



Cayuse IRB

Policy and Procedure Manual

Table of Contents

<u>Cayuse IRB Policy and Procedure Manual</u>	1
<u>Submitting a New IRB Protocol</u>	2
<u>Purpose of the Policy</u>	2
<u>Procedures</u>	2
<u>Modification of an Existing Cayuse IRB Protocol</u>	6
<u>Purpose of the Policy</u>	6
<u>Procedures</u>	6
<u>Renewal/Continuing Review of an Existing Cayuse IRB Protocol</u>	10
<u>Purpose of the Policy</u>	10
<u>Procedures</u>	10
<u>Withdrawal of an Unsubmitted Cayuse IRB Protocol</u>	13
<u>Purpose of the Policy</u>	13
<u>Procedures</u>	13
<u>Closure of a Completed Cayuse IRB Protocol</u>	17
<u>Purpose of the Policy</u>	17
<u>Procedures</u>	17
<u>Reporting an Incident in Cayuse IRB</u>	20
<u>Purpose of the Policy</u>	20
<u>Procedures</u>	20

Submitting a New IRB Protocol

Policy Number: IRB101

Policy Date: 12/21/2017

Purpose of the Policy

This policy provides guidelines for the submission of new IRB protocols in Cayuse IRB. The objective of this policy is to ensure users have the proper CITI Human Subject Protections training before being added as an investigator to a study and to ensure proper and consistent setup of new IRB protocols.

Procedures

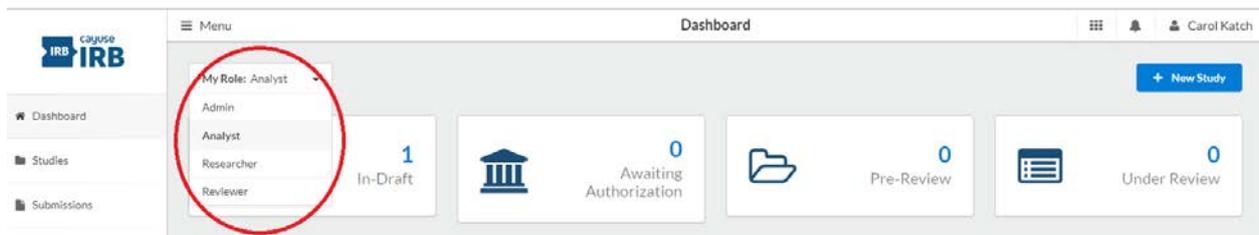
New IRB protocols may be entered by investigator's at any time. A pre-review will be done to determine if any items are missing. You will be made aware of any additional documentation or requirements within 10 business days of receipt by the ORSP. Typically, protocols that are classified as "Exempt" or "Expedited" will also have a determination made within the 10 business days. Each time revisions are requested, it may take up to 10 business days from receipt by the IRB staff before a determination can be made.

If it is determined that your study requires Full Convened Board Review, your study will be placed on the agenda for the next monthly meeting of the Board. To ensure your Full Board Protocol is reviewed promptly, it must be submitted by the first of the month to be included on that month's agenda.

NOTE: No protocols will be accepted if any researchers have not completed the required CITI training. The protocol will be denied and returned without review.

Log into the Cayuse Research Suite at the link: <https://uww.cayuse424.com>.

- Choose [Cayuse IRB]
- On the top left of the "Dashboard" page, your current role will be indicated. If you have more than one role, please select [Researcher] from the dropdown menu to beginning entering your study.



(Screen Shot 3)

- Choose the [+ New Study] tab at the top of the screen.
- Enter {The Title of Your Study}.
- Choose []
- Choose [+ New Submission]
- Choose [Initial]

On the Submission Details Page,

- Choose [Edit]

