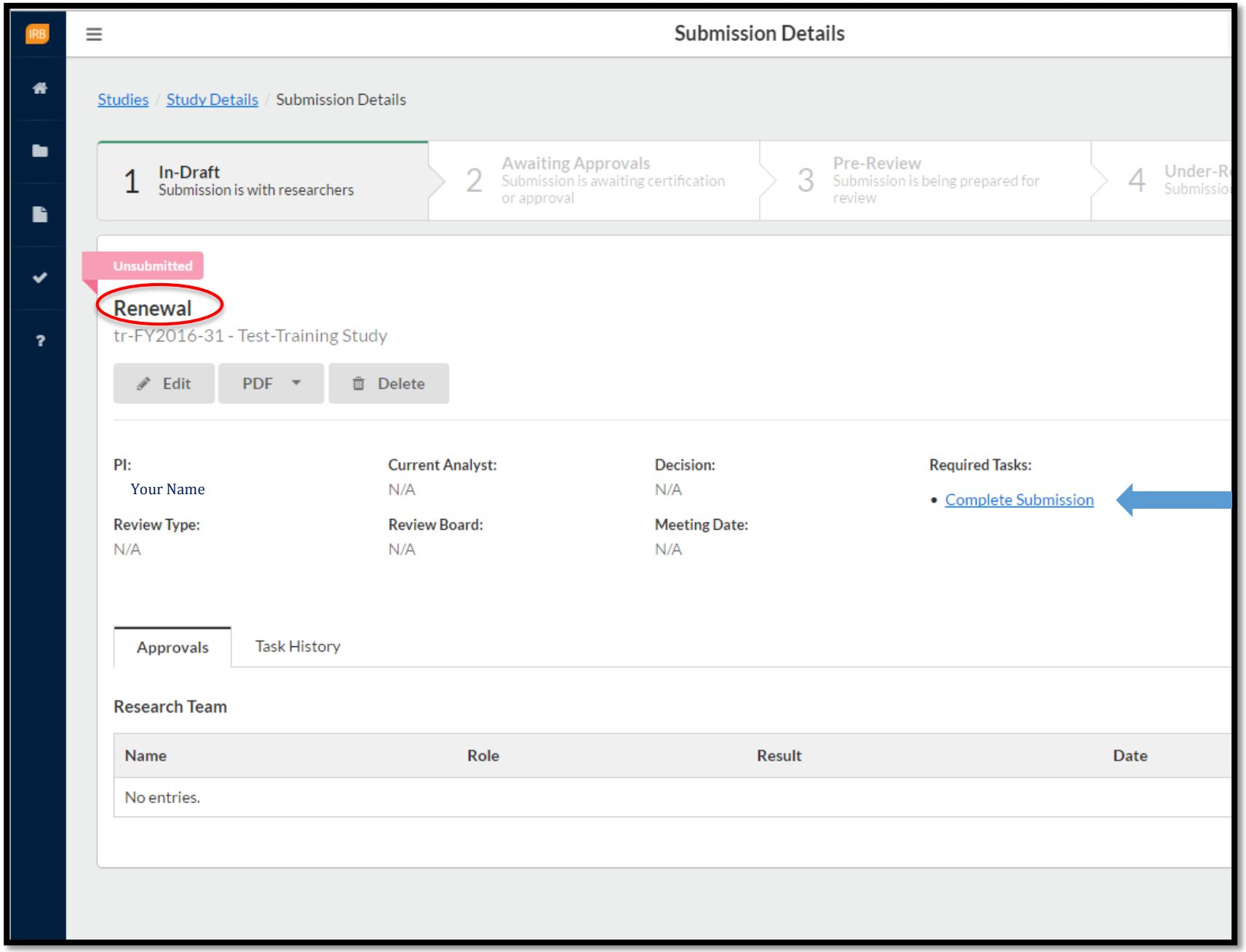
Closure - A closure submission indicates that the research is complete and will not be continuing. Closed studies are marked as finalized and can no longer be modified.

Legacy - Used for studies imported from previous systems. The legacy submission replaces the initial submission for imported studies. Once the legacy submission is finalized, you can create additional submissions such as modifications, renewals, etc. An IRB Analyst must create and publish a legacy template before users can create



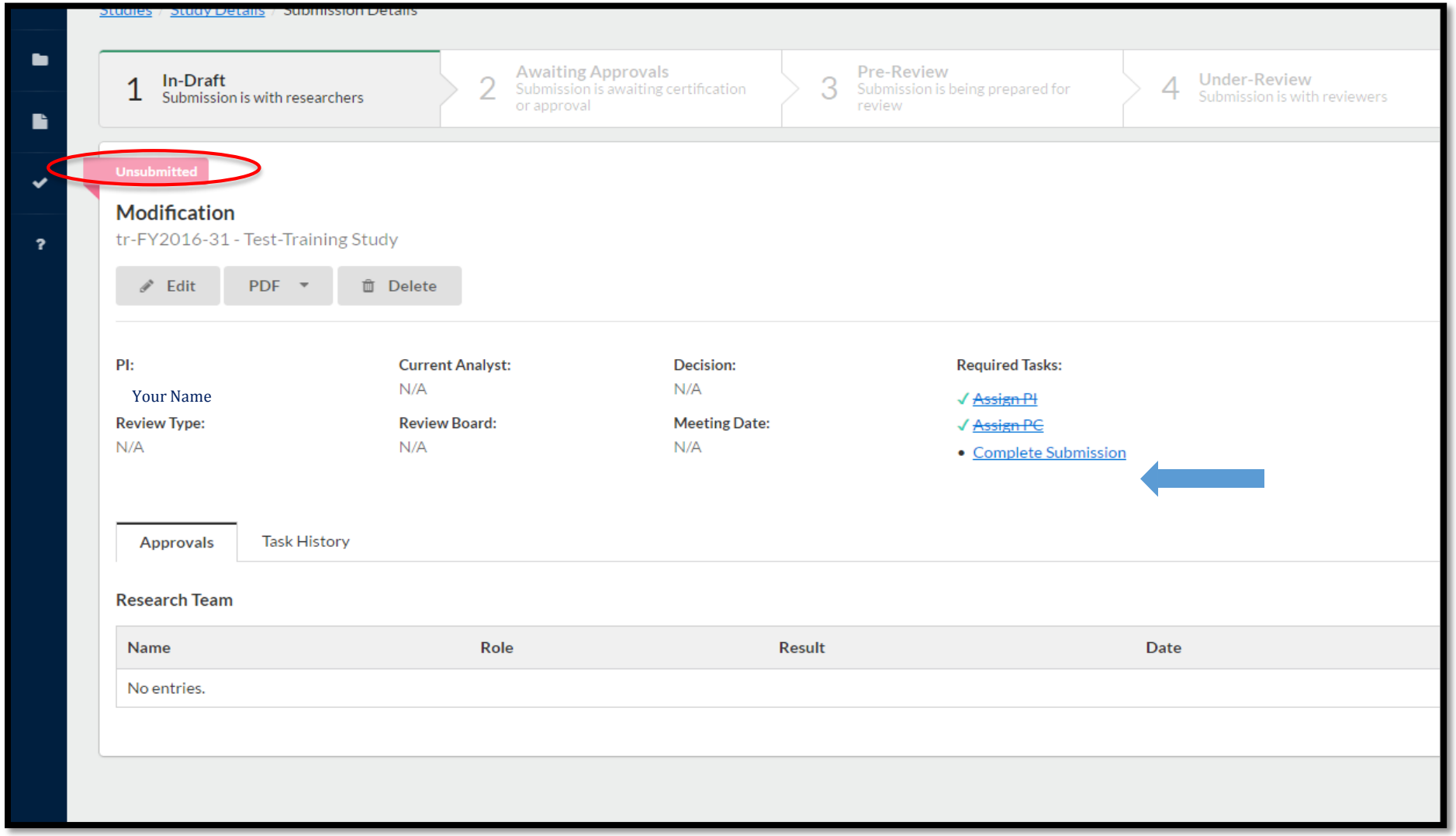
Renewal

If you are planning to renew your study, you will click Renewal and select Complete Submission to begin the Renewal process.



