



Cayuse IRB for Researchers

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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.

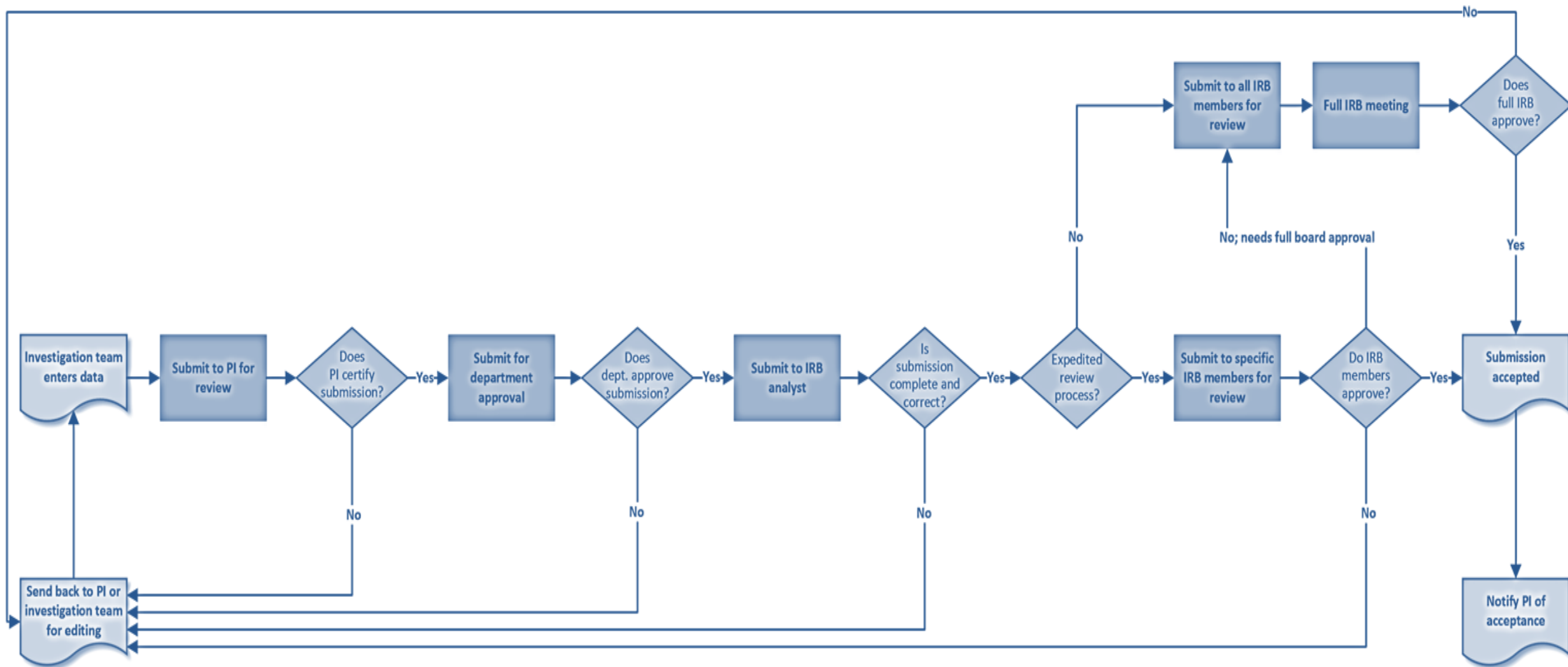
Your role as a UofM Researcher



- ✓ 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).



THE UNIVERSITY OF
MEMPHIS

Login to Memphis Cayuse WebApp

UUID

jmcrris

Password

.....

Login

> Forgot your username?
> Reset your password?
> Initialize your account?
> Need help?

By using this service, you acknowledge that you have read and agree to the terms and conditions of the Acceptable Use of Information Technology Resources Policy (UM1535)

Need help? Contact the ITS Service Desk: (901) 678-8888



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

cayuse IRB | My Role: Researcher | Dashboard | Notifications will appear here. Click bell to view | 23 | Ida PI

Shows the statuses of your submissions

 2 In-Draft	 0 Awaiting Approval	 0 Pre-Review	 9 Under Review
--	---	--	--

Shows all your studies

My Studies	
IRB-FY15-16-27	Cayuse training
IRB-FY15-16-17	Veterans and their children: How they navigate the maze of Veteran Benefits
IRB-FY15-16-18	Focus Group with MSU Student's
View All	

Shows all incomplete tasks

My Tasks	
IRB-FY15-16-29	Complete Submission
IRB-FY2016-10	Complete Submission
View All	

Shows you all your submissions

Submissions by Type	
Initial	10
Withdrawal	1
Modification	3
Renewal	0
Incident	1
Closure	0
Legacy	0

Shows you your approved studies

Approved Studies	
IRB-FY15-16-27	Cayuse training

Shows soon-to-expire studies

Studies Expiring in 30 days ▼

Shows expired studies

Expired Studies

Other ways to access the same things

- Dashboard
- Studies
- Submissions
- Tasks
- Help

[+ New Study](#)

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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.

The screenshot displays the CayuseIRB Dashboard. The left sidebar contains a navigation menu with the following items: Dashboard, Studies, Submissions, Tasks, and a Help dropdown menu. The Help dropdown is expanded, showing options: Open Help, Release Notes, View Dashboard Tutorial, and View Visual Search Tutorial. The main dashboard area features a top header with the title 'Dashboard', a notification bell icon with '11', and the user's name 'Your Name'. A '+ New Study' button is located in the top right. Below the header, there are four status cards: 'In-Draft' (4), 'Awaiting Approval' (0), 'Pre-Review' (0), and 'Under Review' (0). The 'Awaiting Approval' card includes a building icon. Below these cards, there are three main sections: 'Test-Training Study' (with a 'View All' link), 'My Tasks' (listing four tasks with the link 'tr-FY2016-31' and the action 'Complete Submission', with a 'View All' link), and 'Submissions by Type' (a table showing counts for various submission types). At the bottom, there are two more sections: 'Test-Training Study' (with a 'View All' link) and 'Studies Expiring in 30 days' (showing 'No Expiring Studies' with a smiley face icon). The 'Expired Studies' section also shows 'No Expired Studies' with a smiley face icon.

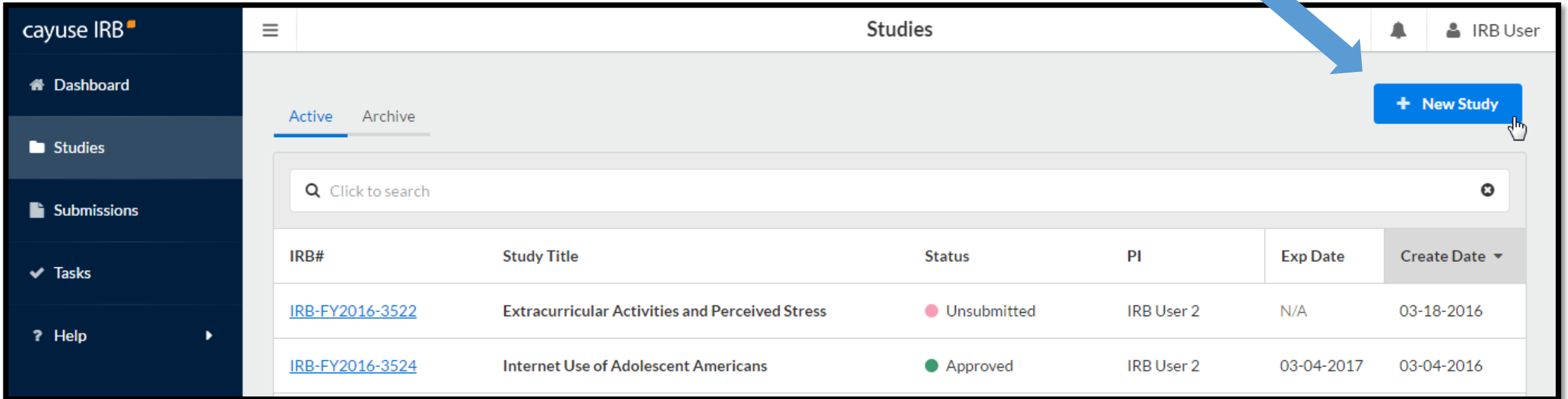
Submission Type	Count
Initial	1
Withdrawal	0
Modification	1
Renewal	1
Incident	1
Closure	1
Legacy	0



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.



The screenshot shows the 'cayuse IRB' interface. The left sidebar contains navigation links: Dashboard, Studies (selected), Submissions, Tasks, and Help. The main content area is titled 'Studies' and features tabs for 'Active' and 'Archive'. A search bar is present above a table of studies. The table has columns for IRB#, Study Title, Status, PI, Exp Date, and Create Date. Two studies are listed: 'Extracurricular Activities and Perceived Stress' (Unsubmitted) and 'Internet Use of Adolescent Americans' (Approved). A blue button labeled '+ New Study' is located in the top right corner of the main content area, with a blue arrow pointing to it from the text above.

IRB#	Study Title	Status	PI	Exp Date	Create Date
IRB-FY2016-3522	Extracurricular Activities and Perceived Stress	Unsubmitted	IRB User 2	N/A	03-18-2016
IRB-FY2016-3524	Internet Use of Adolescent Americans	Approved	IRB User 2	03-04-2017	03-04-2016

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Study Title

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

The screenshot displays the 'cayuse IRB' interface. On the left is a dark blue sidebar with navigation links: Dashboard, Studies, Submissions, Tasks, and Help. The main content area is titled 'Study Details' and includes a breadcrumb 'Studies / Study Details' and a '+ New Submission' button. Below this is a tabbed interface with 'Study Details' (active) and 'Submissions'. The 'Study Details' tab contains a large text input field with the text 'Social Effects of Early Onset Hair Loss'. A large blue arrow points to this field. Below the input field are 'PDF' and 'Delete' buttons. To the right of the input field is a blue 'Save' button with a checkmark and a grey 'Cancel' button with an 'X'. A blue arrow points to the 'Save' button. At the bottom, there is a table of study information.

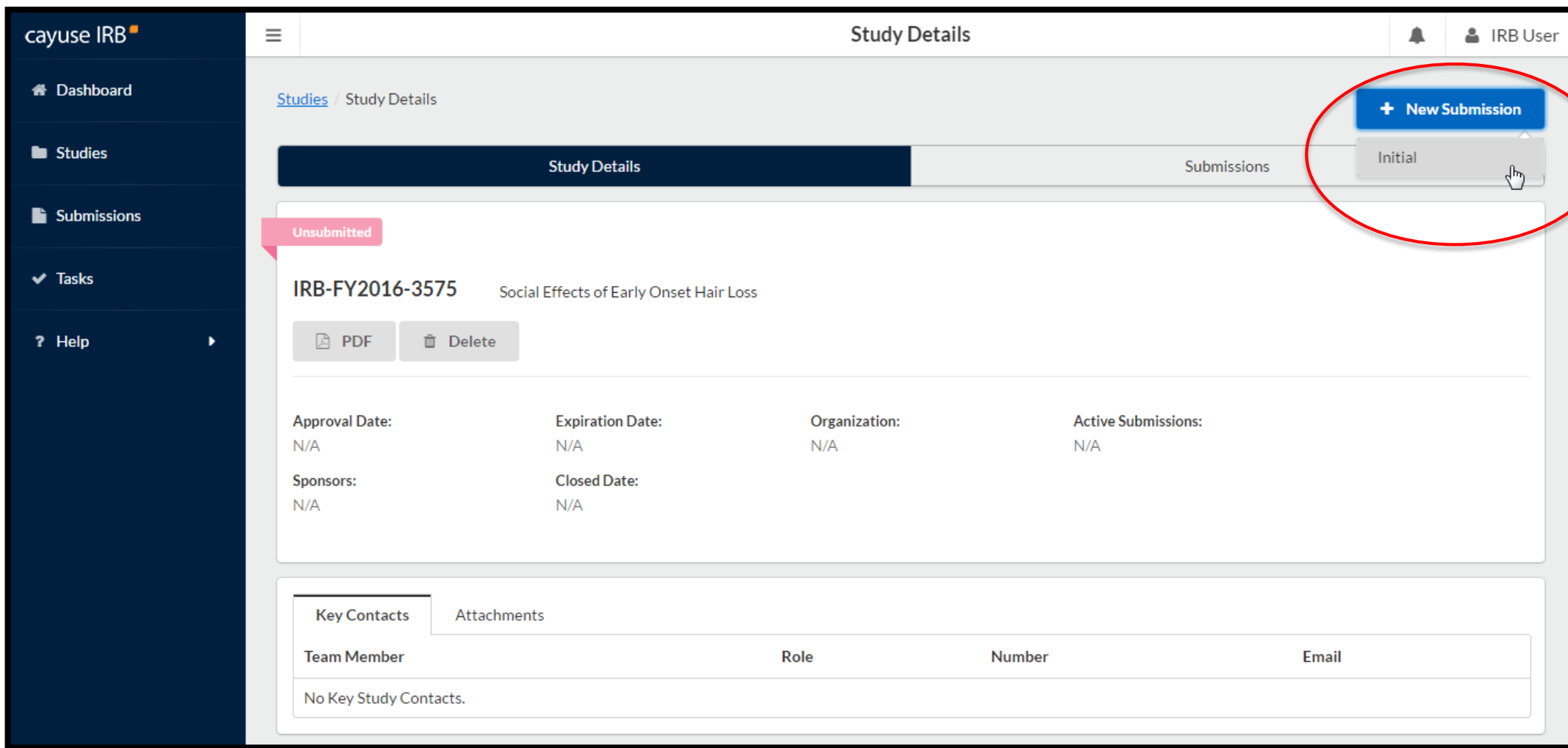
Approval Date:	Expiration Date:	Organization:	Active Submissions:
N/A	N/A	N/A	
Sponsors:	Closed Date:		
N/A	N/A		