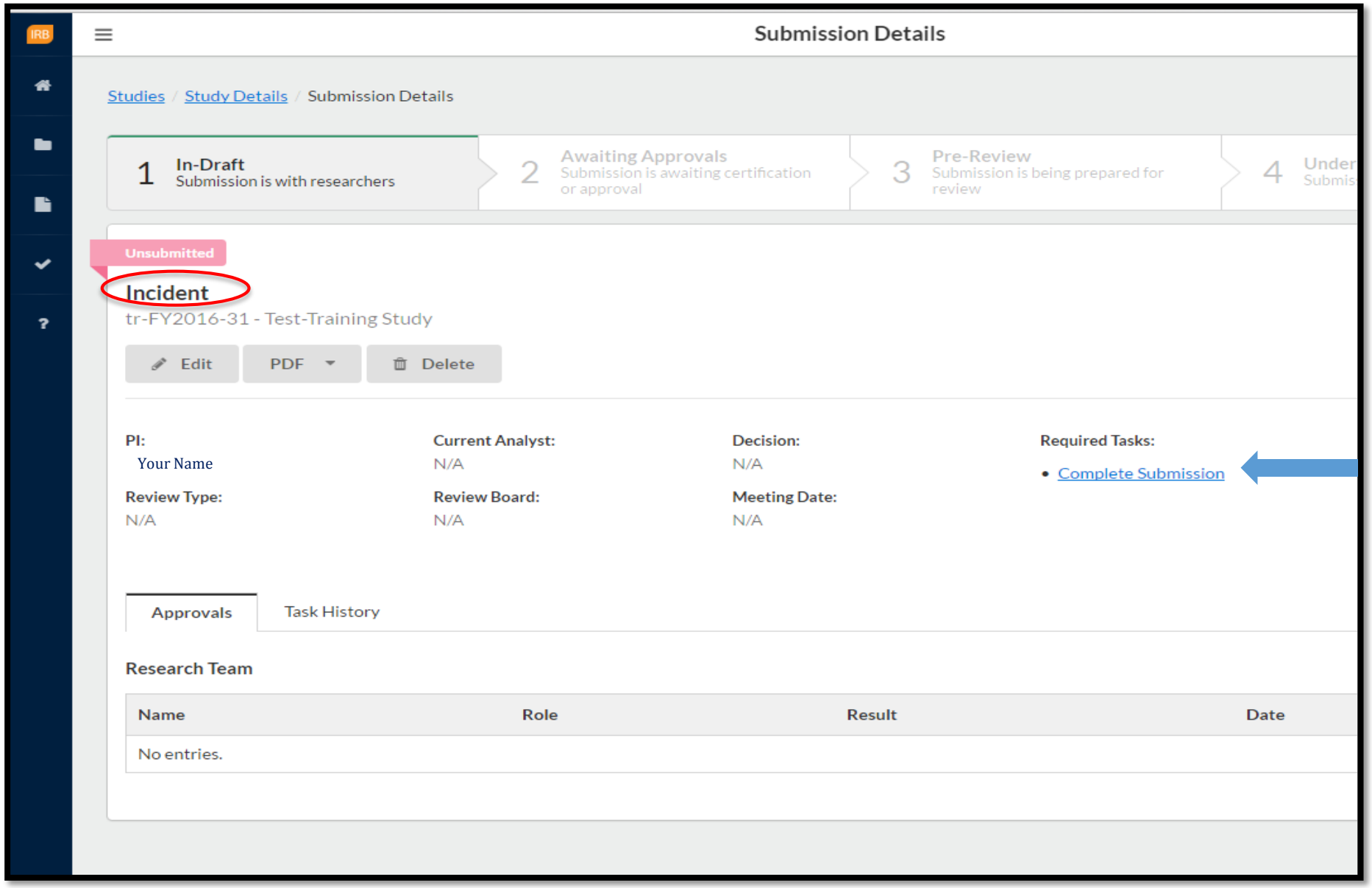
Modification

If you are modifying your study, you will click **Modification** and select **Complete Submission** to begin the modification process, making all necessary changes.



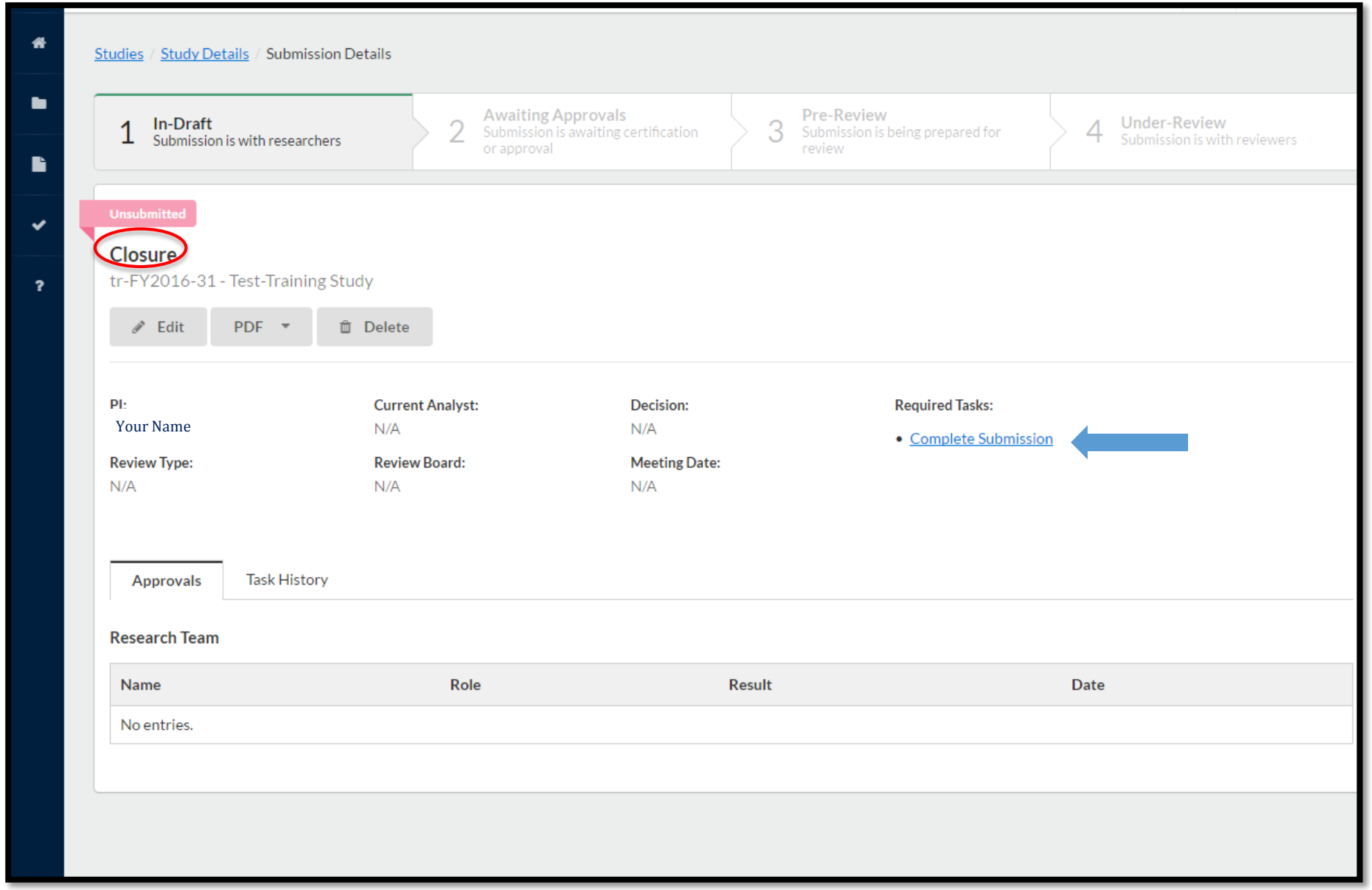
Incident

If an incident or adverse event occurs during your study-research, you will click **Incident** and select **Complete Submission** to begin the noting ALL adverse events and incidents that have occurred.



Closure

When you have completed your research and are ready to Close your Study, you will click **Closure** and select **Complete Submission** to begin the process of completing the closure of your Study.



Decision Types

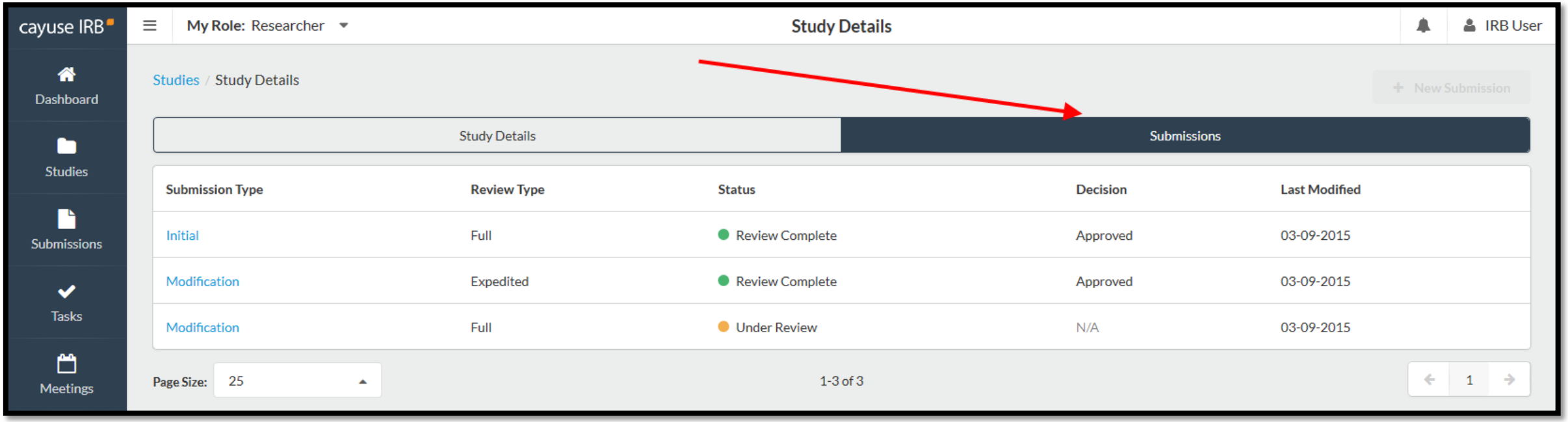
When entering decisions, you can choose from the following selections. You will see different options depending on the type of review. **Click Here** for full Decision Types chart.

Decision	Explanation	Resulting Study Status	Routing
Approved	The study is approved.	Approved	Submission is approved and no longer editable. The research team can add additional submissions to the study.
No Engagement in Research	The study does not constitute research and therefore does not require IRB approval.	Approved	Submission is approved and no longer editable. The research team can add additional submissions to the study.
No Human Subjects Research	The study does not include human subjects research and therefore does not require IRB approval.	Approved	Submission is approved and no longer editable. The research team can add additional submissions to the study.
Noted	The incident report has been noted by the IRB.	Approved	Submission is approved and no longer editable. The research team can add additional submissions to the study.
Rely on External IRB	The study and submission were reviewed and approved by an external IRB and their decision has been recorded by the IRB.	Approved	Submission is approved and no longer editable. The research team can add additional submissions to the study.
Rely on NCI-CIRB	The study and submission were reviewed and approved by an NCI-CIRB and their decision has been recorded by the IRB.	Approved	Submission is approved and no longer editable. The research team can add additional submissions to the study.
Exempt	The study is exempt because it fits into one of the specified categories for exemption.	Exempt	Submission is approved and no longer editable. The research team can add additional submissions to the study.
Suspended	A study is suspended when the IRB decides that the research needs to stop until changes have been made to the research. A suspended decision is available on Incident Reports, Modifications, and Renewals. Suspension can only be lifted by selecting the "Suspension Removed" decision for a modification submission after it has had a full, full expedited, or expedited review. Lifting the suspension changes the study's status back to "Approved". Note: Renewal submissions for an expired suspended study can receive a decision of "Approved" in order to extend the date without lifting the suspension, or "Suspension Removed" in order to extend the date and lift the suspension.	Suspended	Submission is returned to the PI and is no longer editable.
Closed	A closure submission is created and submitted when the research is done and the study can be closed.	Closed	The study is closed and no further research can be done.
Withdrawn	The research team decided not to proceed with the initial submission. This decision is only available for withdrawal submissions. The research team can choose to withdraw the study at any point until the initial submission has been approved. If the initial submission has been approved, the research team must create a closure submission instead.	Withdrawn	The study is closed and no further research can be done.
Disapproved	The full board identified major issues with the study or submission and disapproved the research. In the case of a disapproved initial study, a new study and submission will need to be created. For disapproved renewal, modification, etc. submissions, the research team will need to create a new submission if they wish to proceed.	Disapproved	The submission and/or study are disapproved and no longer editable. Disapproving an initial submission archives the study.
Deferred	The reviewer(s) identified major issues that the research team must correct before the submission can be approved.		Submission is returned to the PI and reopened for editing.
Minor Stipulations	The reviewer(s) identified minor issues that the research team must correct before the submission can be approved.	Requires Changes	Submission is returned to the PI and reopened for editing.
Return to PI	The study is being returned to the research team to make changes because the IRB will not approve it as-is.	Requires Changes	Submission is returned to the PI and reopened for editing.
Not Expedited/Not Exempt	The study will be returned to the IRB Analyst to reassign it to the correct review type.	N/A	Submission is returned to the Analyst to reassign the review type and reviewers.
Not Reviewed	Documents that the submission was unable to be discussed at the meeting. The "Not Reviewed" decision is logged in the decision history so that a new decision can be made at a subsequent meeting. This decision type is only available for full board reviews of initial, modification, incident, and renewal submissions.	N/A	Submission is returned to the Analyst to assign to a new meeting.

Viewing Submission History

Viewing Submission History

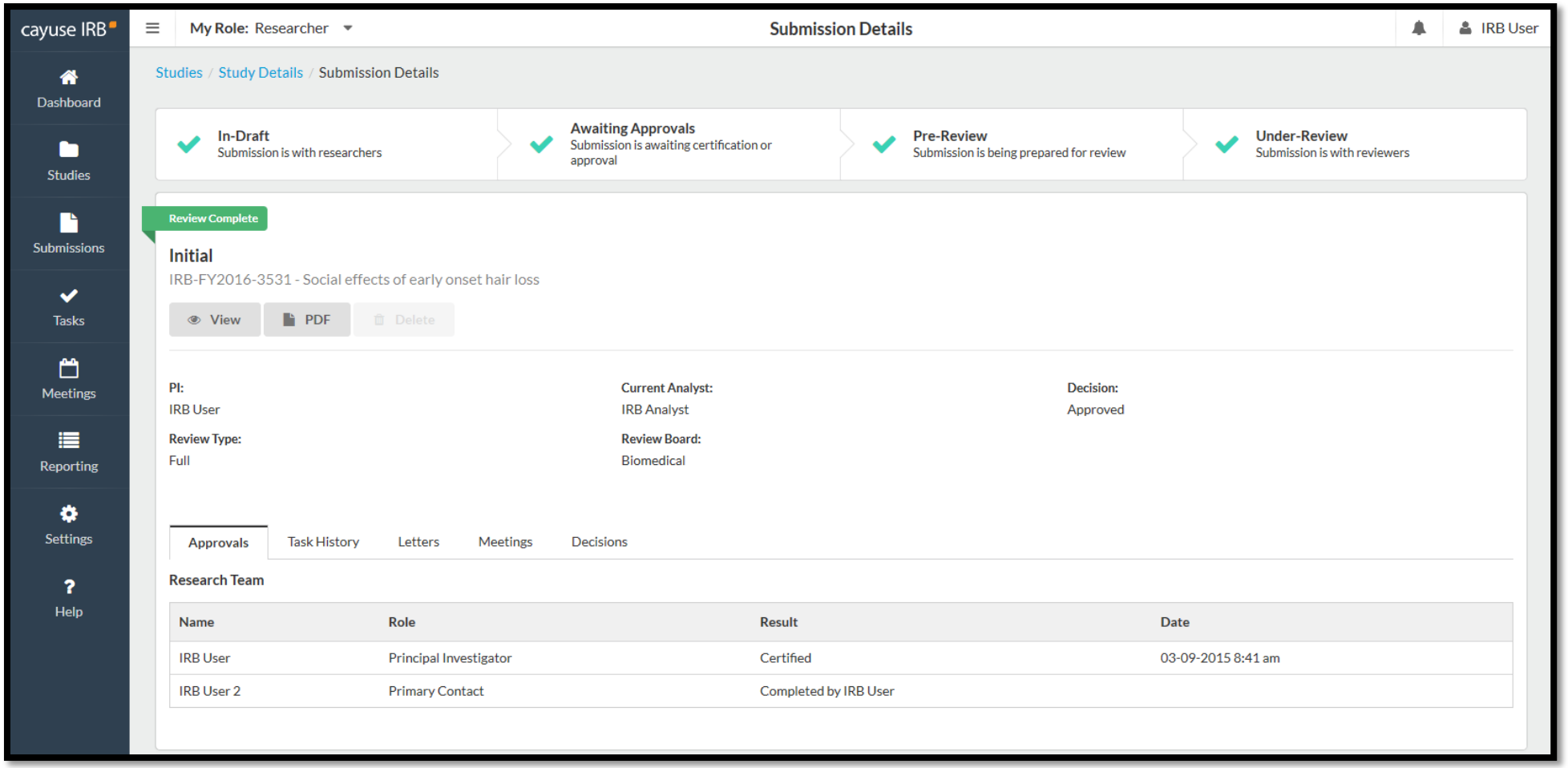
To view the submission history for a study, go to the Study Details page and click on the Submissions tab.



Viewing Submission History

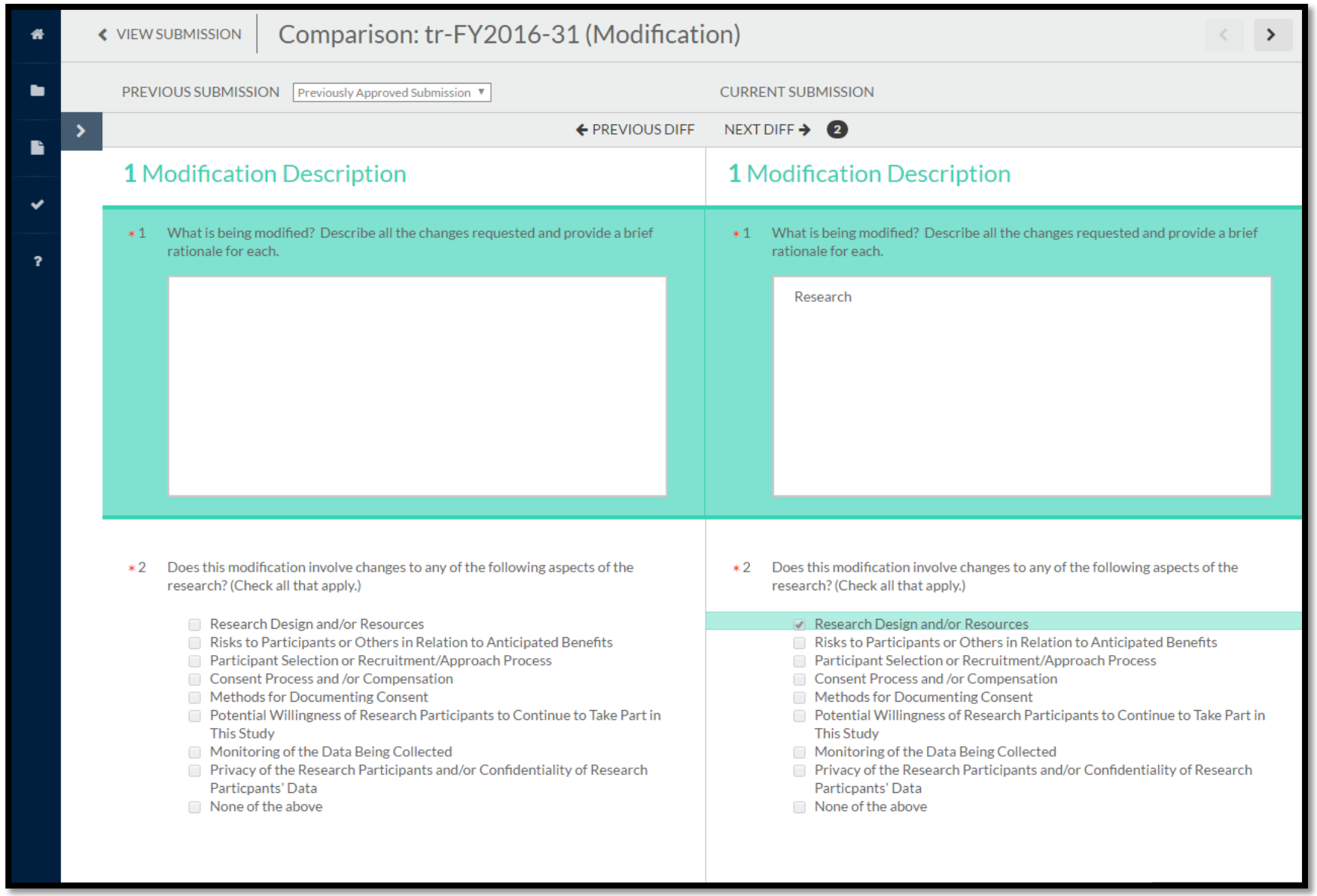
The Submissions tab shows the list of submissions associated with the study, including the submission type, review type and status, decision, and last modified date. Click on any submission in the list to go to its Submission Details screen.

Notice the Approvals, Task History, Letters, Meetings, and Decisions tabs showing for the initial submission. Click on the desired tab to locate the information you require.



Comparing Submissions

Comparing Two Versions of a Submission



The sidebar shows the number of differences found in each section. Within each section, each difference is highlighted for you to review.