Completing Forms

Begin Submitting Information & Documents

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



The screenshot shows the 'cayuse IRB' interface. On the left is a dark blue sidebar with navigation links: Dashboard, Studies, Submissions, Tasks, and Help. The main content area is titled 'Study Details' and shows the study 'IRB-FY2016-3575' with the title 'Social Effects of Early Onset Hair Loss'. A pink 'Unsubmitted' tag is visible. Below the study title are 'PDF' and 'Delete' buttons. A table of study details is shown below, with fields for Approval Date, Expiration Date, Organization, Active Submissions, Sponsors, and Closed Date, all currently showing 'N/A'. At the bottom, there are tabs for 'Key Contacts' and 'Attachments'. The 'Key Contacts' tab is active, showing a table with columns for Team Member, Role, Number, and Email. The table is currently empty, displaying 'No Key Study Contacts.'.

Study Details

[Studies](#) / Study Details

[+ New Submission](#)

Initial

Unsubmitted

IRB-FY2016-3575 Social Effects of Early Onset Hair Loss

PDF Delete

Approval Date:	Expiration Date:	Organization:	Active Submissions:
N/A	N/A	N/A	N/A
Sponsors:	Closed Date:		
N/A	N/A		

Key Contacts Attachments

Team Member	Role	Number	Email
No Key Study Contacts.			

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.

cayuse IRB

- Dashboard
- Studies
- Submissions
- Tasks
- Help

Submission Details

[Studies](#) / [Study Details](#) / Submission Details

- 1 In-Draft**
Submission is with researchers
- 2 Awaiting Approvals**
Submission is awaiting certification or approval
- 3 Pre-Review**
Submission is being prepared for review
- 4 Under-Review**
Submission is with reviewers

Unsubmitted

Initial
IRB-FY2016-3575 - Social Effects of Early Onset Hair Loss

Edit **PDF** **Delete**

PI: IRB User	Current Analyst: N/A	Decision: N/A	Required Tasks: ✓ Assign PI • Assign PC • Complete Submission
Review Type: N/A	Review Board: N/A	Meeting Date: N/A	

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.

The screenshot shows the 'Initial Submission Form' for the University of Memphis Institutional Review Board. The top navigation bar includes a home icon, a '< STUDY' link (circled in red), the IRB number 'tr-FY2016-31', the study title 'Test-Training Study - Initial' (with 'Initial' circled in red), and buttons for 'CREATE PDF', 'COMPARE', and 'SAVE'. The left sidebar shows 'Sections' with 'Section 1 Institutional Revi...' selected. The main content area is titled 'Section 1 Institutional Review Board Protocol Application' and features the University of Memphis logo and 'Human Research Protections Program Institutional Review Board' text. Below this is a form for the 'Principal Investigator' (marked with a red asterisk). The form includes a table with columns for Name, Organization, Address, Phone, and Email. The table contains one entry for Peter Bridson, Chemistry, at 315 Administration Building, Memphis, TN 38152-3370, with phone 901-67... and email CayuseTraining@memphis.... Below the table is a section for 'Your UofM Appointment Status' (1a) with checkboxes for Professor, Associate Professor, Assistant Professor, Instructor, Student, Staff, and Other. Further down is a section for 'Primary Contact' (2) with a 'FIND PEOPLE' button. At the bottom is a section for 'Co-Investigators' (3) with a text area and a note: 'Use the text area for investigators outside UofM, and use the Find People button below for UofM investigators.'

IRB NUMBER: tr-FY2016-31

< STUDY Test-Training Study - Initial

CREATE PDF COMPARE SAVE

Sections

Section 1 Institutional Revi...

Section 1 Institutional Review Board Protocol Application

THE UNIVERSITY OF MEMPHIS

Human Research Protections Program
Institutional Review Board

* 1 Principal Investigator

Name	Organization	Address	Phone	Email
Peter Bridson	Chemistry	315 Administration Building , Memphis, TN 38152-3370	901-67...	CayuseTraining@memphis... ✕

1a Your UofM Appointment Status

- ☐ Professor
- ☐ Associate Professor
- ☐ Assistant Professor
- ☐ Instructor
- ☐ Student
- ☐ Staff
- ☐ Other

* 2. Primary Contact

FIND PEOPLE

3 Co-Investigators

Use the text area for investigators outside UofM, and use the Find People button below for UofM investigators.

Questions marked with a red asterisk are **required**. Make sure to save your work!

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.

IRB NUMBER: tr-FY2016-31

Test-Training Study - Initial

CREATE PDF COMPARE SAVE

Sections

Section 1 Institutional Review

* 1 Principal Investigator

Name	Organization	Address	Phone	Email
Peter Bridson	Chemistry	315 Administration Building, Memphis, TN 38152-3370	901-67...	CayuseTraining@memphis...

1a Your UofM Appointment Status

- ☐ Professor
- ☐ Associate Professor
- ☐ Assistant Professor
- ☐ Instructor
- ☐ Student
- ☐ Staff
- ☐ Other

* 2. Primary Contact

FIND PEOPLE

3 Co-Investigators

Use the text area for investigators outside UofM, and use the Find People button below for UofM investigators.

B I U S L R G A

Please choose your UofM investigator(s) here:

Questions marked with a red star are **required**. Make sure to save your work!

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Primary Contact & Research Team

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

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

IRB NUMBER: tr-EY2016-31

STUDY

Sections

Section 1 Institutional Review Board

Section 2 Determination of Human Subjects Research

PRIMARY CONTACT

bridson

Name	Organization	Email	Phone	
Research Team	Chemistry	CayuseTraining@memphi...	901-678-4423	+
Your Name	Chemistry	CayuseTraining@memphi...	901-678-4423	+

Selected Records * Select a single record.

No records selected. Select a record and click **Save** to apply.

CANCEL SAVE

*2. Primary Contact

FIND PEOPLE

3 Co-Investigators

Use the text area for investigators outside UofM, and use the Find People button below for UofM investigators.

B I U S :≡ :≡ G A

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

The image displays two side-by-side screenshots of the IRB Test-Training Study - Initial form, illustrating the process of selecting a financial sponsor.

Left Screenshot:

- Section 3 Co-Investigators:** A text area for investigators outside UofM, and a "FIND PEOPLE" button for UofM investigators.
- Section 4 Is there a financial sponsor for this study?**
 - ☒ Yes
 - Select Sponsor
 - FIND SPONSORS** (indicated by a blue arrow)
 - ☐ No
- Section 5 Determination:** Do you need a determination for whether or not your study is human subjects research requiring IRB review?
 - Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.
 - Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Right Screenshot:

- Section 3 Co-Investigators:** A text area for investigators outside UofM, and a "FIND PEOPLE" button for UofM investigators.
- Section 4 Is there a financial sponsor for this study?**
 - ☐ Yes
 - ☒ No
- Section 5 Determination:** Do you need a determination for whether or not your study is human subjects research requiring IRB review?
 - Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.
 - Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

20

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 NUMBER: tr-FY2016-32

Memphis Test Trial - 2 - Initial

CREATE PDF COMPARE SAVE

Sections

- Section 1 Institution... ✓
- Section 3 IRB Protocol Gen...
- Section 4 IRB Protocol
- Section 5 Informed Consent

Please choose your UofM investigator(s) here:

FIND PEOPLE

4 Is there a financial sponsor for this study?

☐ Yes

☒ No

5 Determination

Do you need a determination for whether or not your study is human subjects research requiring IRB review?

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

☐ Yes. Proceed to determination questions for submission

☒ No. Proceed with your protocol submission

Evisions Research Suite

Leave Feedback | Contact Support

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21 IRB Protocol General Information CITI Training

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

STUDY

IRB NUMBER: tr-FY2016-32

Memphis Test Trial - 2 - Initial

CREATE PDF

COMPARE

SAVE

<

>

Sections

Section 1 Institution... ✓

Section 3 IRB Protoc... ✓

Section 4 IRB Protocol

Section 5 Informed Consent

Section 3 IRB Protocol General Information

* 6 CITI Training Completion Information

CITI (Collaborative Institutional Training Initiative at the University of Miami) Training in human subjects research is required every two years.

Date of completion:

04/07/2016

←

2016

Jan Feb Mar Apr

May Jun Jul Aug

Sep Oct Nov Dec

Research Investigators

ch

g no more than minimal risk research

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Your Protocol Information

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

STUDY

IRB NUMBER: tr-FY2017-15

Test-Comm - Initial

CREATE PDF

COMPARE

SAVE

<

>

Sections

Section 1 Institution... ✓

Section 3 IRB Protoc... ✓

Section 4 IRB Protocol

Section 5 Informed Consent

Section 4 IRB Protocol

* 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.

B I U

* 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

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

- Describe any economic or other incentives for participation including reimbursement for time and travel.
- 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)
- If the study incentive involves earning course credit, list alternative ways to earn the same credit.

Risk Benefit Analysis

15. Potential Risks

- 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.
- Identify those risks that are minimal and those which are more than minimal.
- Describe the procedures used to minimize any potential risks.

16. Potential Benefits

- Describe the direct potential benefits to the subject. If there are none, this should be so stated.
- 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

- 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.
- Indicate in your study when U of M IRB approval must be issued before the collaborator will commit to the study.
- Specify what data will be provided to the collaborator(s) and sponsor(s).
Collaboration Attachments
Letters of support, IRB approvals / protocols from collaborating institutions