Click the **Previous** or **Next Diff** buttons at the top of the comparison window to jump to the previous/next difference.

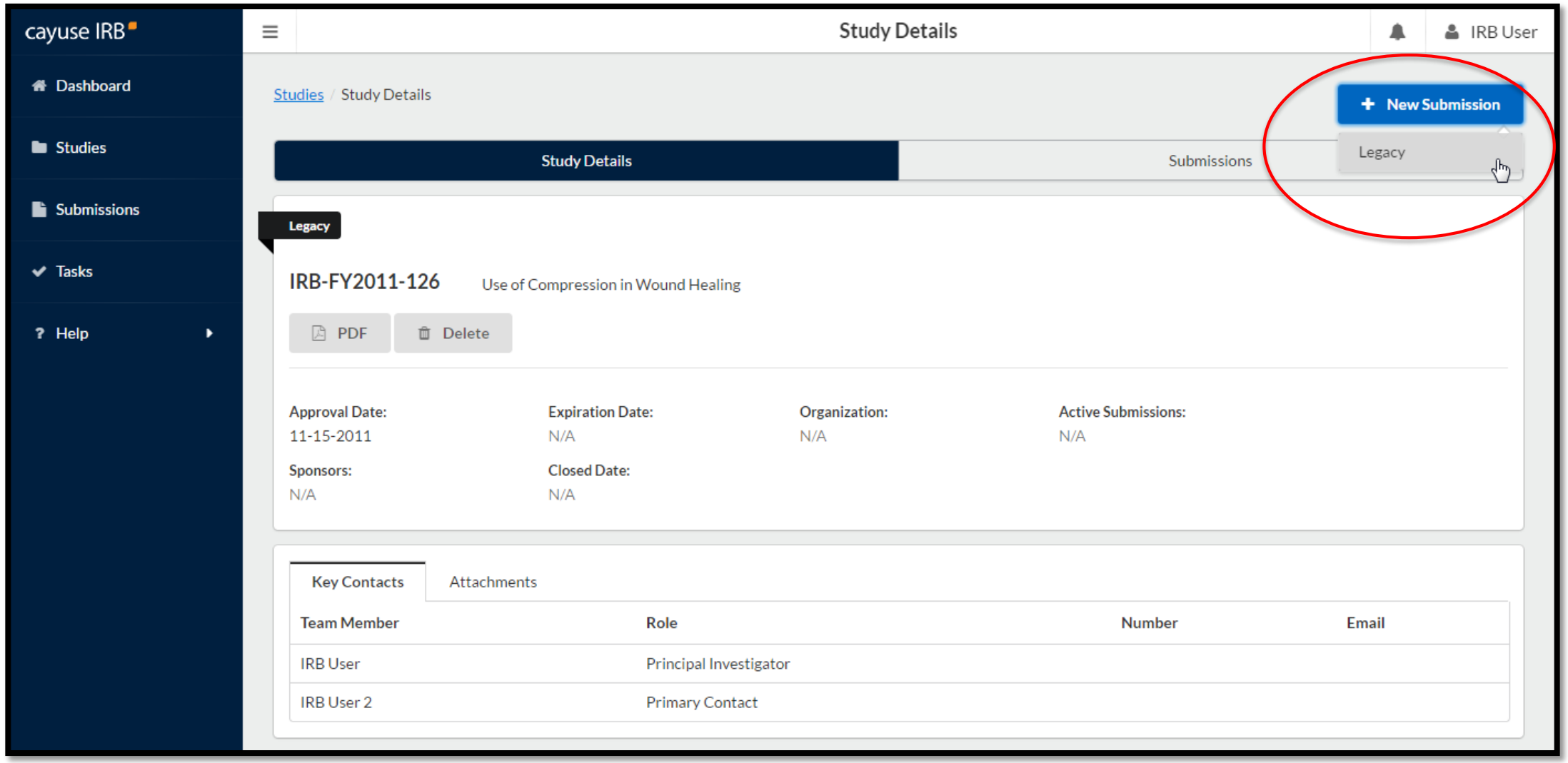
Legacy Studies

What is a Legacy Study?

When a study is first imported from a previous IRB system into Cayuse IRB, the study does not have any submissions associated with it. If an investigator wishes to continue working with the study, they (or an IRB Analyst) must first create a **Legacy** submission for the study. The Legacy submission is used in place of the Initial submission. Once the legacy submission is finalized, you can create additional submissions such as modifications, renewals, etc. and work with the study as you would any other study in Cayuse IRB.

Legacy Study (continued)

When you first open the imported study, the only available submission type is the legacy submission. Click New Submission -> Legacy to proceed.

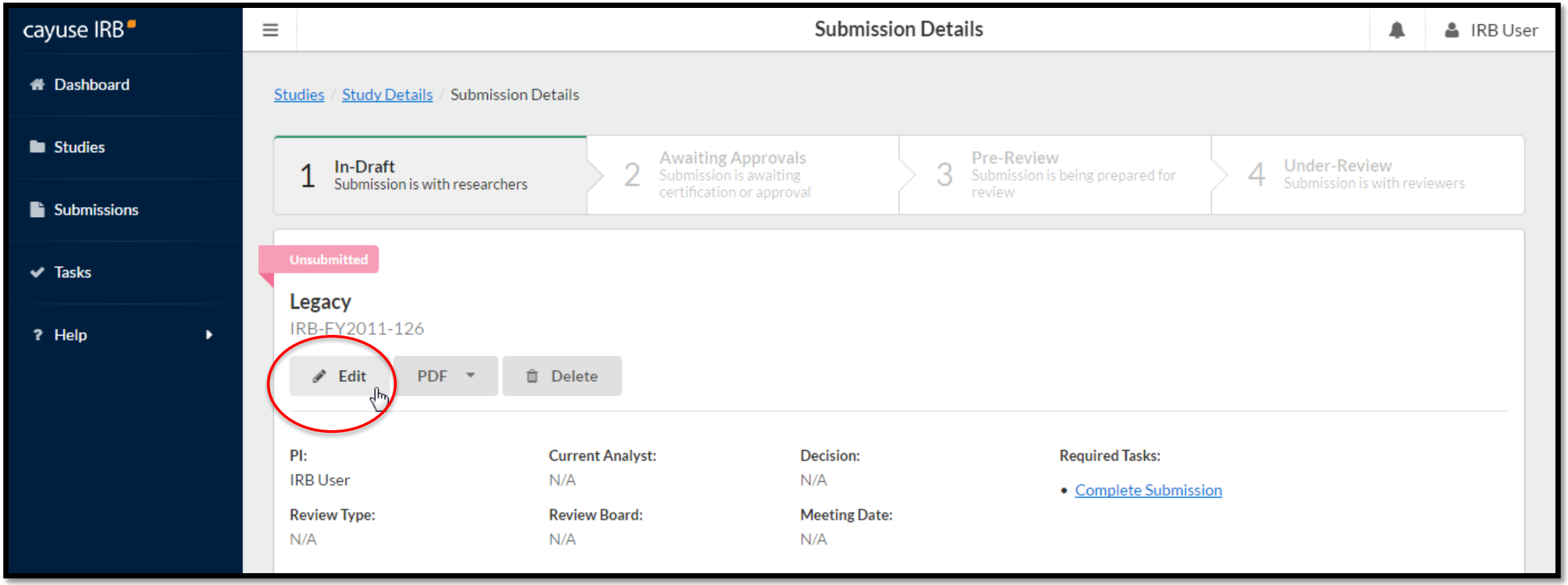


Legacy Study (continued)

The legacy submission is added in a similar manner to the first initial submission, but using the Legacy template instead of the Initial template. Click Edit to see the data on the legacy submission form.

When you are finished editing the form, click Complete to finalize the legacy submission. You then have the option to create additional submissions for this study, such as renewal, modification, incident, or closure submissions.

Note: Some of the data, such as the Principal Investigator, may be prepopulated into the submission form. You must save the form in order for these changes to be remembered.

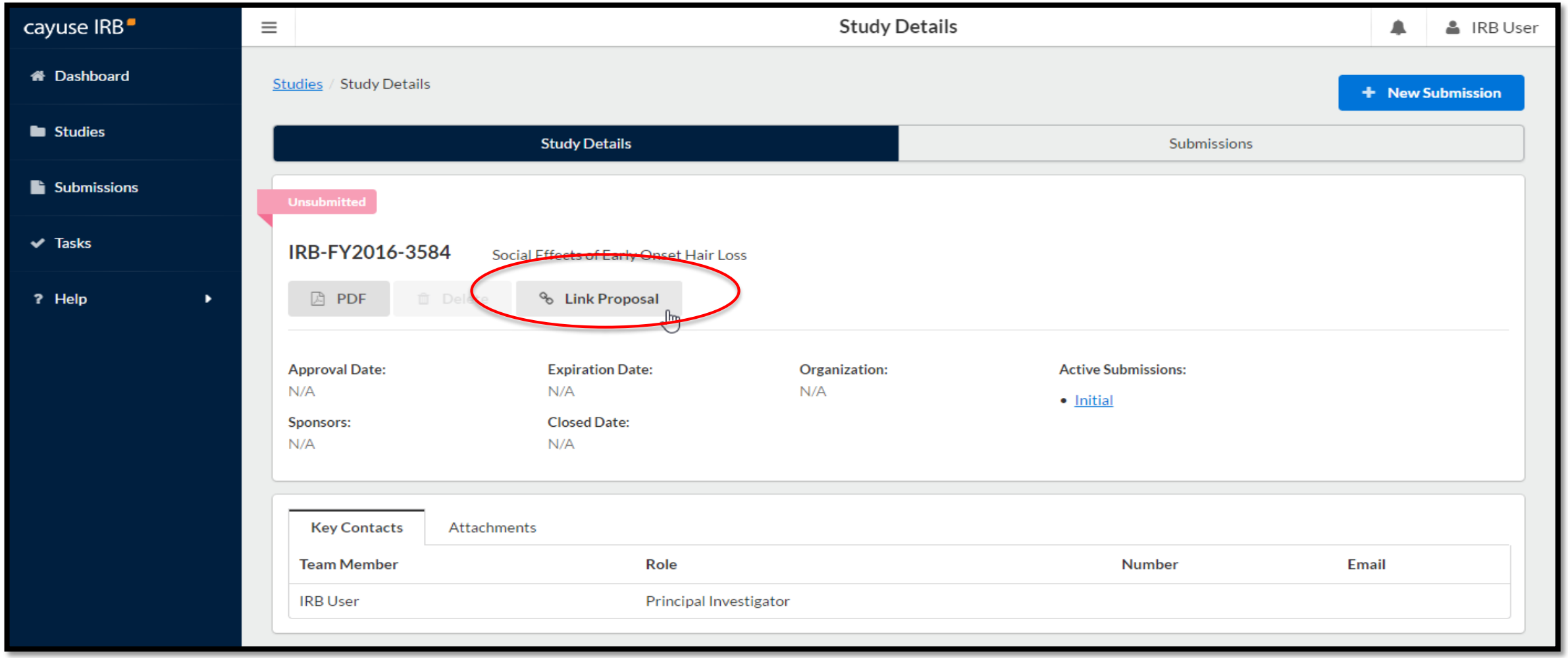


Linking Your Study to Cayuse Sponsored Project(s)

THE UNIVERSITY OF MEMPHIS

Linking a Study to Cayuse SP

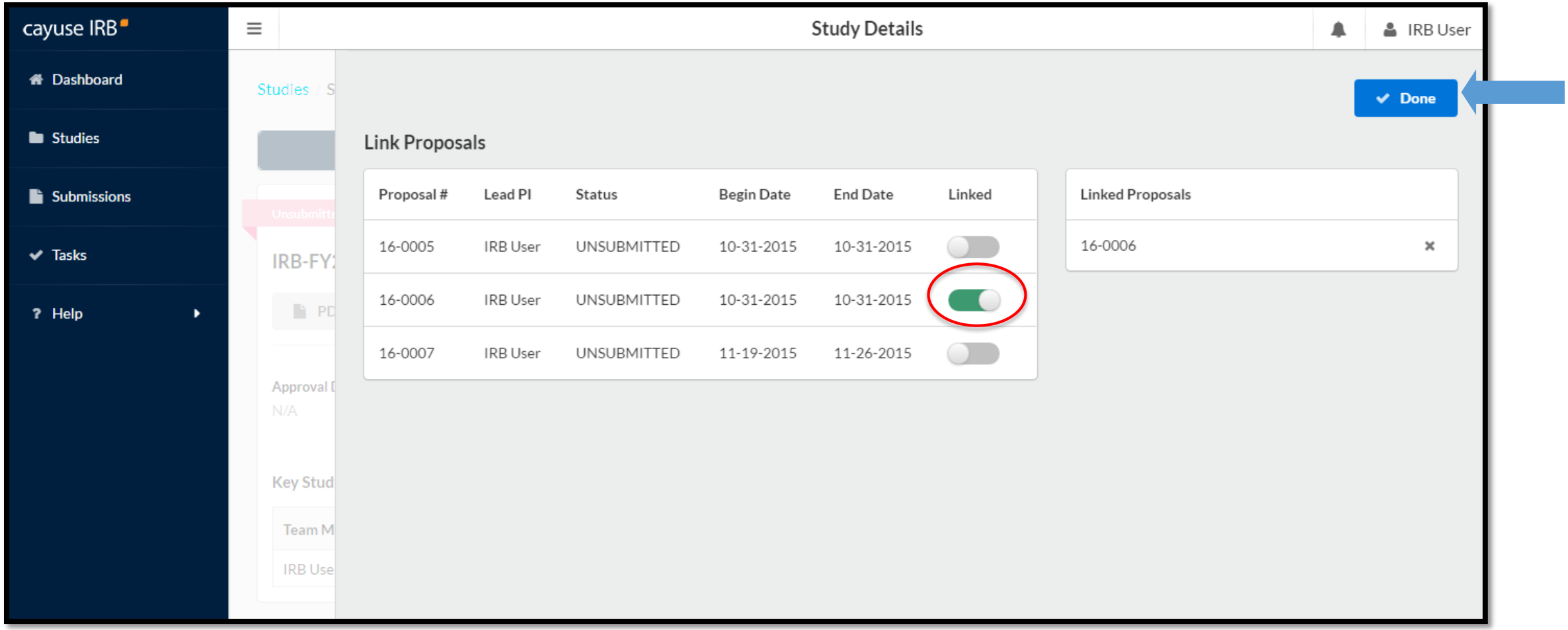
Click the Link Proposal button on the Study Details screen to launch the Proposal Finder.



Linking a Study to Cayuse SP (continued)

Cayuse IRB automatically searches for SP proposals associated with the researchers assigned to the study in Cayuse IRB. If you are not seeing the proposal you want to link, make sure that you have created an initial submission and assigned a PI and the researcher(s) associated with the Cayuse SP proposal.

Select the study or studies you wish to link using the green **Linked** toggle, then click **Done**.