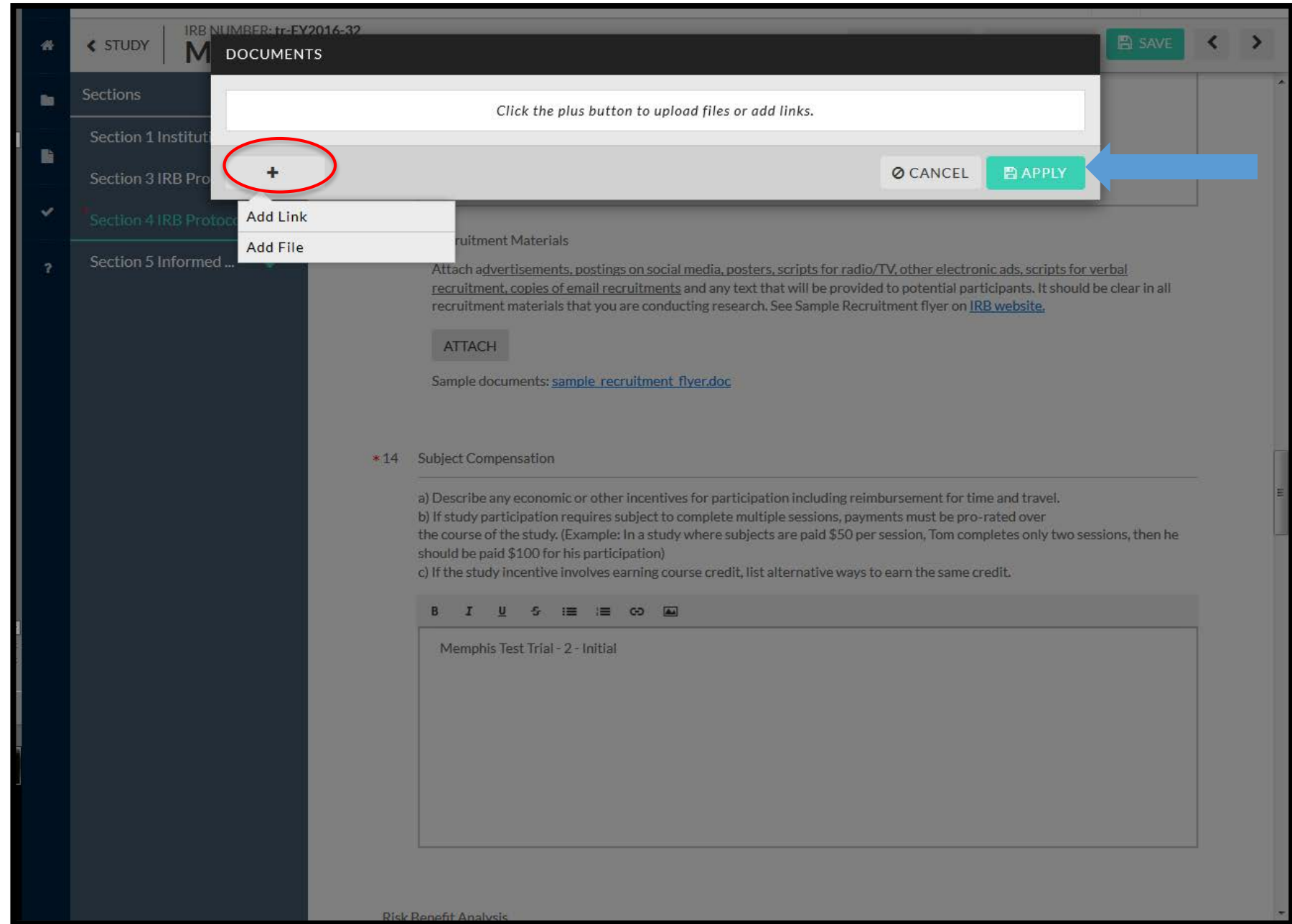
21. Proposal

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

Attachments & Links

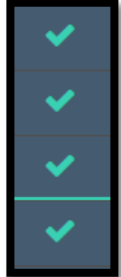
To add a document, link, or any supplemental files, select **ATTACH**. Once selected, click the plus sign (+) and Add Link and/or Add File.

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**.



STUDY

IRB NUMBER: tr-FY2016-32

Memphis Test Trial - 2 - Initial

CREATE PDF

COMPARE

SAVE

Sections

Section 1 Institution... ✓

Section 3 IRB Protoc... ✓

Section 4 IRB Protoc... ✓

Section 5 Informed ... ✓

Routing
Send to PI for certification?

COMPLETE SUBMISSION

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.

B I U S

Memphis Test Trial - 2 - Initial

* 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.

B I U S

Memphis Test Trial - 2 - Initial

27 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**.

The screenshot displays the 'Memphis Test' submission interface. The left sidebar lists sections 1 through 5, all marked with green checkmarks, indicating completion. The 'COMPLETE SUBMISSION' option is highlighted with a blue arrow. A 'SUBMISSION ROUTING' modal is open, asking 'Are you sure you want to continue?' with a red circle around the 'CONFIRM' button. The main content area shows a text editor with the text 'Memphis Test Trial - 2 - Initial' and a section for 'Additional Attachments' with an 'ATTACH' button. The footer includes the 'Evisions Research Suite' logo and contact information.

IRB NUMBER: tr-FY2016-32

Memphis Test

SUBMISSION ROUTING

Are you sure you want to continue?

CANCEL CONFIRM

Consent statement (for exempt research), or waiver requests can go here.

If you have nothing to add here, please type n/a.

Memphis Test Trial - 2 - Initial

Additional questions or concerns can be addressed to either irb@memphis.edu or by calling (901) 678-2705.

Any additional attachments can be added below:

Additional Attachments

ATTACH

Evisions Research Suite

Leave Feedback | Contact Support

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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

The screenshot shows the 'Submission Details' page for a submission titled 'Initial' (tr-FY2016-32 - Memphis Test Trial - 2). The submission is currently in the 'Awaiting Approvals' stage, which is highlighted with a red circle and a tooltip that says 'Awaiting Certification'. The progress bar at the top shows four stages: 1. In-Draft (Submission is with researchers), 2. Awaiting Approvals (Submission is awaiting certification or approval), 3. Pre-Review (Submission is being prepared for review), and 4. Under-Review (Submission is with reviewers). On the right side, there are two buttons: 'Return' and 'Certify'. A blue arrow points from the 'Certify' button to the 'Awaiting Certification' tooltip. Below the submission title, there are buttons for 'View', 'PDF', and 'Delete'. The submission details are organized into a grid with the following information:

PI:	Current Analyst:	Decision:	Required Tasks:
Peter Bridson	N/A	N/A	N/A
Review Type:	Review Board:	Meeting Date:	
N/A	N/A	N/A	

Below the grid, there are two tabs: 'Approvals' and 'Task History'. The 'Research Team' section is also visible, showing a table with the following data:

Name	Role	Result	Date
Peter Bridson	Principal Investigator	Pending Certification	



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.

IRB

STUDY | IRB NUMBER: tr-FY2016-31

Test-Training Study - Initial

CREATE PDF COMPARE SAVE

Sections

- Section 1 Institutional Revi...
- Section 2 Determination Q...

Please choose your UofM investigator(s) here:

FIND PEOPLE

4 Is there a financial sponsor for this study?

☐ Yes
☒ No

5 Determination
Do you need a determination for whether or not your study is human subjects research requiring IRB review?

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

☒ Yes. Proceed to determination questions for submission
☐ No. Proceed with your protocol submission

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Section 2 Determination Questions

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

The screenshot displays a web-based form titled "Test-Training Study - Initial" with the IRB number "tr-FY2016-31". The interface includes a sidebar with a "Sections" menu where "Section 2 Determination Q..." is selected. The main content area contains five numbered questions, each with radio button options for "Yes", "No", or "Unsure". A red oval highlights the "Section 2 Determination Questions" header in the sidebar. The top of the form has navigation buttons: "CREATE PDF", "COMPARE", "SAVE", and arrows for navigation.

IRB NUMBER: tr-FY2016-31
Test-Training Study - Initial

Sections

- Section 1 Institutional Revi...
- Section 2 Determination Q...

* 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

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**

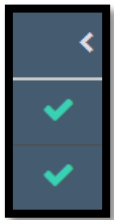
What Observations or prior scientific findings serve as the basis for this study? Why is it important to conduct this study?
10. **Study Design and Methods**

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.

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Completing Determination Submission

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



If so, select **COMPLETE SUBMISSION**.

IRB

STUDY | IRB NUMBER: tr-FY2016-31

Test-Training Study - Initial

CREATE PDF COMPARE SAVE

Sections

- Section 1 Institution... ✓
- Section 2 Determina... ✓

Routing
Send to PI for certification?

COMPLETE SUBMISSION

* 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?

B I U S : : G

Test-Training Study - Initial

11 Additional information or comments for the reviewer.

B I U S : : G

Test-Training Study - Initial

Completing Determination Submission (continued)

Select **CONFIRM** to
continue submitting
your determination.

The screenshot displays the IRB submission interface for a study titled "Test-Training". The top navigation bar includes the IRB logo, a menu icon, the study title, and the IRB number "tr-FY2016-31". A user profile dropdown shows "Your Name". The left sidebar contains a "Sections" list with "Section 1 Institution..." and "Section 2 Determina..." marked with green checkmarks, and a "Routing" section with a question mark icon and the text "Send to PI for certification?". Below this is a "COMPLETE SUBMISSION" button with a right-pointing arrow. The main content area is titled "SUBMISSION ROUTING" and displays a confirmation dialog box with the text "Are you sure you want to continue?". The dialog has two buttons: "CANCEL" and "CONFIRM". The "CONFIRM" button is highlighted with a red circle. Below the dialog, the "Study Design and Methods" section is visible, containing a text area with the text "Test-Training Study - Initial". The "Additional information or comments for the reviewer" section is also visible, containing a text area with the text "Test-Training Study - Initial".

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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.

[Studies](#) / [Study Details](#) / Submission Details

In-Draft
Submission is with researchers

2

Awaiting Approvals
Submission is awaiting certification or approval

3

Pre-Review
Submission is being prepared for review

4

Under-Review
Submission is with reviewers

Awaiting Certification

Initial
tr-FY2016-31 - Test-Training Study

View

PDF ▾

Delete

Routing:

Return

Certify

PI:

Current Analyst:

Decision:

Required Tasks:

Peter Bridson

N/A

N/A

N/A

Review Type:

Review Board:

Meeting Date:

N/A

N/A

N/A

Approvals

Task History

Research Team

36

Certifying Your Determination Submission (continued)

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

Studies / Study Details / Submission Details

1 In-Draft Submission is with researchers

2 Awaiting Approvals Submission is awaiting certification or approval

3 Pre-Review Submission is being prepared for review

4 Under-Review Submission is with reviewers

Awaiting Certification

Initial tr-FY2016

View

PI: Peter Bridson

Review Type: N/A


Approvals

Research Team

Name: Peter Bridson Principal Investigator Pending Certification

Date

Certify



I confirm that I have the proper training, expertise and resources to conduct this study. I understand and accept my responsibilities as the Principal Investigator and Primary Contact for this study. I confirm that I have no significant financial conflict of interest in this project or have disclosed a conflict per institutional policies and federal requirements. I confirm that the information provided in this application is true, complete, and accurate to the best of my knowledge; that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties; and agree to accept responsibility for the oversight and scientific conduct of the project.

Cancel Confirm

37

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.

The screenshot displays the 'Submission Details' page in an IRB system. The top navigation bar includes the IRB logo, a menu icon, the title 'Submission Details', a notification bell with a red '3', and the user's name 'Your Name'. The breadcrumb trail shows 'Studies / Study Details / Submission Details'. A progress bar at the top indicates four stages: 1. In-Draft (Submission is with researchers), 2. Awaiting Approvals (Submission is awaiting certification or approval), 3. Pre-Review (Submission is being prepared for review), and 4. Under-Review (Submission is with reviewers). The 'Pre-Review' stage is currently active. On the left sidebar, the 'Under Pre-Review' status is highlighted with a red circle. The main content area shows the submission title 'Initial' and 'tr-FY2016-32 - Memphis Test Trial - 2'. Below the title are buttons for 'View', 'PDF', and 'Delete'. A table lists submission details: PI (Peter Bridson), Current Analyst (N/A), Decision (N/A), Required Tasks (N/A), Review Type (N/A), Review Board (N/A), and Meeting Date (N/A). At the bottom, there are tabs for 'Approvals' and 'Task History', and a 'Research Team' section with a table listing team members.

Name	Role	Result	Date
Peter Bridson	Principal Investigator	Certified	06-22-2016 1:58 PM

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)

40

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**.

The screenshot displays the IRB Dashboard interface. At the top, the title 'Dashboard' is centered, and the user's name 'Your Name' is on the right. A navigation sidebar on the left contains icons for home, folder, document, checkmark, and question mark. The main content area features several widgets:

- Status Summary:** Four cards at the top show submission counts: 'In-Draft' (0), 'Awaiting Approval' (2, circled in red), 'Pre-Review' (1), and 'Under Review' (0).
- My Studies:** A table listing studies with links to details. A blue arrow points from the text 'My Studies' to the first study entry.
- My Tasks:** A table showing tasks. A blue arrow points from the first task entry to the 'Certify Submission' button, which is circled in red.
- Submissions by Type:** A table showing counts for various submission types.
- Approved Studies:** A table showing approved studies.
- Studies Expiring in 30 days:** A section showing no expiring studies.
- Expired Studies:** A section showing no expired studies.

Submissions by Type	
Initial	4
Withdrawal	0
Modification	0
Renewal	0
Incident	0
Closure	0
Legacy	0

Approved Studies	
tr-FY2017-20	3- Advisor Test

Studies Expiring in 30 days	
No Expiring Studies	

Expired Studies	
No Expired 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.

Submissions

Search: Status: Awaiting Certification | Status: Awaiting Org Approval

IRB#	Submission	Status	Review Type	PI	My Assignment	Decision	Create Date ▼
tr-FY2017-24	TWO Advisor Test 7/20 Initial	Awaiting Certification	N/A	Peter Bridson	Co-Principal Investigator	--	07-20-2016
tr-FY2017-17	Test-Advise Initial	Awaiting Certification	N/A	Andrew Meyers	Principal Investigator	--	07-12-2016

1-2 of 2

< 1 >

25 per page ▲

<https://memphis-t.cayuse424.com/rs/irb/#study/109778/87812>

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.

Submission Details

Studies / Study Details / Submission Details

In-Draft
Submission is with researchers

2 Awaiting Approvals
Submission is awaiting certification or approval

3 Pre-Review
Submission is being prepared for review

4 Under-Review
Submission is with reviewers

Awaiting Certification

Initial
tr-FY2017-24 - TWO Advisor Test 7/20

[View](#) [PDF](#) [Delete](#)

[Submission](#)

PI: Peter Bridson
Current Analyst: N/A
Decision: N/A
Required Tasks: N/A

Review Type: N/A
Review Board: N/A
Meeting Date: N/A

Approvals **Task History**

Research Team

Name	Role	Result	Date
Andrew Meyers	Co-Principal Investigator	Pending Certification	
Peter Bridson	Principal Investigator	Certified	

Routing: [Return](#) [Certify](#)

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.

IRB NUMBER: tr-FY2017-24

TWO Advisor Test 7/20 - Initial

CREATE PDF COMPARE SAVE

34

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.

tr-FY2017-24 TWO Advisor Test 7/20 - Initial

* 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 deidentified 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., preexisting programs, interventions, or classroom exercises).

tr-FY2017-24 TWO Advisor Test 7/20 - Initial

44 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.

Submission Details

Studies / Study Details / Submission Details

In-Draft
Submission is with researchers

2 Awaiting Approvals
Submission is awaiting certification or approval

3 Pre-Review
Submission is being prepared for review

4 Under-Review
Submission is with reviewers

Awaiting Certification

Initial
tr-FY2017-24 - TWO Advisor Test 7/20

[View](#) [PDF](#) [Delete](#)

[Return To Investigators](#)

[Return](#) [Certify](#)

PI:
Peter Bridson

Current Analyst:
N/A

Decision:
N/A

Required Tasks:
N/A

Review Type:
N/A

Review Board:
N/A

Meeting Date:
N/A

Approvals **Task History**

Research Team

Name	Role	Result	Date
Andrew Meyers	Co-Principal Investigator	Pending Certification	
Peter Bridson	Principal Investigator	Certified	07-20-2016 12:45 PM

Reviewing & Certifying the Submission (Advisor) continued

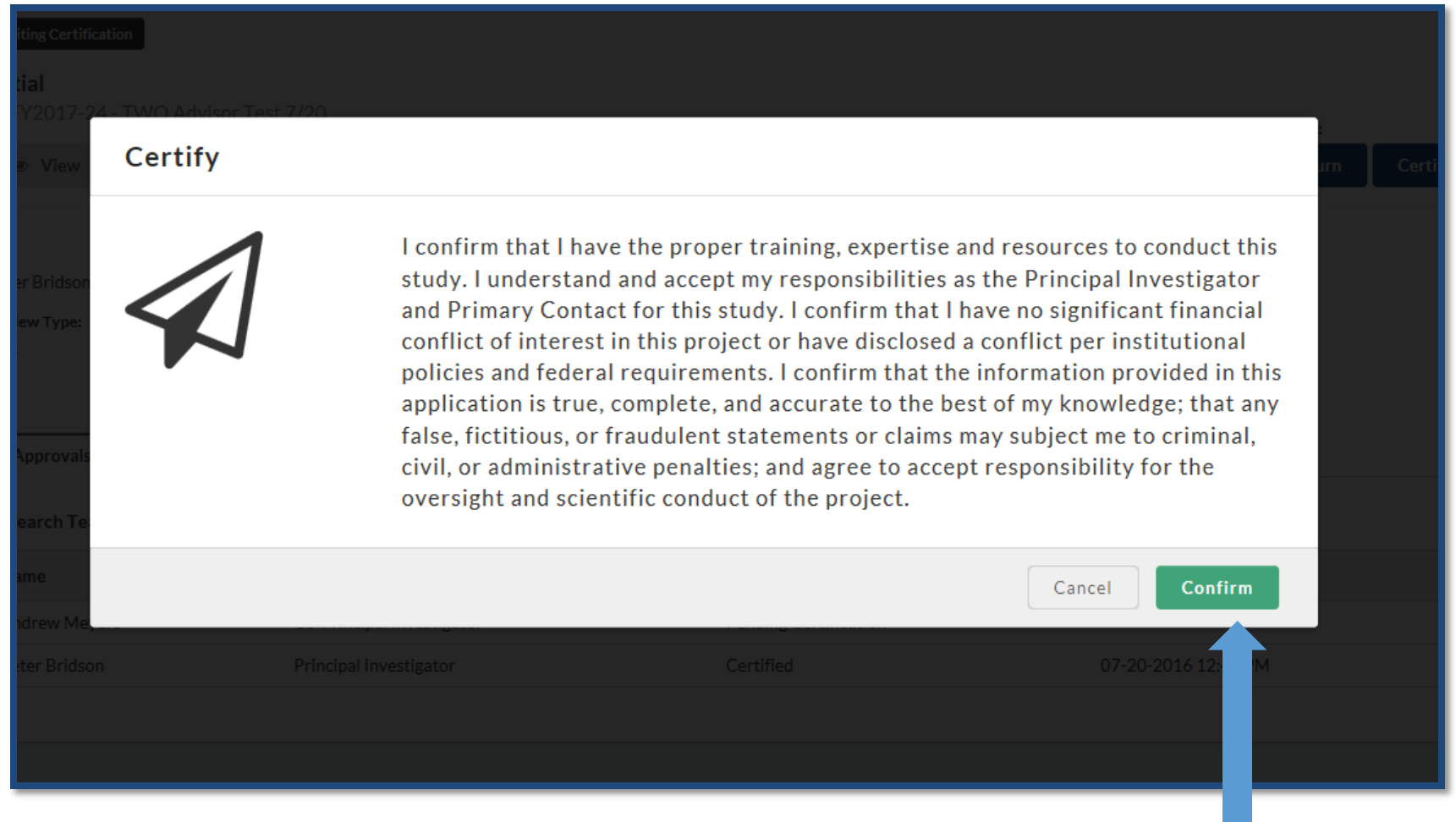
If you found the submission satisfactory and feel that is read to proceed to the IRB Analyst, select **Certify**.

The screenshot displays the IRB Submission Details page. At the top, the title 'Submission Details' is centered. Below it, a progress bar shows four stages: 1. In-Draft (Submission is with researchers), 2. Awaiting Approvals (Submission is awaiting certification or approval), 3. Pre-Review (Submission is being prepared for review), and 4. Under-Review (Submission is with reviewers). The 'Awaiting Approvals' stage is currently active. Below the progress bar, the submission title 'Initial' and ID 'tr-FY2017-24 - TWO Advisor Test 7/20' are shown. Action buttons for 'View', 'PDF', and 'Delete' are available. On the right, a 'Routing' section contains 'Return' and 'Certify' buttons, with a blue arrow pointing to the 'Certify' button. Below this, a table lists submission details: PI (Peter Bridson), Current Analyst (N/A), Decision (N/A), Required Tasks (N/A), Review Type (N/A), Review Board (N/A), and Meeting Date (N/A). At the bottom, there are tabs for 'Approvals' and 'Task History', and a 'Research Team' table.


Name	Role	Result	Date
Andrew Meyers	Co-Principal Investigator	Pending Certification	
Peter Bridson	Principal Investigator	Certified	07-20-2016 12:45 PM

Reviewing & Certifying the Submission (Advisor) continued

Select read the Certify statement and Confirm to proceed.



Certify



I confirm that I have the proper training, expertise and resources to conduct this study. I understand and accept my responsibilities as the Principal Investigator and Primary Contact for this study. I confirm that I have no significant financial conflict of interest in this project or have disclosed a conflict per institutional policies and federal requirements. I confirm that the information provided in this application is true, complete, and accurate to the best of my knowledge; that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties; and agree to accept responsibility for the oversight and scientific conduct of the project.

Principal Investigator Certified 07-20-2016 12:30 PM

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.

The screenshot displays the 'Submission Details' page in an IRB system. At the top, a progress bar shows four stages: 'In-Draft' (Submission is with researchers), 'Awaiting Approvals' (Submission is awaiting certification or approval), 'Pre-Review' (Submission is being prepared for review), and 'Under-Review' (Submission is with reviewers). The 'Pre-Review' stage is highlighted with a green border, and an orange button labeled 'Under Pre-Review' is circled in red on the left sidebar. Below the progress bar, the submission is identified as 'Initial' with ID 'tr-FY2017-24 - TWO Advisor Test 7/20'. Action buttons for 'View', 'PDF', and 'Delete' are present. A summary section lists key details: PI (Peter Bridson), Current Analyst (N/A), Decision (N/A), Required Tasks (N/A), Review Type (N/A), Review Board (N/A), and Meeting Date (N/A). At the bottom, the 'Research Team' table lists the Co-Principal Investigator and Principal Investigator, both certified on 07-20-2016.

Submission Details

[Studies](#) / [Study Details](#) / Submission Details

In-Draft
Submission is with researchers

Awaiting Approvals
Submission is awaiting certification or approval

3 Pre-Review
Submission is being prepared for review

4 Under-Review
Submission is with reviewers

Under Pre-Review

Initial
tr-FY2017-24 - TWO Advisor Test 7/20

[View](#) [PDF](#) [Delete](#)

PI:
Peter Bridson

Current Analyst:
N/A

Decision:
N/A

Required Tasks:
N/A

Review Type:
N/A

Review Board:
N/A

Meeting Date:
N/A

Approvals **Task History**

Research Team

Name	Role	Result	Date
Andrew Meyers	Co-Principal Investigator	Certified	07-20-2016 12:52 PM
Peter Bridson	Principal Investigator	Certified	07-20-2016 12:45 PM



Addressing Feedback & Contingencies

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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.

The screenshot displays the IRB Dashboard interface. At the top, the title 'Dashboard' is centered, and the user's name 'Your Name' is on the right. A notification bell icon shows 4 alerts. A '+ New Study' button is in the top right corner. Below the header, four status cards are shown: 'In-Draft' (1), 'Awaiting Approval' (0), 'Pre-Review' (1), and 'Under Review' (0). The main content area is divided into three columns. The left column, 'My Studies', lists two studies: 'tr-FY2016-31 Test-Training Study' and 'tr-FY2016-32 Memphis Test Trial - 2'. The middle column, 'My Tasks' (highlighted with a red circle), shows a task for 'tr-FY2016-31' to 'Complete Submission' with a large blue upward arrow. The right column, 'Submissions by Type', is a table with submission counts for various types. At the bottom, three sections are visible: 'Approved Studies' (No Approved Studies), 'Studies Expiring in 30 days' (No Expiring Studies), and 'Expired Studies' (No Expired Studies).

Type	Count
Initial	2
Withdrawal	0
Modification	0
Renewal	0
Incident	0
Closure	0
Legacy	0

50

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**.

IRB

Submission Details

Studies / Study Details / Submission Details

1 In-Draft
Submission is with researchers

2 Awaiting Approvals
Submission is awaiting certification or approval

3 Pre-Review
Submission is being prepared for review

4 Under-Review
Submission is with reviewers

Reopened

Initial
tr-FY2016-31 - Test-Training Study

Edit PDF Delete

PI:
Peter Bridson

Current Analyst:
Jessica McMorris

Decision:
N/A

Review Type:
Full

Review Board:
University of Memphis Full Board

Meeting Date:
N/A

Required Tasks:

- ✓ Assign PI
- ✓ Assign PC
- Complete Submission

Approvals Task History

Research Team

Name	Role	Result	Date
No entries.			

51

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.

STUDY

IRB NUMBER: tr-FY2016-31

Test-Training Study - Initial

CREATE PDF

COMPARE

SAVE

<

>

Sections

Section 1 Institutional Review Board Protocol Application 1

Section 2 Determination of Human Research Protections Program

Routing Send to PI for certification?

COMPLETE SUBMISSION

THE UNIVERSITY OF MEMPHIS

Human Research Protections Program
Institutional Review Board

* 1 Principal Investigator

Name	Organization	Address	Phone	Email	
Peter Bridson	Chemistry	315 Administration Building, Memphis, TN 38152-3370	901-67...	CayuseTraining@memphis...	x

1a Your UofM Appointment Status

☒ Professor

☐ Associate Professor

☐ Assistant Professor

☐ Instructor

☐ Student

☐ Staff

☐ Other

* 2. Primary Contact

Name	Organization	Address	Phone	Email	
Peter Bridson	Chemistry	315 Administration Building, Memphis, TN 38152-3370	901-6...	CayuseTraining@memphis...	x

Addressing Comments

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

IRB NUMBER: tr-FY2016-31

Test-Training Study - Initial

CREATE PDF COMPARE SAVE

Sections

- Section 1 Institutional Review 1
- Section 2 Determination ✓
- Routing ? Send to PI for certification?
- COMPLETE SUBMISSION ➤

Please choose your UofM investigator(s) here:

FIND PEOPLE

4 Is there a financial sponsor for this study?

☐ Yes

☒ No

5 Determination

Do you need a determination for whether or not your study is human subjects research requiring IRB review?