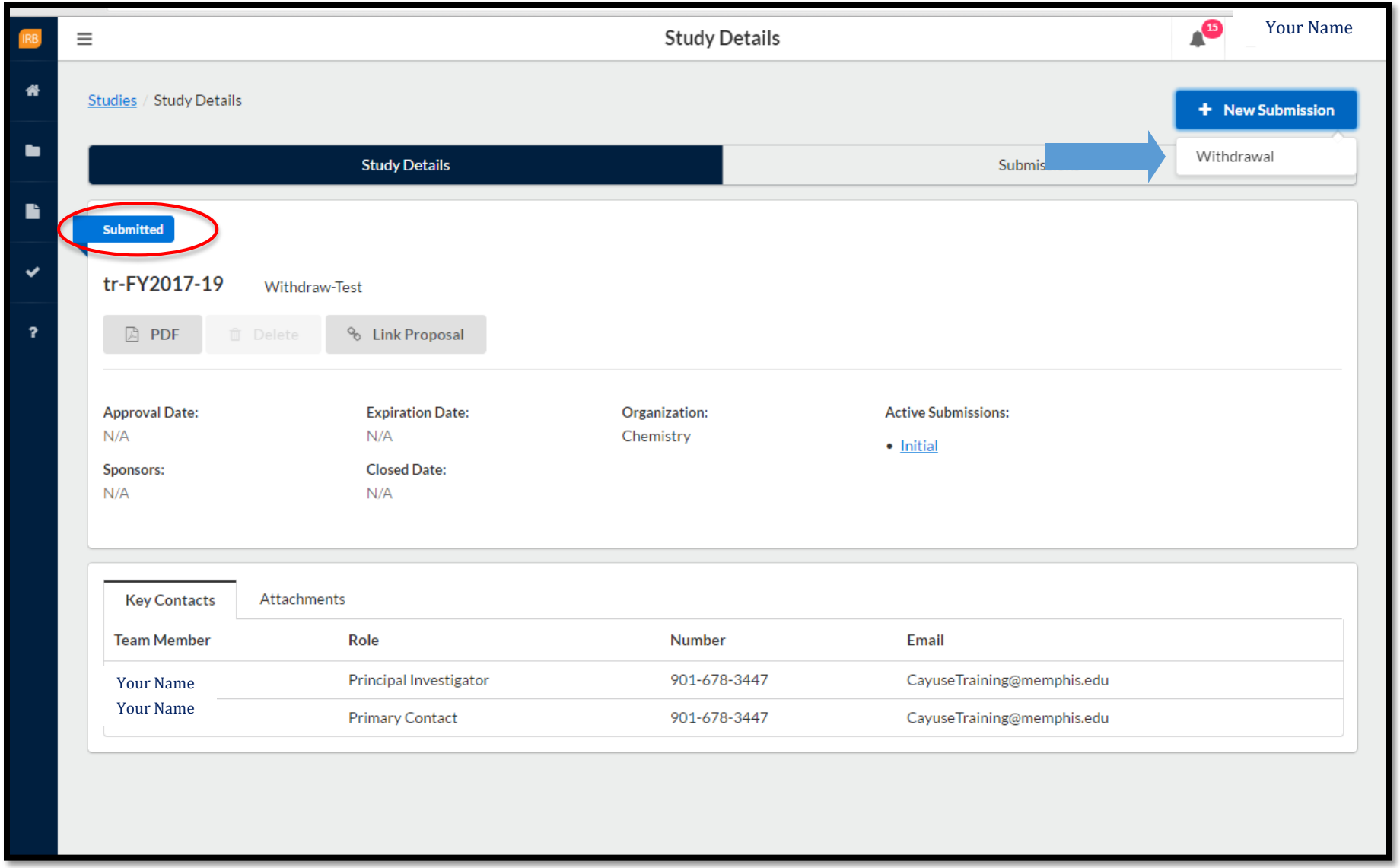


Withdrawing a Study

87 Withdrawal

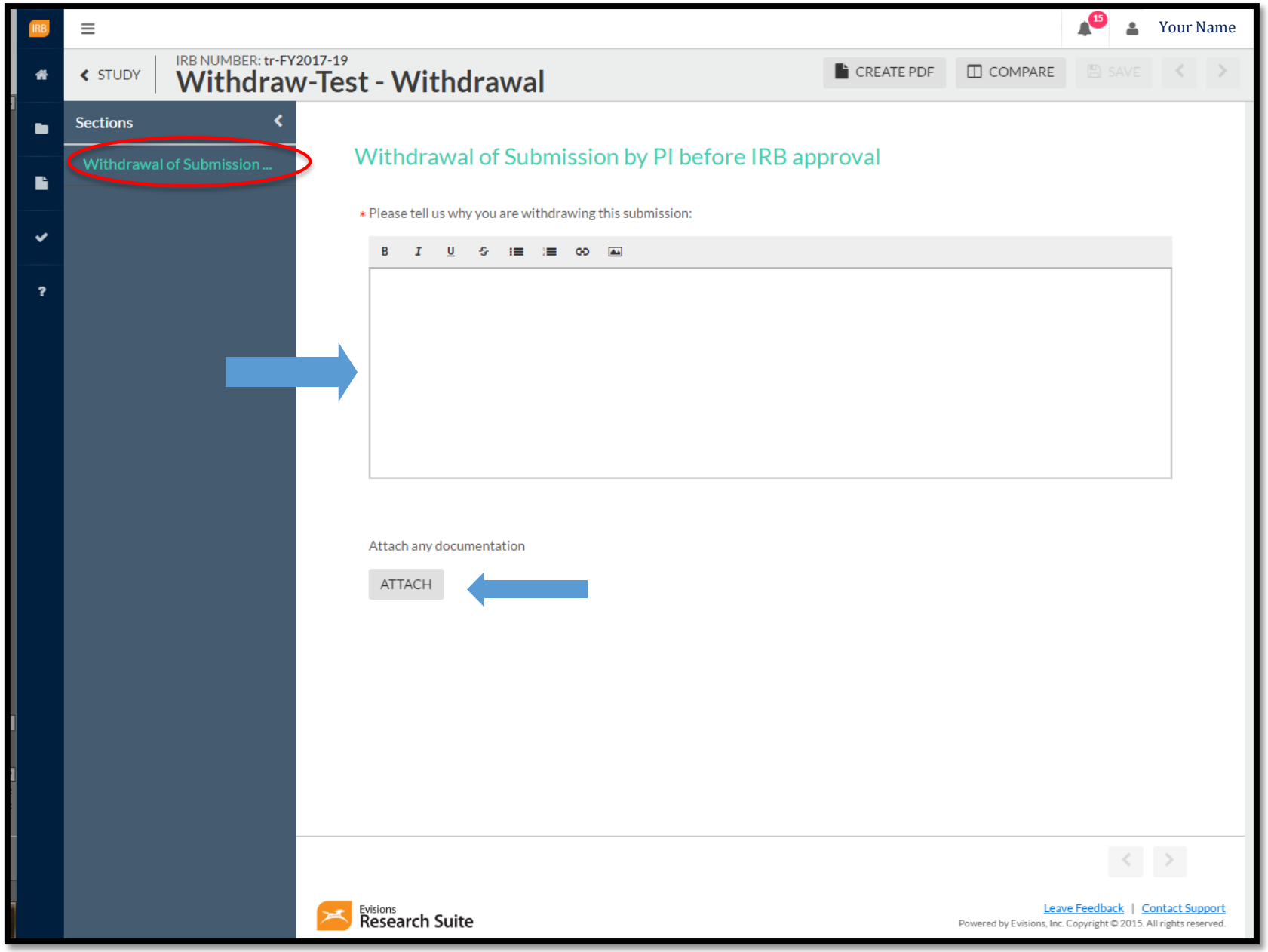
You can withdraw your submission after it has been submitted. Click + New Submission and select Withdrawal.

If it's been approved, you will not have the option to Withdraw, but will have to Close (See Closure section).



Withdrawal (continued)

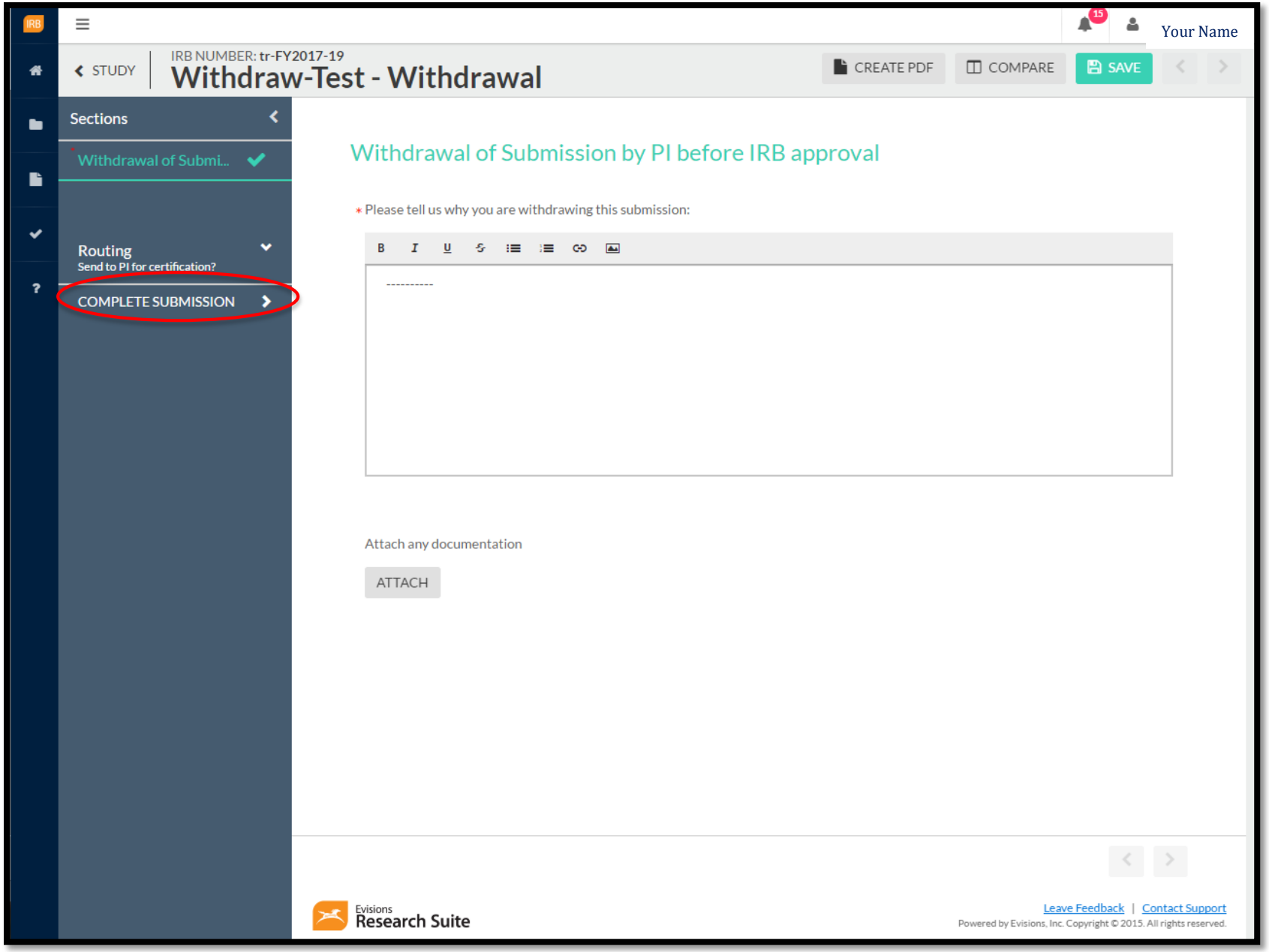
Withdrawal Submission requires you to explain why the submission is being withdrawn. If any, feel free to attach any necessary documents



Withdrawal (continued)

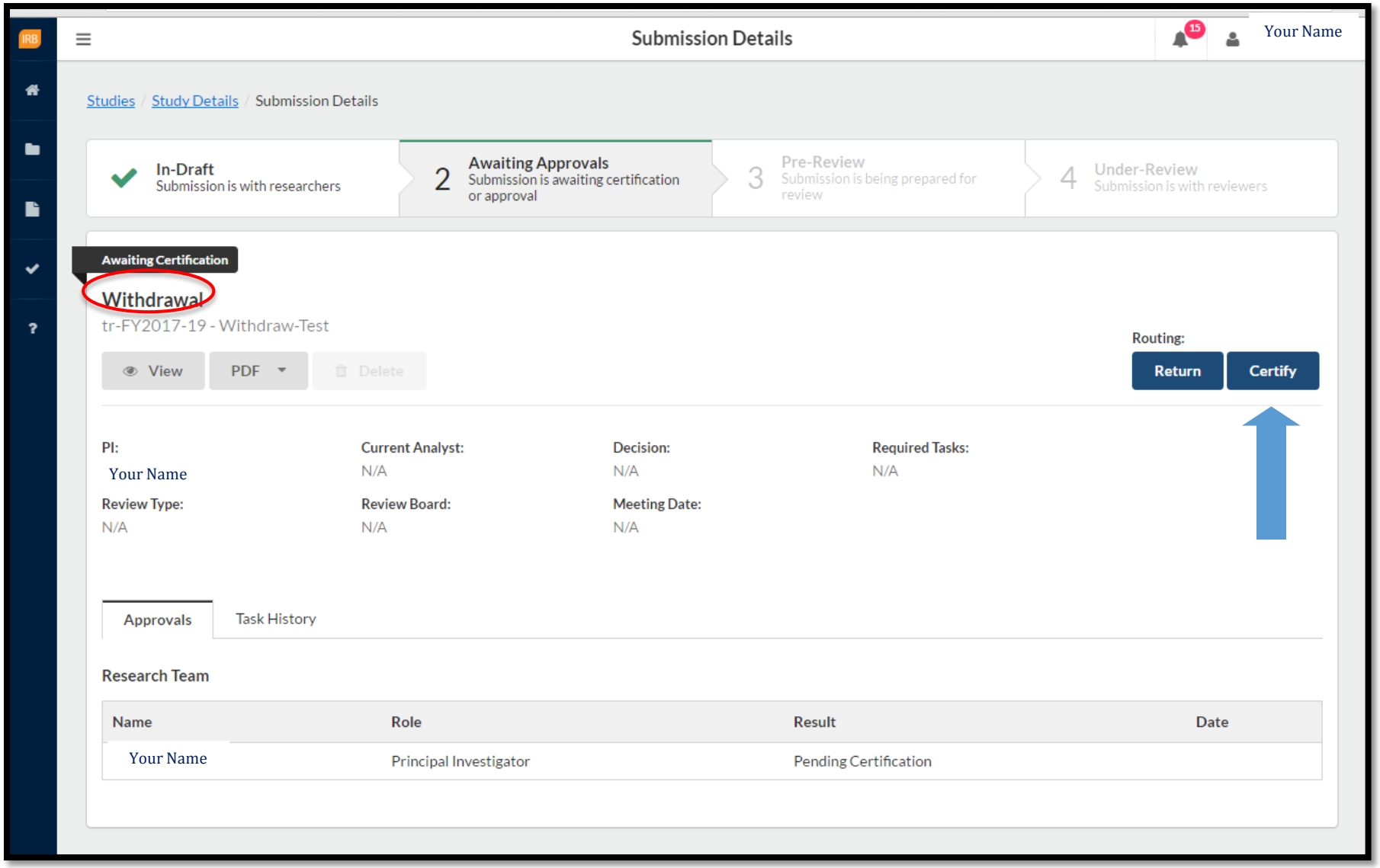
Once you have answered the questions, click anywhere outside of the box to go on to **Complete Submission** so the withdrawal can be certified.