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

☒ Yes. Proceed to determination questions for submission

☐ No. Proceed with your protocol submission

1 Expand Comments

Evisions Research Suite

[Leave Feedback](#) | [Contact Support](#)

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Addressing Comments (continued)

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

The screenshot displays the Evisions Research Suite interface for a study titled "Test-Training Study - Initial" (IRB NUMBER: tr-FY2016-31). The left sidebar shows a navigation menu with sections: "Section 1 Institutional Revi..." (marked with a red '1' in a speech bubble), "Section 2 Determina..." (marked with a green checkmark), "Routing" (Send to PI for certification?), and "COMPLETE SUBMISSION".

The main content area shows a form with the following elements:

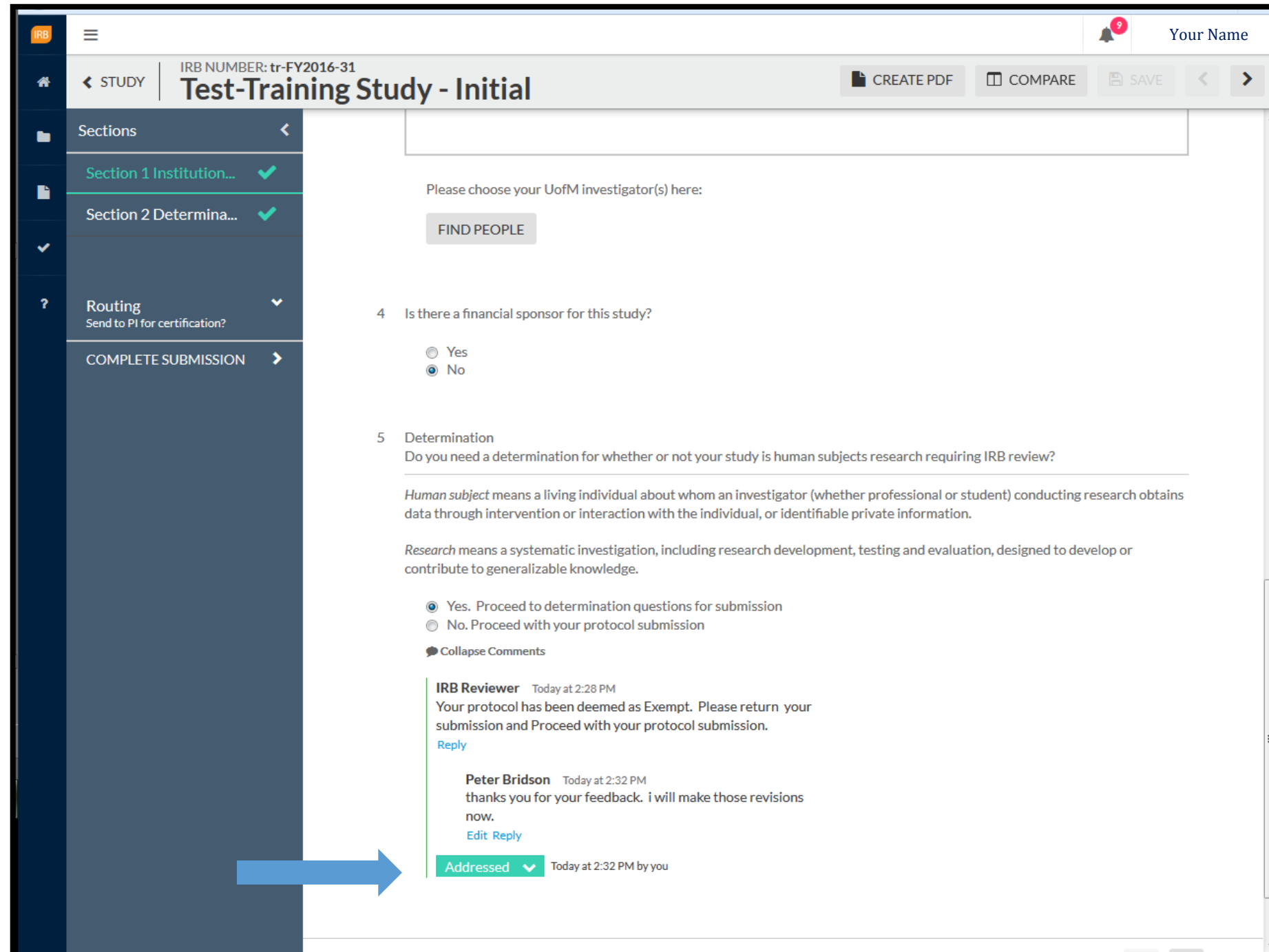
- A header bar with "STUDY" and "Test-Training Study - Initial", along with buttons for "CREATE PDF", "COMPARE", and "SAVE".
- A section titled "Please choose your UofM investigator(s) here:" with a "FIND PEOPLE" button.
- Question 4: "Is there a financial sponsor for this study?" with radio buttons for "Yes" and "No" (selected).
- Question 5: "Determination" with the text "Do you need a determination for whether or not your study is human subjects research requiring IRB review?". Below this, definitions for "Human subject" and "Research" are provided.
- Radio buttons for "Yes. Proceed to determination questions for submission" (selected) and "No. Proceed with your protocol submission".
- A "Collapse Comments" button (speech bubble icon with '1').
- A comment from an "IRB Reviewer" dated "Today at 2:28 PM": "Your protocol has been deemed as Exempt. Please return your submission and Proceed with your protocol submission." with a "Reply" link.
- A dropdown menu to address the comment with options: "Not Addressed" (selected), "Address", and "Unaddress".

Two blue arrows point from the text on the left to the "Collapse Comments" button and the "Address" dropdown option, respectively.

The footer includes the Evisions Research Suite logo and the text "Powered by Evisions, Inc. Copyright © 2015. All rights reserved." along with links for "Leave Feedback" and "Contact Support".

Addressing Comments (continued)

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



The screenshot shows the IRB Test-Training Study - Initial form. The left sidebar contains a navigation menu with sections: Sections, Section 1 Institution..., Section 2 Determina..., Routing (Send to PI for certification?), and COMPLETE SUBMISSION. The main content area displays the form for 'Test-Training Study - Initial' (IRB NUMBER: tr-FY2016-31). It includes a 'Please choose your UofM investigator(s) here:' section with a 'FIND PEOPLE' button. Below this are two questions: '4 Is there a financial sponsor for this study?' (with 'Yes' and 'No' radio buttons, 'No' selected) and '5 Determination' (with a text area for 'Do you need a determination for whether or not your study is human subjects research requiring IRB review?'). The 'Determination' section includes definitions for 'Human subject' and 'Research'. At the bottom, there is a comment from an 'IRB Reviewer' dated 'Today at 2:28 PM' stating 'Your protocol has been deemed as Exempt. Please return your submission and Proceed with your protocol submission.' Below this is a reply from 'Peter Bridson' dated 'Today at 2:32 PM' stating 'thanks you for your feedback. i will make those revisions now.' The status of the comment is 'Addressed' (indicated by a green checkmark icon) and it was updated 'Today at 2:32 PM by you'. A blue arrow points from the text 'comment status will be changed to Addressed' to the 'Addressed' status indicator.

IRB

STUDY

IRB NUMBER: tr-FY2016-31

Test-Training Study - Initial

CREATE PDF COMPARE SAVE

Sections

Section 1 Institution... ✓

Section 2 Determina... ✓

Routing
Send to PI for certification?

COMPLETE SUBMISSION

Please choose your UofM investigator(s) here:

FIND PEOPLE

4 Is there a financial sponsor for this study?

☐ Yes
☒ No

5 Determination
Do you need a determination for whether or not your study is human subjects research requiring IRB review?

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

☒ Yes. Proceed to determination questions for submission
☐ No. Proceed with your protocol submission

Collapse Comments

IRB Reviewer Today at 2:28 PM
Your protocol has been deemed as Exempt. Please return your submission and Proceed with your protocol submission.
[Reply](#)

Peter Bridson Today at 2:32 PM
thanks you for your feedback. i will make those revisions now.
[Edit](#) [Reply](#)

Addressed ✓ Today at 2:32 PM by you

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.

The screenshot displays the IRB submission routing interface for a study titled "Test-Training" with IRB number "tr-FY2016-31". A modal dialog box titled "SUBMISSION ROUTING" is open, asking "Are you sure you want to continue?". The dialog has two buttons: "CANCEL" and "CONFIRM". The "CONFIRM" button is highlighted with a red circle. In the background, the "COMPLETE SUBMISSION" button is visible in the left sidebar. The main content area shows a list of questions for the submission, including "Is there a financial sponsor for this study?" and "Determination: Do you need a determination for whether or not your study is human subjects research requiring IRB review?". The "Determination" section includes definitions for "Human subject" and "Research", and two radio button options: "Yes. Proceed to determination questions for submission" (selected) and "No. Proceed with your protocol submission". A comment from an "IRB Reviewer" is visible, stating "Your protocol has been deemed as Exempt. Please return your submission and Proceed with your protocol submission." with a "Reply" link. Below the comment, a response from "Peter Bridson" is shown, stating "thanks you for your feedback. i will make those revisions now." with "Edit" and "Reply" links. At the bottom, a green "Addressed" button is visible, indicating the submission has been addressed.

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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.

The screenshot displays the IRB Submission Details page. At the top, the title 'Submission Details' is centered. Below it, a progress bar shows four stages: 1. In-Draft (Submission is with researchers), 2. Awaiting Approvals (Submission is awaiting certification or approval), 3. Pre-Review (Submission is being prepared for review), and 4. Under-Review (Submission is with reviewers). The 'Awaiting Approvals' stage is currently active.

Below the progress bar, a section titled 'Awaiting Certification' is visible. It includes a sub-header 'Initial' and the study identifier 'tr-FY2016-31 - Test-Training Study'. There are three buttons: 'View', 'PDF', and 'Delete'. To the right, under the 'Routing:' label, there are two buttons: 'Return' and 'Certify'. The 'Certify' button is highlighted with a red circle.

Below the routing buttons, there is a table with four columns: PI, Current Analyst, Decision, and Required Tasks. The data is as follows:

PI:	Current Analyst:	Decision:	Required Tasks:
Peter Bridson	Jessica McMorris	N/A	N/A

Below this table, there is another table with four columns: Review Type, Review Board, and Meeting Date. The data is as follows:

Review Type:	Review Board:	Meeting Date:
Full	University of Memphis Full Board	N/A

Below the tables, there are two tabs: 'Approvals' and 'Task History'. The 'Approvals' tab is currently selected.

Below the tabs, there is a section titled 'Research Team' which contains a table with four columns: Name, Role, Result, and Date. The data is as follows:

Name	Role	Result	Date
Peter Bridson	Principal Investigator	Pending Certification	

Certifying Your Submission (continued)

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

The screenshot displays the 'Submission Details' page in a web application. At the top, a navigation bar shows 'Submission Details' and a user profile 'Your Name'. Below this, a progress bar indicates four stages: 1. In-Draft (Submission is with researchers), 2. Awaiting Approvals (Submission is awaiting certification or approval), 3. Pre-Review (Submission is being prepared for review), and 4. Under-Review (Submission is with reviewers). The current stage is 'Awaiting Approvals'. A modal dialog titled 'Certify' is open, featuring a paper plane icon and a confirmation statement: 'I confirm that I have the proper training, expertise and resources to conduct this study. I understand and accept my responsibilities as the Principal Investigator and Primary Contact for this study. I confirm that I have no significant financial conflict of interest in this project or have disclosed a conflict per institutional policies and federal requirements. I confirm that the information provided in this application is true, complete, and accurate to the best of my knowledge; that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties; and agree to accept responsibility for the oversight and scientific conduct of the project.' At the bottom of the modal, there are 'Cancel' and 'Confirm' buttons. The 'Confirm' button is highlighted with a red circle. In the background, a table lists submission details for 'Initial tr-FY2016', including the Principal Investigator 'Peter Bridson', Review Type 'N/A', and a status of 'Pending Certification'.

Submission Details

Studies / Study Details / Submission Details

1 In-Draft
Submission is with researchers

2 Awaiting Approvals
Submission is awaiting certification or approval

3 Pre-Review
Submission is being prepared for review

4 Under-Review
Submission is with reviewers

Awaiting Certification

Initial tr-FY2016

View

PI: Peter Bridson

Review Type: N/A

Approvals

Research Team

Name: Peter Bridson

Principal Investigator

Pending Certification

Date

Confirm

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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.

The screenshot displays the 'Submission Details' page in an IRB system. The top navigation bar includes the IRB logo, a menu icon, the title 'Submission Details', a notification bell with a red '3', and the user's name 'Your Name'. The breadcrumb trail shows 'Studies / Study Details / Submission Details'. A progress bar at the top indicates four stages: 1. In-Draft (Submission is with researchers), 2. Awaiting Approvals (Submission is awaiting certification or approval), 3. Pre-Review (Submission is being prepared for review), and 4. Under-Review (Submission is with reviewers). The 'Pre-Review' stage is currently active. On the left sidebar, the 'Under Pre-Review' status is highlighted with a red circle. Below this, the submission is identified as 'Initial' for 'tr-FY2016-32 - Memphis Test Trial - 2'. Action buttons for 'View', 'PDF', and 'Delete' are provided. A table of submission details follows, with columns for PI, Current Analyst, Decision, Required Tasks, Review Type, Review Board, and Meeting Date. Below this, there are tabs for 'Approvals' and 'Task History'. The 'Research Team' section contains a table with columns for Name, Role, Result, and Date.

PI:	Current Analyst:	Decision:	Required Tasks:
Peter Bridson	N/A	N/A	N/A

Review Type:	Review Board:	Meeting Date:
N/A	N/A	N/A

Name	Role	Result	Date
Peter Bridson	Principal Investigator	Certified	06-22-2016 1:58 PM

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.

The screenshot displays the 'Submission Details' page in the CayuseIRB system. The top navigation bar includes the IRB logo, a menu icon, the title 'Submission Details', a notification bell with '11' alerts, and the user's name 'Your Name'. The main content area is divided into two sections: 'Approvals' and 'Task History'. The 'Task History' tab is highlighted with a red circle. Below the tabs is a table with four columns: 'Name', 'Role', 'Routing Action', and 'Completion Date'. The table lists 14 entries of submission history. At the bottom, there is a pagination control showing '1-14 of 14' and a '25 per page' dropdown menu.

Name	Role	Routing Action	Completion Date
Primary Reviewer	Primary Reviewer	Review Completed	06-22-2016 2:48 PM
Jessica McMorris	Analyst	Reviewers Assigned	06-22-2016 2:45 PM
Jessica McMorris	Analyst	Review Type/Board Assigned	06-22-2016 2:45 PM
Your Name	Principal Investigator	Certified	06-22-2016 2:33 PM
Your Name	Principal Investigator	Submission Completed	06-22-2016 2:33 PM
Jessica McMorris	Analyst	Reopened for Edit	06-22-2016 2:31 PM
Your Name	Principal Investigator	Certified	06-22-2016 2:26 PM
Your Name	Principal Investigator	Submission Completed	06-22-2016 2:26 PM
Your Name	Principal Investigator	Returned for Edit	06-22-2016 2:26 PM
Your Name	Principal Investigator	Submission Completed	06-22-2016 2:26 PM
Jessica McMorris	Analyst	Reopened for Edit	06-22-2016 2:24 PM
Jessica McMorris	Analyst	Analyst Assigned	06-22-2016 2:24 PM
Your Name	Principal Investigator	Certified	06-22-2016 1:41 PM
Your Name	Principal Investigator	Submission Completed	06-22-2016 1:41 PM

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.



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**.

The screenshot displays the 'Study Details' page in the CayuseIRB system. The study ID is 'tr-FY2016-31' and the title is 'Test-Training Study'. The status 'Approved' is highlighted with a red circle. The page includes a sidebar with navigation icons, a top navigation bar with a bell icon (11 notifications) and the user's name 'Your Name', and a 'New Submission' button. The study details section shows various dates and organizational information. Below this, there are tabs for 'Key Contacts' and 'Attachments'. The 'Key Contacts' tab is active, showing a table with two team members: 'Your Name' as the Principal Investigator and 'Your Name' as the Primary Contact, both with the phone number 901-678-3447 and email CayuseTraining@memphis.edu.

Study Details

[Studies](#) / Study Details + New Submission

Study Details Submissions

Approved

tr-FY2016-31 Test-Training Study

[PDF](#) [Delete](#) [Link Proposal](#)

Approval Date: 06-22-2016 **Expiration Date:** N/A **Organization:** Chemistry **Active Submissions:** N/A

Sponsors: N/A **Closed Date:** N/A

Key Contacts Attachments

Team Member	Role	Number	Email
Your Name	Principal Investigator	901-678-3447	CayuseTraining@memphis.edu
Your Name	Primary Contact	901-678-3447	CayuseTraining@memphis.edu



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.



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.

The screenshot shows the CayuseIRB 'Studies' interface. On the left sidebar, the 'Archive' button is circled in red. The main content area displays a table of studies. The table has columns for IRB#, Study Title, Status, PI, Archive Date, and Create Date. A single study is listed with the IRB# [tr-FY2016-32](#), Study Title 'Memphis Test Trial - 2', Status 'Disapproved' (indicated by a red dot), PI 'Peter Bridson', Archive Date '06-22-2016', and Create Date '06-22-2016'. Below the table, there is a pagination control showing '1-1 of 1' and a '25 per page' dropdown menu.

IRB#	Study Title	Status	PI	Archive Date	Create Date
tr-FY2016-32	Memphis Test Trial - 2	Disapproved	Peter Bridson	06-22-2016	06-22-2016

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Disapproved Studies (continued)

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

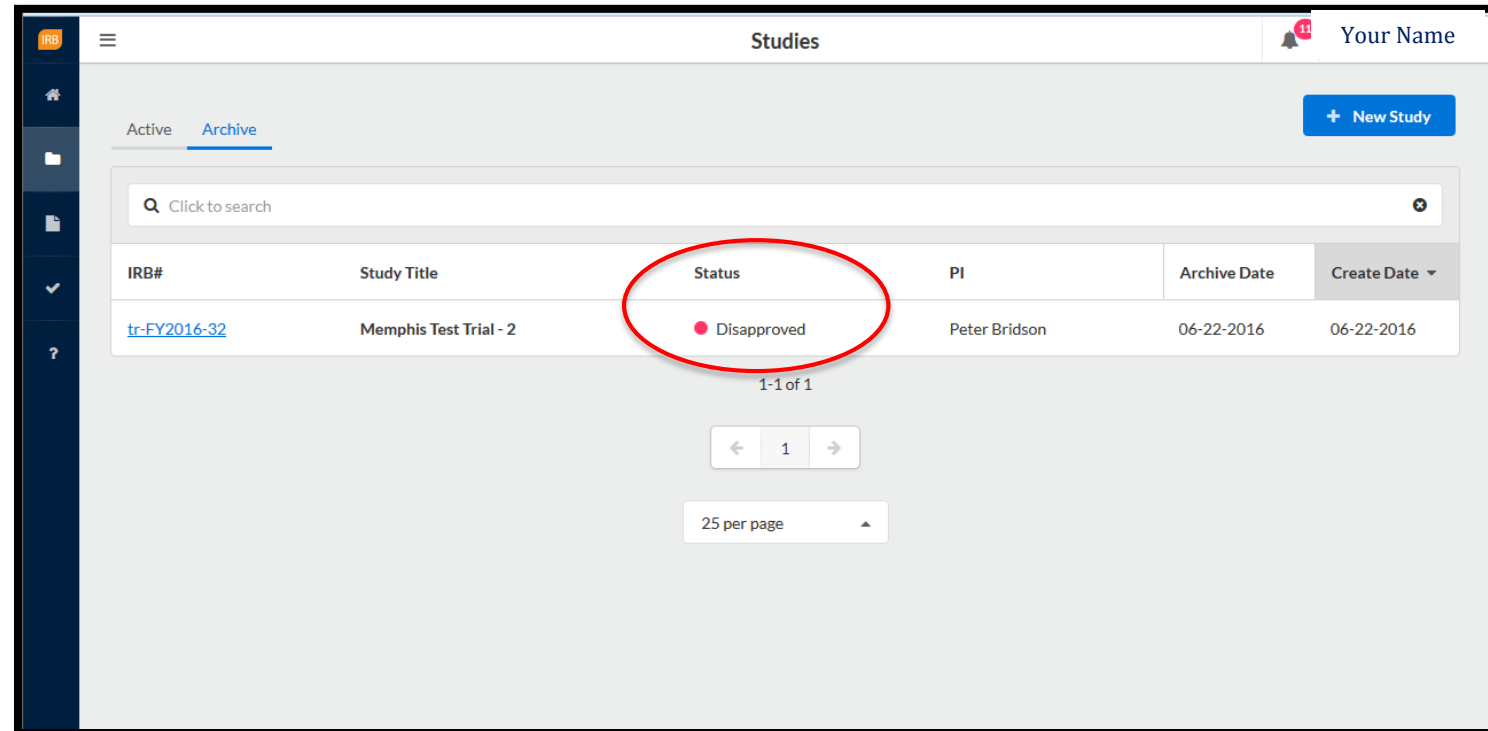
The screenshot shows the IRB Study Details page for a study named "tr-FY2016-32 Memphis Test Trial - 2". The study status is "Disapproved", indicated by a red label and a blue arrow pointing to it. The page includes a sidebar with navigation icons, a top header with the IRB logo, a menu icon, the title "Study Details", a notification bell with 11 alerts, and the user's name "Your Name". A "New Submission" button is located in the top right. The main content area has tabs for "Study Details" (selected) and "Submissions". Below the tabs, the study ID "tr-FY2016-32" and name "Memphis Test Trial - 2" are displayed, along with buttons for "PDF", "Delete", and "Link Proposal". A table of study details follows, showing fields like Approval Date, Expiration Date, Organization, Active Submissions, Sponsors, and Closed Date. At the bottom, there are tabs for "Key Contacts" and "Attachments", with the "Key Contacts" tab active, displaying a table of team members and their roles.

Team Member	Role	Number	Email
Peter Bridson	Principal Investigator	901-678-3447	CayuseTraining@memphis.edu
Peter Bridson	Primary Contact	901-678-3447	CayuseTraining@memphis.edu

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.



The screenshot shows the IRB Studies interface. The top navigation bar includes the IRB logo, a menu icon, the title "Studies", a notification bell with a red "11" badge, and the user's name "Your Name". Below the navigation bar, there are tabs for "Active" and "Archive", with "Archive" being the selected tab. A blue button labeled "+ New Study" is in the top right corner. A search bar with the placeholder "Click to search" is located below the tabs. The main content area displays a table with the following columns: IRB#, Study Title, Status, PI, Archive Date, and Create Date. A red circle highlights the "Status" column, which shows a red dot and the text "Disapproved" for the study "Memphis Test Trial - 2". The IRB# is "tr-FY2016-32". The PI is "Peter Bridson". The Archive Date is "06-22-2016" and the Create Date is "06-22-2016". Below the table, there is a pagination control showing "1-1 of 1" and a "25 per page" dropdown menu.

IRB#	Study Title	Status	PI	Archive Date	Create Date
tr-FY2016-32	Memphis Test Trial - 2	Disapproved	Peter Bridson	06-22-2016	06-22-2016



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

The screenshot displays the 'Study Details' page for a study identified as 'tr-FY2016-31 Test-Training Study'. The study status is 'Approved'. A sidebar on the right contains a '+ New Submission' button and a dropdown menu with options: 'Renewal', 'Modification', 'Incident', and 'Closure'. Below the study title, there are buttons for 'PDF', 'Delete', and 'Link Proposal'. A table lists key details: Approval Date (06-22-2016), Expiration Date (N/A), Organization (Chemistry), and Active Submissions (N/A). Below this, there are tabs for 'Key Contacts' and 'Attachments'. The 'Attachments' tab is active, showing a search bar and a table with columns 'Filename', 'Uploader', and 'Date Uploaded'. The table currently shows 'No Attachments'. At the bottom, there are navigation arrows and a '10 per page' setting.

Renewal

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

The screenshot displays the IRB Submission Details page. At the top, a progress bar shows four stages: 1 In-Draft (Submission is with researchers), 2 Awaiting Approvals (Submission is awaiting certification or approval), 3 Pre-Review (Submission is being prepared for review), and 4 Under Review (Submission is being reviewed). Below the progress bar, a pink 'Unsubmitted' label is present. The 'Renewal' button is circled in red. The study title is 'tr-FY2016-31 - Test-Training Study'. Below the title are buttons for 'Edit', 'PDF', and 'Delete'. The page is divided into four columns: 'PI:' (Your Name), 'Current Analyst:' (N/A), 'Decision:' (N/A), and 'Required Tasks:' (Complete Submission). Below these are 'Review Type:' (N/A), 'Review Board:' (N/A), and 'Meeting Date:' (N/A). A blue arrow points to the 'Complete Submission' link. At the bottom, there are tabs for 'Approvals' and 'Task History', and a 'Research Team' table with columns for Name, Role, Result, and Date. The table currently shows 'No entries.'