Click **Complete Submission** to confirm withdrawal.



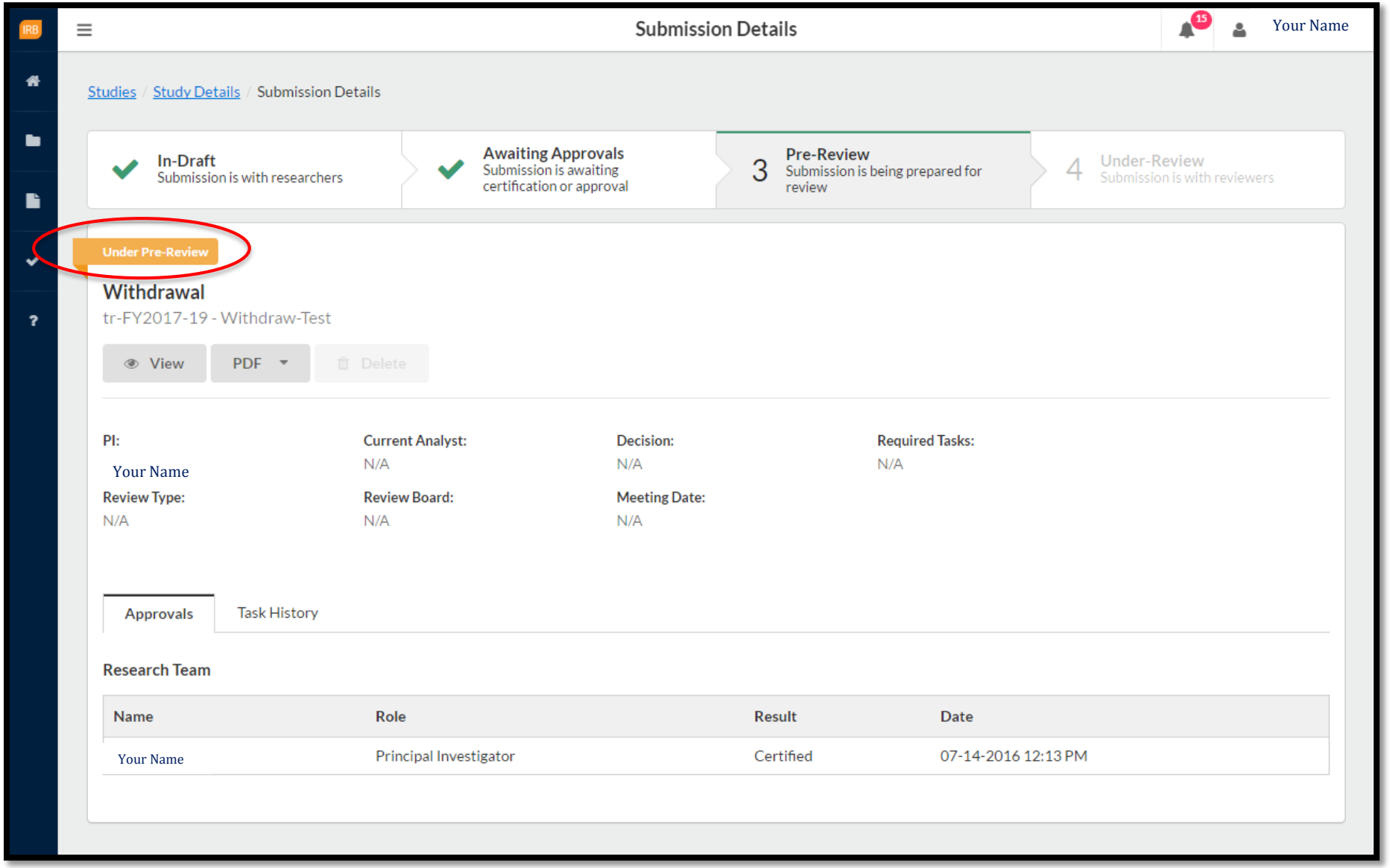
Withdrawal (continued)

Certify your Withdrawal by clicking Certify. Students, your faculty advisor must also Certify your withdrawal, before it can proceed to next step.



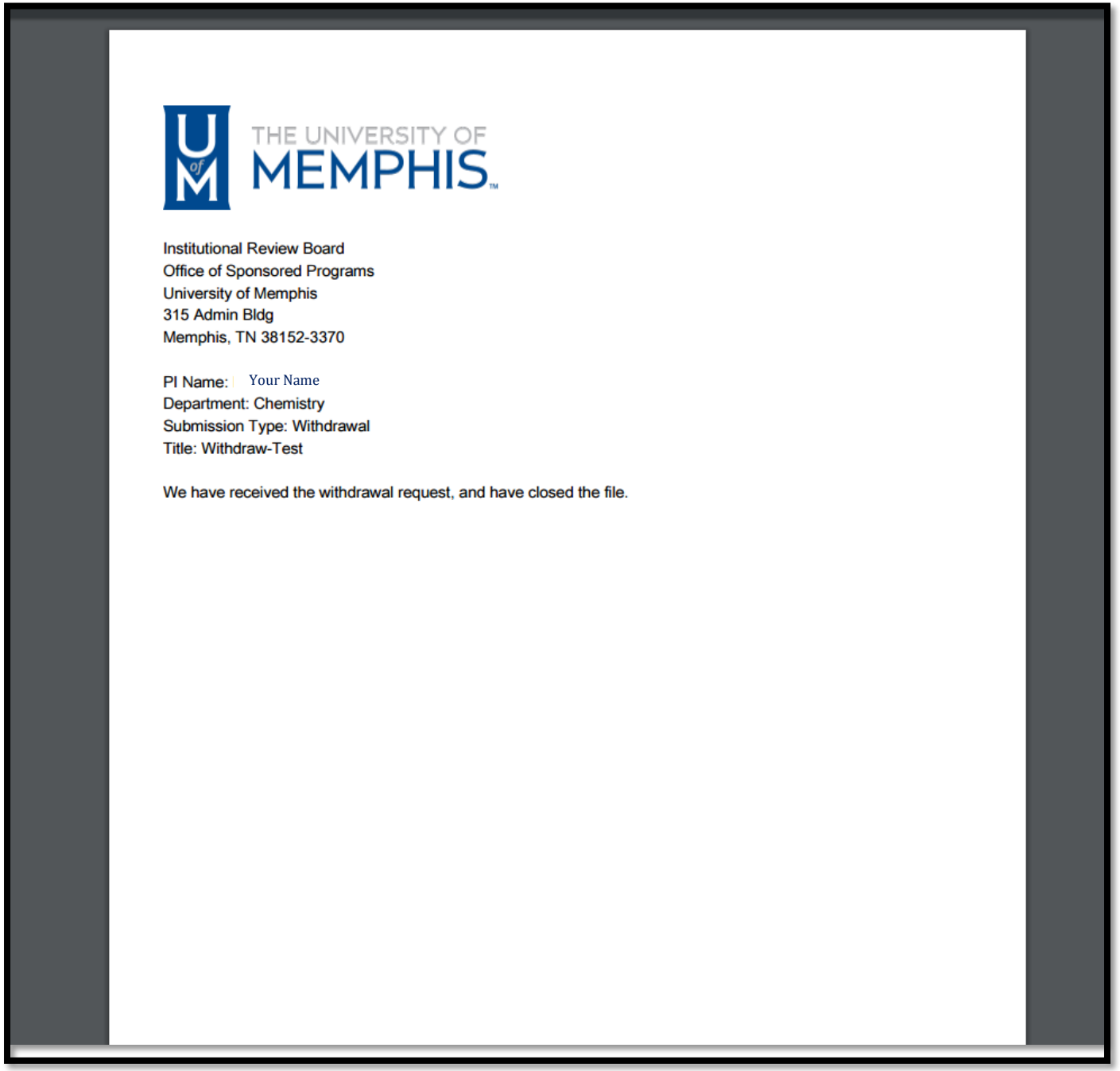
Withdrawal (continued)

Once the Withdrawal Submission has been certified by necessary individuals, it will proceed to IRB Analyst for Pre-Review.



Withdrawal (continued)

Once the IRB Analyst completes reviewing and acknowledging your Withdrawal submission, you will be receive an email stating the results from receiving the withdrawal



THE UNIVERSITY OF MEMPHIS

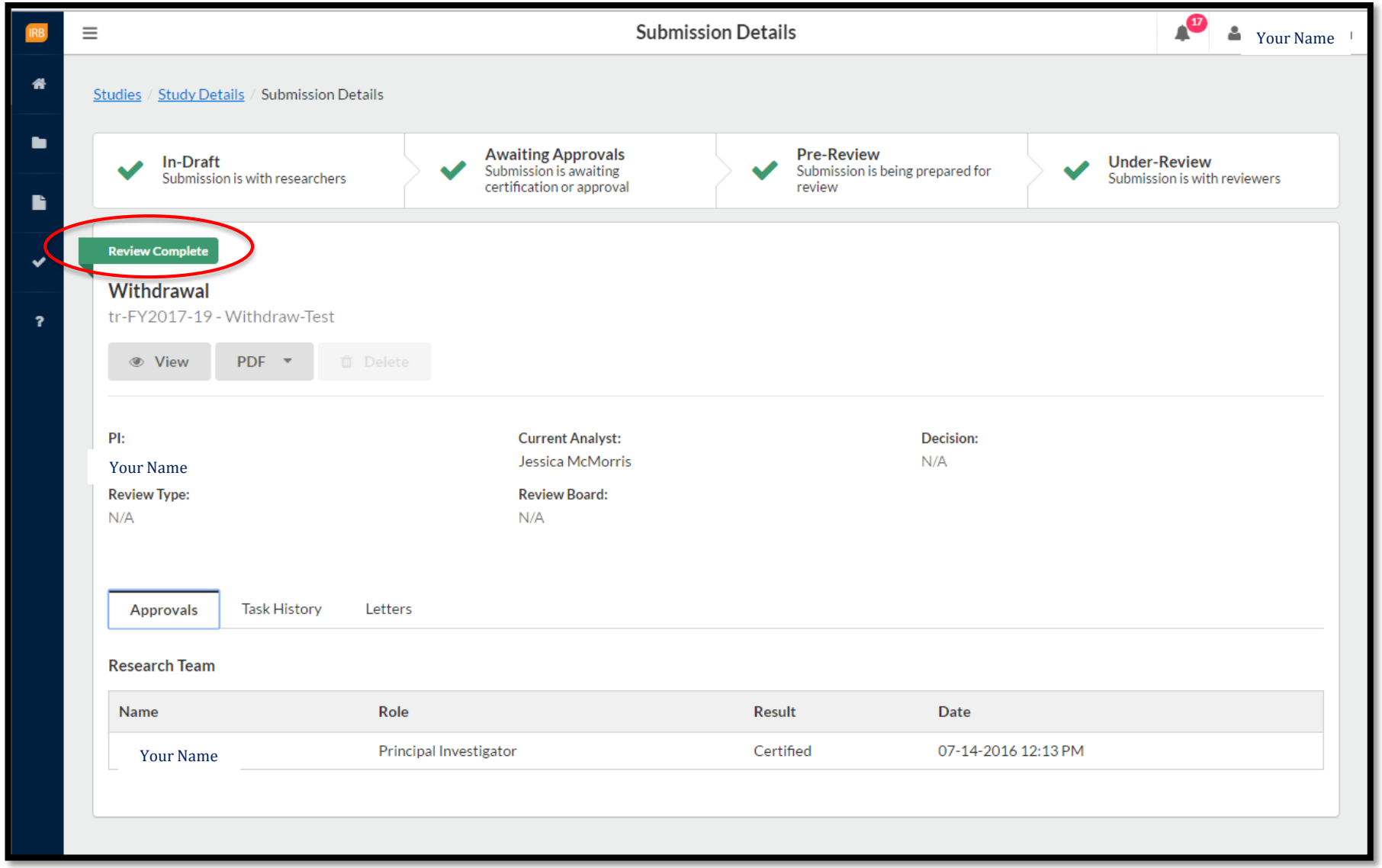
Institutional Review Board
Office of Sponsored Programs
University of Memphis
315 Admin Bldg
Memphis, TN 38152-3370

PI Name: Your Name
Department: Chemistry
Submission Type: Withdrawal
Title: Withdraw-Test

We have received the withdrawal request, and have closed the file.

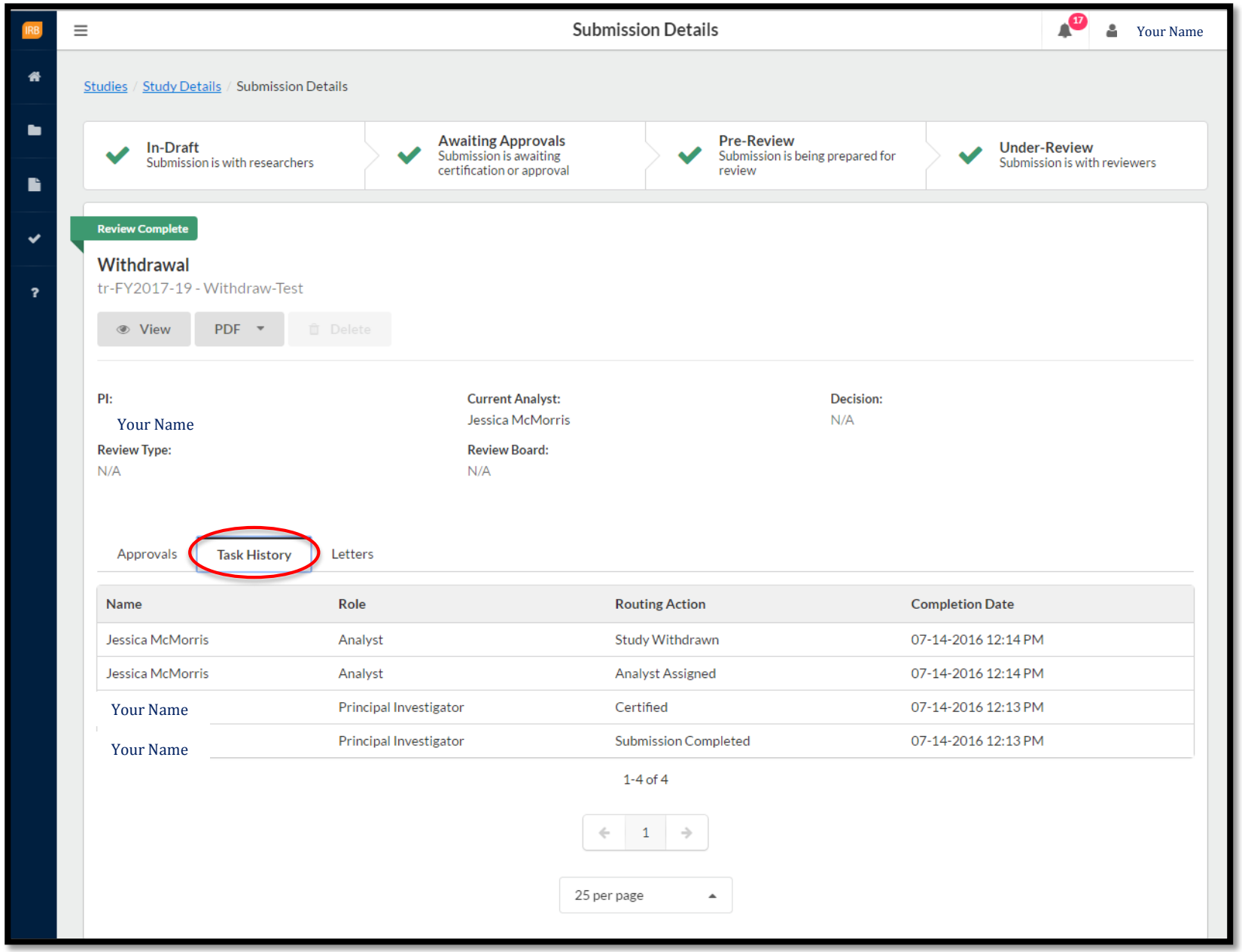
Withdrawal (continued)

When you check your Withdrawn submission, you will notice that the status is now Review Complete.



Withdrawal (continued)

You can also view the submission's Task History to see Routing Actions.



How will I know my study has been approved?

- You will be notified via CayuseIRB notifications and email! All Study Submission statues will be located in the study.

- The study will appear on your dashboard under **Approved Studies**.

- All approved documents will appear under your approved study – those are the documents you need to use for your active research.

FAQs

Do I still need to complete CITI Training?
✓Yes, all research team members, including students' faculty advisor, will still have to complete CITI training every 365 days.

Do I still need to email irb@memphis.edu my protocol & study-related documents?
✓No, you will also not be sent any protocol forms. All protocol information must be entered in CayuseIRB. And all study-related documents must be attached to protocol information within CayuseIRB.

How do I renew, modify, report an incident, and/or close my study if it was approved before CayuseIRB?
- ✓ ***The first step:*** you must complete your Legacy Submission by uploading & submitting all of you last approved documents (Screenshot Manual).
- ✓ ***The second step in the process*:** you will be able to MODIFY, RENEW, report an INCIDENT, or CLOSE your study(ies) by going back to that same study, click "New Submission", and then select your submission of choice. Click "edit" and begin following the directions within the submission. When complete, and ALL checkmarks are by each section, click "Complete Submission". Lastly, review and "Certify" your submission.

Do I still need to complete apply for continuing review?
✓Yes, you will eventually have to fill out a renewal submission if your study is not exempt and your are still conducting study procedures. Once your study is completed, submit a Closure. If you do not submit a Closure or Renewal, your study will Expire.

How will I know my the status of my study and its submission(s)?
- ✓ You will be notified via CayuseIRB notifications and email of all correspondences and any updates. If approved, the study will appear on your dashboard under Approved Studies.

As an advisor, how would I review my students' submission(s)?
- ✓ Every STUDENT must list their Faculty Advisor. You will receive a notification that your student has submitted their protocol and you, their Faculty Advisor, must review and certify their submission before it can proceed to the IRB Analyst.

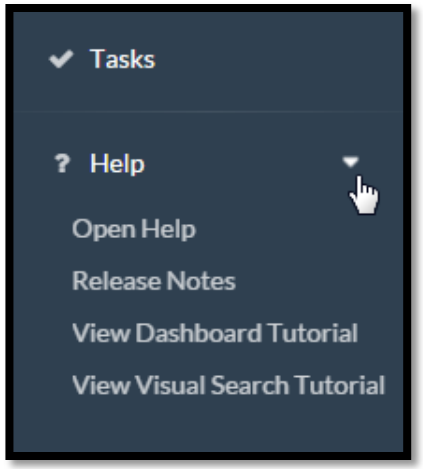
For more Cayuse IRB FAQs, go to http://www.memphis.edu/rsp/compliance/faq_cayuse.php.

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.

For additional online assistance visit http://webhelp.evisions.com/HelpFiles/IRB/1.0/en/Default.htm.



Questions?

Contact the **IRB Administrator/Research Compliance Coordinator**

The University of Memphis
Division of Research & Sponsored Programs
293 Administration Building
Memphis, TN 38152-3370
P: 901.678.2705
F: 901.678.4409
Email: irb@memphis.edu
memphis.edu/rsp/compliance