Submission Details

Studies / Study Details / Submission Details

1 In-Draft
Submission is with researchers

2 Awaiting Approvals
Submission is awaiting certification or approval

3 Pre-Review
Submission is being prepared for review

4 Under Review
Submission is being reviewed

Unsubmitted

Renewal

tr-FY2016-31 - Test-Training Study

Edit PDF Delete

PI: Your Name

Current Analyst: N/A

Decision: N/A

Required Tasks:

- [Complete Submission](#)

Review Type: N/A

Review Board: N/A

Meeting Date: N/A

Approvals Task History

Research Team

Name	Role	Result	Date
No entries.			

Modification

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

The screenshot displays the 'Submission Details' page for a study titled 'tr-FY2016-31 - Test-Training Study'. The page is divided into four main stages: 1. In-Draft (Submission is with researchers), 2. Awaiting Approvals (Submission is awaiting certification or approval), 3. Pre-Review (Submission is being prepared for review), and 4. Under-Review (Submission is with reviewers). The 'Unsubmitted' status is highlighted in a red box. Below the status bar, the 'Modification' section is visible, showing the study title and a list of required tasks: 'Assign PI', 'Assign PC', and 'Complete Submission'. A blue arrow points to the 'Complete Submission' link. The 'Research Team' section is also visible, showing a table with columns for Name, Role, Result, and Date, and a note that there are no entries.

Unsubmitted

Modification
tr-FY2016-31 - Test-Training Study

Edit PDF Delete

PI: Your Name
Review Type: N/A

Current Analyst: N/A
Review Board: N/A

Decision: N/A
Meeting Date: N/A

Required Tasks:
✓ Assign PI
✓ Assign PC
• [Complete Submission](#)

Approvals Task History

Research Team

Name	Role	Result	Date
No entries.			

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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.

Submission Details

[Studies](#) / [Study Details](#) / Submission Details

1 **In-Draft**
Submission is with researchers

2 **Awaiting Approvals**
Submission is awaiting certification or approval

3 **Pre-Review**
Submission is being prepared for review

4 **Under Submission**

Unsubmitted

Incident

tr-FY2016-31 - Test-Training Study

[Edit](#) [PDF](#) [Delete](#)

PI: Your Name
Current Analyst: N/A
Decision: N/A
Review Type: N/A
Review Board: N/A
Meeting Date: N/A

Required Tasks:

- [Complete Submission](#)

Approvals **Task History**

Research Team

Name	Role	Result	Date
No entries.			

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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.

[Studies](#) / [Study Details](#) / Submission Details

- 1 In-Draft**
Submission is with researchers
- 2 Awaiting Approvals**
Submission is awaiting certification or approval
- 3 Pre-Review**
Submission is being prepared for review
- 4 Under-Review**
Submission is with reviewers

Unsubmitted

Closure

tr-FY2016-31 - Test-Training Study

[Edit](#) [PDF](#) [Delete](#)

PI: Your Name Current Analyst: N/A Decision: N/A Required Tasks: [Complete Submission](#)

Review Type: N/A Review Board: N/A Meeting Date: N/A

[Approvals](#) [Task History](#)

Research Team

Name	Role	Result	Date
No entries.			

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.

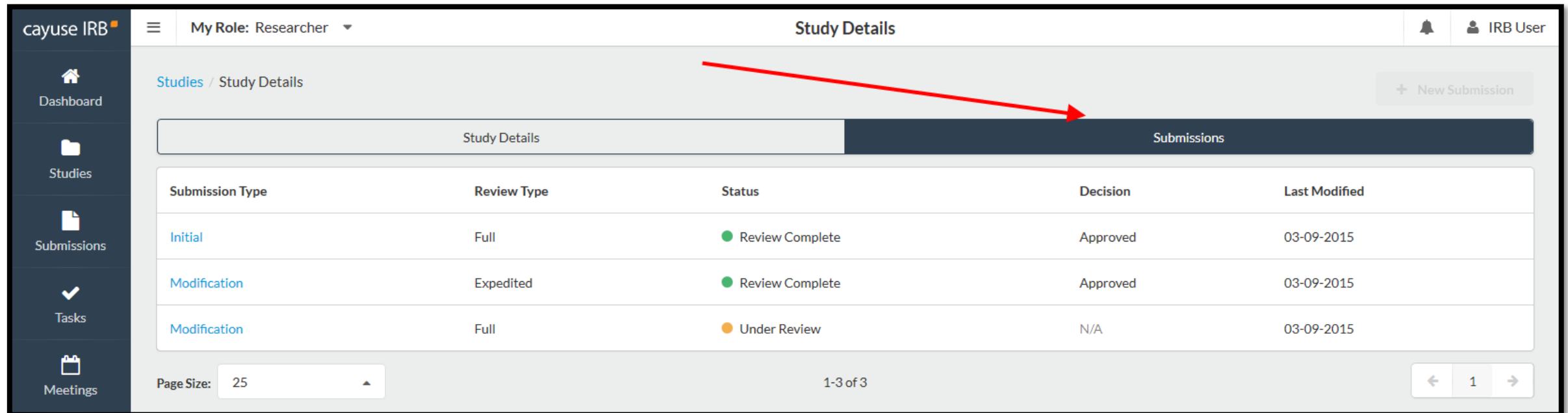
Decision	Explanation	Resulting Study Status	Routing
Approved	The study is approved.	Approved	Submission is approved and no longer editable. The research team can add additional submissions to the study.
No Engagement in Research	The study does not constitute research and therefore does not require IRB 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	<p>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.</p> <p>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".</p> <p>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.</p>	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.



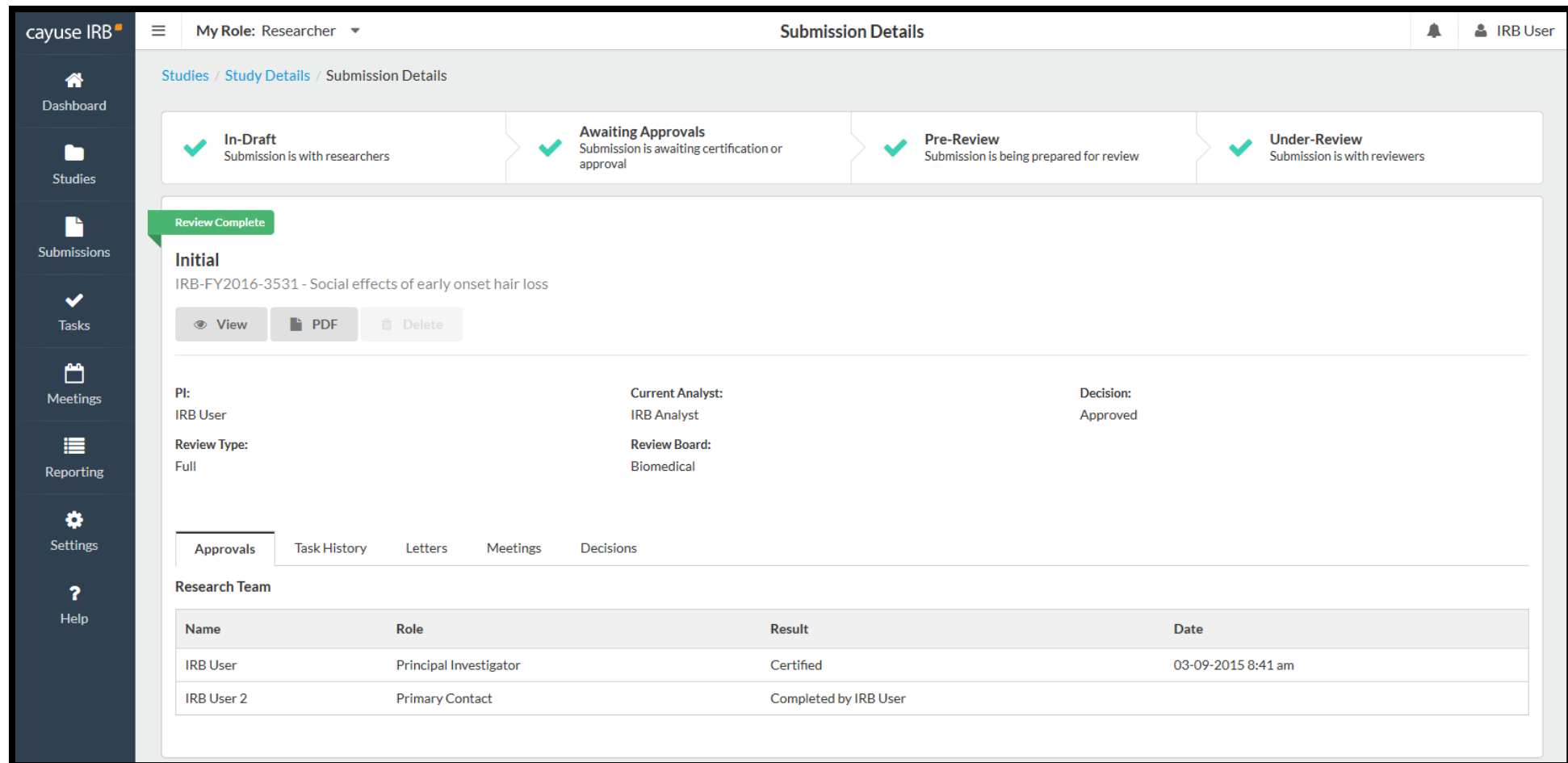
The screenshot displays the cayuse IRB interface. On the left is a dark sidebar with navigation links: Dashboard, Studies, Submissions, Tasks, and Meetings. The main content area is titled "Study Details" and shows a breadcrumb "Studies / Study Details". A red arrow points to the "Submissions" tab, which is currently active. Below the tabs is a table with submission history. The table has five columns: Submission Type, Review Type, Status, Decision, and Last Modified. There are three rows of data. At the bottom, there is a "Page Size" dropdown set to 25, a pagination indicator "1-3 of 3", and navigation buttons for previous, current page (1), and next.

Submission Type	Review Type	Status	Decision	Last Modified
Initial	Full	● Review Complete	Approved	03-09-2015
Modification	Expedited	● Review Complete	Approved	03-09-2015
Modification	Full	● Under Review	N/A	03-09-2015

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.



cayuse IRB | My Role: Researcher | Submission Details | IRB User

[Studies](#) / [Study Details](#) / Submission Details

✓ **In-Draft**
Submission is with researchers

✓ **Awaiting Approvals**
Submission is awaiting certification or approval

✓ **Pre-Review**
Submission is being prepared for review

✓ **Under-Review**
Submission is with reviewers

Review Complete

Initial
IRB-FY2016-3531 - Social effects of early onset hair loss

[View](#) [PDF](#) [Delete](#)

PI:
IRB User

Current Analyst:
IRB Analyst

Decision:
Approved

Review Type:
Full

Review Board:
Biomedical

Approvals

Task History

Letters

Meetings

Decisions

Research Team

Name	Role	Result	Date
IRB User	Principal Investigator	Certified	03-09-2015 8:41 am
IRB User 2	Primary Contact	Completed by IRB User	



Comparing Submissions

Comparing Two Versions of a Submission

The screenshot displays a web interface for comparing two versions of a submission. The title bar reads "Comparison: tr-FY2016-31 (Modification)". Below this, there are tabs for "PREVIOUS SUBMISSION" (labeled "Previously Approved Submission") and "CURRENT SUBMISSION". Navigation buttons include "VIEW SUBMISSION", "PREVIOUS DIFF", and "NEXT DIFF" (which is highlighted with a "2" in a circle). The main content area is split into two columns. Each column has a section titled "1 Modification Description" with a text area for input. Below this is a section titled "2 Does this modification involve changes to any of the following aspects of the research? (Check all that apply.)" with a list of checkboxes. In the "CURRENT SUBMISSION" column, the "Research Design and/or Resources" checkbox is checked.

Comparison: tr-FY2016-31 (Modification)

PREVIOUS SUBMISSION: Previously Approved Submission

CURRENT SUBMISSION

PREVIOUS DIFF NEXT DIFF 2

1 Modification Description

* 1 What is being modified? Describe all the changes requested and provide a brief rationale for each.

2 Does this modification involve changes to any of the following aspects of the research? (Check all that apply.)

- ☐ Research Design and/or Resources
- ☐ Risks to Participants or Others in Relation to Anticipated Benefits
- ☐ Participant Selection or Recruitment/Approach Process
- ☐ Consent Process and /or Compensation
- ☐ Methods for Documenting Consent
- ☐ Potential Willingness of Research Participants to Continue to Take Part in This Study
- ☐ Monitoring of the Data Being Collected
- ☐ Privacy of the Research Participants and/or Confidentiality of Research Participants' Data
- ☐ None of the above

1 Modification Description

* 1 What is being modified? Describe all the changes requested and provide a brief rationale for each.

Research

2 Does this modification involve changes to any of the following aspects of the research? (Check all that apply.)

- ☒ Research Design and/or Resources
- ☐ Risks to Participants or Others in Relation to Anticipated Benefits
- ☐ Participant Selection or Recruitment/Approach Process
- ☐ Consent Process and /or Compensation
- ☐ Methods for Documenting Consent
- ☐ Potential Willingness of Research Participants to Continue to Take Part in This Study
- ☐ Monitoring of the Data Being Collected
- ☐ Privacy of the Research Participants and/or Confidentiality of Research Participants' Data
- ☐ None of the above

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.



81 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.

The screenshot shows the 'cayuse IRB' interface. On the left is a dark blue sidebar with navigation links: Dashboard, Studies, Submissions, Tasks, and Help. The main content area is titled 'Study Details' and shows a breadcrumb 'Studies / Study Details'. Below this is a tabbed interface with 'Study Details' and 'Submissions'. A red circle highlights a dropdown menu in the top right corner of the main area, which contains a blue '+ New Submission' button and a grey 'Legacy' button with a mouse cursor pointing at it. The 'Legacy' button is selected. Below the tabs, a 'Legacy' label is shown next to the study ID 'IRB-FY2011-126' and title 'Use of Compression in Wound Healing'. There are 'PDF' and 'Delete' buttons. A table of metadata follows: Approval Date (11-15-2011), Expiration Date (N/A), Organization (N/A), Active Submissions (N/A), Sponsors (N/A), and Closed Date (N/A). At the bottom, there are tabs for 'Key Contacts' and 'Attachments'. The 'Key Contacts' tab is active, showing a table with columns: Team Member, Role, Number, and Email.

Team Member	Role	Number	Email
IRB User	Principal Investigator		
IRB User 2	Primary Contact		

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.

The screenshot shows the Cayuse IRB interface. On the left is a dark blue sidebar with navigation links: Dashboard, Studies, Submissions, Tasks, and Help. The main content area is titled "Submission Details" and shows a progress bar with four stages: 1 In-Draft (Submission is with researchers), 2 Awaiting Approvals (Submission is awaiting certification or approval), 3 Pre-Review (Submission is being prepared for review), and 4 Under-Review (Submission is with reviewers). Below the progress bar, a pink "Unsubmitted" tag is visible. The submission is titled "Legacy" with ID "IRB-FY2011-126". Below the title, there are three buttons: "Edit" (circled in red with a hand cursor), "PDF", and "Delete". At the bottom, there is a table of submission details:

PI:	Current Analyst:	Decision:	Required Tasks:
IRB User	N/A	N/A	• Complete Submission
Review Type:	Review Board:	Meeting Date:	
N/A	N/A	N/A	



Linking Your Study to Cayuse Sponsored Project(s)

Linking a Study to Cayuse SP

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

The screenshot displays the Cayuse IRB interface. On the left is a dark blue sidebar with navigation links: Dashboard, Studies, Submissions, Tasks, and Help. The main content area is titled 'Study Details' and shows the details for study 'IRB-FY2016-3584' titled 'Social Effects of Early Onset Hair Loss'. A red circle highlights the 'Link Proposal' button, which is located next to 'PDF' and 'Delete' buttons. Below the buttons, there are fields for 'Approval Date', 'Expiration Date', 'Organization', 'Sponsors', 'Closed Date', and 'Active Submissions'. The 'Active Submissions' field shows a link to 'Initial'. At the bottom, there is a table for 'Key Contacts' with columns for 'Team Member', 'Role', 'Number', and 'Email'. The table lists 'IRB User' as the 'Principal Investigator'.

Study Details

Studies / Study Details

[+ New Submission](#)

Study Details Submissions

Unsubmitted

IRB-FY2016-3584 Social Effects of Early Onset Hair Loss

[PDF](#) [Delete](#) [Link Proposal](#)

Approval Date: N/A Expiration Date: N/A Organization: N/A Active Submissions: [Initial](#)

Sponsors: N/A Closed Date: N/A

Key Contacts Attachments

Team Member	Role	Number	Email
IRB User	Principal Investigator		

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**.

The screenshot displays the 'Study Details' interface in Cayuse IRB. On the left is a dark blue sidebar with navigation links: Dashboard, Studies, Submissions, Tasks, and Help. The main content area has a header with a menu icon, the title 'Study Details', a notification bell, and the user 'IRB User'. Below the header is a 'Link Proposals' section containing a table with the following data:

Proposal #	Lead PI	Status	Begin Date	End Date	Linked
16-0005	IRB User	UNSUBMITTED	10-31-2015	10-31-2015	<input type="checkbox"/>
16-0006	IRB User	UNSUBMITTED	10-31-2015	10-31-2015	<input checked="" type="checkbox"/>
16-0007	IRB User	UNSUBMITTED	11-19-2015	11-26-2015	<input type="checkbox"/>

To the right of the table is a 'Linked Proposals' box containing the entry '16-0006' with a close icon (x). In the top right corner of the main area is a blue 'Done' button with a checkmark icon, which is highlighted by a blue arrow.



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).

The screenshot displays the IRB Study Details interface. At the top, the title 'Study Details' is centered, and the user's name 'Your Name' is in the top right corner. A notification bell icon shows 15 alerts. Below the title, a breadcrumb trail reads 'Studies / Study Details'. A blue button labeled '+ New Submission' is located in the top right. A blue arrow points from the 'Submitted' tab to the 'Withdrawal' option in a dropdown menu. The 'Submitted' tab is highlighted with a red circle. The main content area shows the study ID 'tr-FY2017-19' and the title 'Withdraw-Test'. Below this are three buttons: 'PDF', 'Delete', and 'Link Proposal'. The study details section includes fields for 'Approval Date: N/A', 'Expiration Date: N/A', 'Organization: Chemistry', and 'Active Submissions: • Initial'. At the bottom, there are two tabs: 'Key Contacts' and 'Attachments'. The 'Key Contacts' tab is active, showing a table with columns for 'Team Member', 'Role', 'Number', and 'Email'.

Team Member	Role	Number	Email
Your Name	Principal Investigator	901-678-3447	CayuseTraining@memphis.edu
Your Name	Primary Contact	901-678-3447	CayuseTraining@memphis.edu

Withdrawal (continued)

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

IRB

STUDY

IRB NUMBER: tr-FY2017-19

Withdraw-Test - Withdrawal

CREATE PDF

COMPARE

SAVE

Sections

Withdrawal of Submission ...

Withdrawal of Submission by PI before IRB approval

Please tell us why you are withdrawing this submission:

B I U

ATTACH

Evisions Research Suite

Leave Feedback | Contact Support

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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.

The screenshot displays the Evisions Research Suite interface for IRB management. The top navigation bar includes the IRB logo, a menu icon, and the text 'IRB NUMBER: tr-FY2017-19'. The main title is 'Withdraw-Test - Withdrawal'. On the right, there are buttons for 'CREATE PDF', 'COMPARE', and 'SAVE', along with a user profile icon labeled 'Your Name'.

The left sidebar contains a 'Sections' menu with the following items: 'Withdrawal of Submi...' (checked), 'Routing' (with a dropdown arrow and the subtext 'Send to PI for certification?'), and 'COMPLETE SUBMISSION' (highlighted with a red circle and a right-pointing arrow). Below the sidebar, the main content area is titled 'Withdrawal of Submission by PI before IRB approval'. It includes a text prompt: 'Please tell us why you are withdrawing this submission:', followed by a rich text editor with a toolbar (B, I, U, etc.) and a large text area. Below the text area is an 'Attach any documentation' section with an 'ATTACH' button.

The footer of the interface features the Evisions Research Suite logo on the left and links for 'Leave Feedback' and 'Contact Support' on the right, with a copyright notice: 'Powered by Evisions, Inc. Copyright © 2015. All rights reserved.'

Withdrawal (continued)

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

The screenshot shows the IRB Submission Details page. The top navigation bar includes the IRB logo, a menu icon, the title 'Submission Details', a notification bell with '15', and a user profile icon labeled 'Your Name'. The breadcrumb trail is 'Studies / Study Details / Submission Details'. The main content area features a progress bar with four steps: 1. In-Draft (Submission is with researchers), 2. Awaiting Approvals (Submission is awaiting certification or approval), 3. Pre-Review (Submission is being prepared for review), and 4. Under-Review (Submission is with reviewers). Below the progress bar, a dropdown menu is open, showing 'Awaiting Certification' and 'Withdrawal' (highlighted with a red circle). The submission title is 'tr-FY2017-19 - Withdraw-Test'. Action buttons include 'View', 'PDF', 'Delete', 'Return', and 'Certify' (highlighted with a blue arrow). The 'Routing:' section is empty. The 'Research Team' table lists the Principal Investigator as 'Your Name' with a 'Pending Certification' result.

Name	Role	Result	Date
Your Name	Principal Investigator	Pending Certification	

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Withdrawal (continued)

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

IRB

Submission Details

15

Your Name

[Studies](#) / [Study Details](#) / Submission Details

✓ In-Draft
Submission is with researchers

✓ Awaiting Approvals
Submission is awaiting certification or approval

3 Pre-Review
Submission is being prepared for review

4 Under-Review
Submission is with reviewers

Under Pre-Review

Withdrawal

tr-FY2017-19 - Withdraw-Test

View PDF Delete

PI:

Your Name

Current Analyst:

N/A

Decision:

N/A

Required Tasks:

N/A

Review Type:

N/A

Review Board:

N/A

Meeting Date:

N/A

Approvals

Task History

Research Team

Name	Role	Result	Date
Your Name	Principal Investigator	Certified	07-14-2016 12:13 PM

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



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.

The screenshot displays the IRB Submission Details page. At the top, the title 'Submission Details' is centered, with a notification bell icon showing 17 alerts and a user profile icon labeled 'Your Name' on the right. The breadcrumb trail reads 'Studies / Study Details / Submission Details'. Below this, a progress bar shows four stages: 'In-Draft' (Submission is with researchers), 'Awaiting Approvals' (Submission is awaiting certification or approval), 'Pre-Review' (Submission is being prepared for review), and 'Under-Review' (Submission is with reviewers). A green button labeled 'Review Complete' is highlighted with a red circle. Below the button, the submission title 'Withdrawal' and identifier 'tr-FY2017-19 - Withdraw-Test' are shown. Action buttons for 'View', 'PDF', and 'Delete' are available. The submission details are organized into two columns: 'PI: Your Name' and 'Review Type: N/A' on the left; 'Current Analyst: Jessica McMorris' and 'Review Board: N/A' on the right; and 'Decision: N/A' on the far right. Below these details are tabs for 'Approvals', 'Task History', and 'Letters'. The 'Research Team' section contains a table with the following data:

Name	Role	Result	Date
Your Name	Principal Investigator	Certified	07-14-2016 12:13 PM

Withdrawal (continued)

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

The screenshot displays the IRB Submission Details page. At the top, the status bar shows four stages: In-Draft, Awaiting Approvals, Pre-Review, and Under-Review, all with green checkmarks. Below this, a green banner indicates 'Review Complete'. The main section is titled 'Withdrawal' for submission 'tr-FY2017-19 - Withdraw-Test'. It includes buttons for 'View', 'PDF', and 'Delete'. Below these are fields for PI (Your Name), Current Analyst (Jessica McMorris), Decision (N/A), Review Type (N/A), and Review Board (N/A). A red circle highlights the 'Task History' tab, which is selected. Below the tabs is a table showing routing actions.

Name	Role	Routing Action	Completion Date
Jessica McMorris	Analyst	Study Withdrawn	07-14-2016 12:14 PM
Jessica McMorris	Analyst	Analyst Assigned	07-14-2016 12:14 PM
Your Name	Principal Investigator	Certified	07-14-2016 12:13 PM
Your Name	Principal Investigator	Submission Completed	07-14-2016 12:13 PM

1-4 of 4

Navigation: < 1 >

25 per page



How will I know my study has been approved?

- You will be notified via CayuseIRB notifications and email! All Study Submission statuses 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.

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 your 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 you 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.

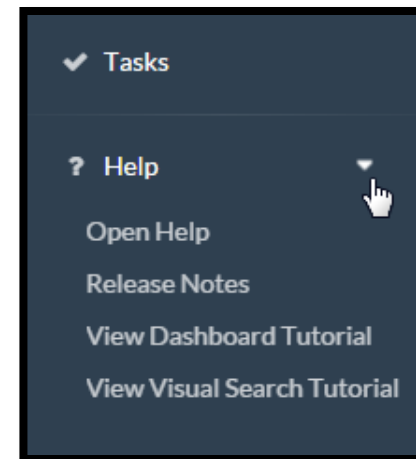


Additional Assistance

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