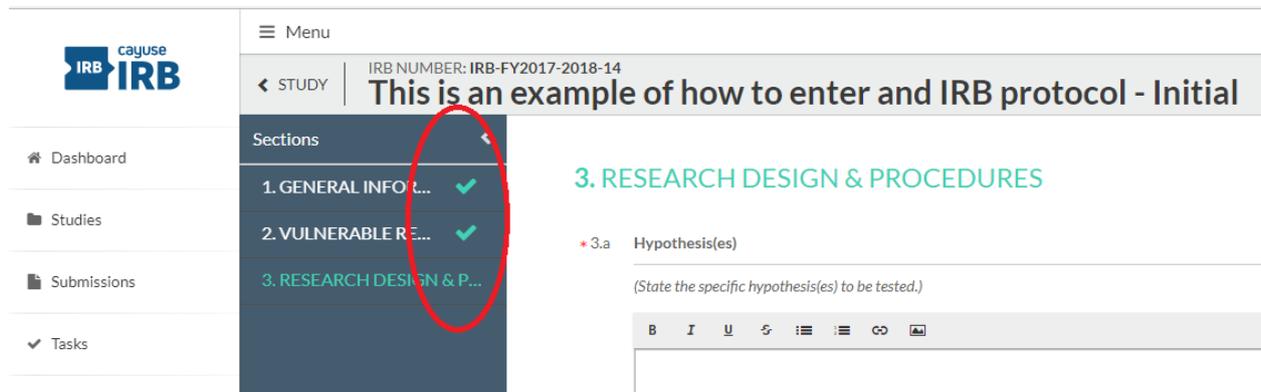
Follow the step-by-step instructions in the Cayuse IRB Initial Application. Most sections of the application must be answered.

Each section that needs to be completed will be listed in the pane at the left side of your screen. You can move between the sections by clicking on the section in the pane on the left side of your screen, or by using the forward/backward arrow keys on the top right side of your screen (see Screen Shot 4).



(Screen Shot 4)

The section is completed when it has a green checkmark next to it in this pane (see Screen Shot 5).



(Screen Shot 5)

- Choose [Complete Submission]
- Choose [Confirm] or you may [Cancel] and make changes.

Once you have “confirmed” your study, you will be taken to the Submission details page, and the status has now changed to “awaiting certification”. An email will be sent to the P.I., Co-Investigators and Student’ Investigators for certification. Each investigator must login to Cayuse IRB and certify that they agree to the Investigator’s Certification Statement.

There is a link to Cayuse IRB in the email however, you may also;

Log into the Cayuse Research Suite at the link: <https://uww.cayuse424.com>.

- Choose [Cayuse IRB]
- On the of the Dashboard page, Choose [Awaiting Authorization]
- Choose [The number of the protocol you wish to Certify]
- On the right side of the screen, Choose [Certify].
 - You may also choose to [Return] the protocol to the investigators to re-certify the protocol if changes were made by an investigator.
- Read Investigator’s certification statement and Choose [Confirm].
 - The protocol will not proceed for the Administrative Review process until all investigators have certified their agreement.

Once all investigators have completed the certification process, they will receive an email notification that the study has been certified and sent to the IRB for review.

The Study is sent to an IRB Administrator (Analyst) for pre-view. You will be notified if any information is still required. If no additional information is required, the IRB Administrator will make a determination on the classification of the study. If the study is classified as "Exempt" or "Expedited" you will receive an email notice within approximately 10 working days. If the study is classified as "Full Board Review" you will be notified of the date and time of the IRB Meeting where it will be reviewed. Your attendance is encouraged, but not required at the meeting of the fully convened board.

Modification of an Existing Cayuse IRB Protocol

Policy Number: IRB102

Policy Date: 12/21/2017

Purpose of the Policy

This policy provides guidelines for the modification of existing IRB protocols in Cayuse IRB. The objective of this policy is to ensure proper and consistent modification of IRB protocols.

Procedures

After a study has been approved by the UWW IRB, the only way to make changes is through a modification. A pre-review will be done to determine if any items are missing or if the modification you have requested changes the category of the protocol (e.g.: from expedited to Full Board). You will be made aware of any additional documentation or requirements within 10 business days of receipt by the ORSP. Typically, protocols that are classified as “Exempt” or “Expedited” will also have a determination made within the 10 business days. Each time revisions are requested, it may take up to 10 business days from receipt by the IRB staff before a determination can be made.

If it is determined that your study requires Full Convened Board Review, your study will be placed on the agenda for the next monthly meeting of the Board.

NOTE: No protocol modification will be accepted if any added researchers have not completed the required CITI training. The protocol will be denied and returned without review.

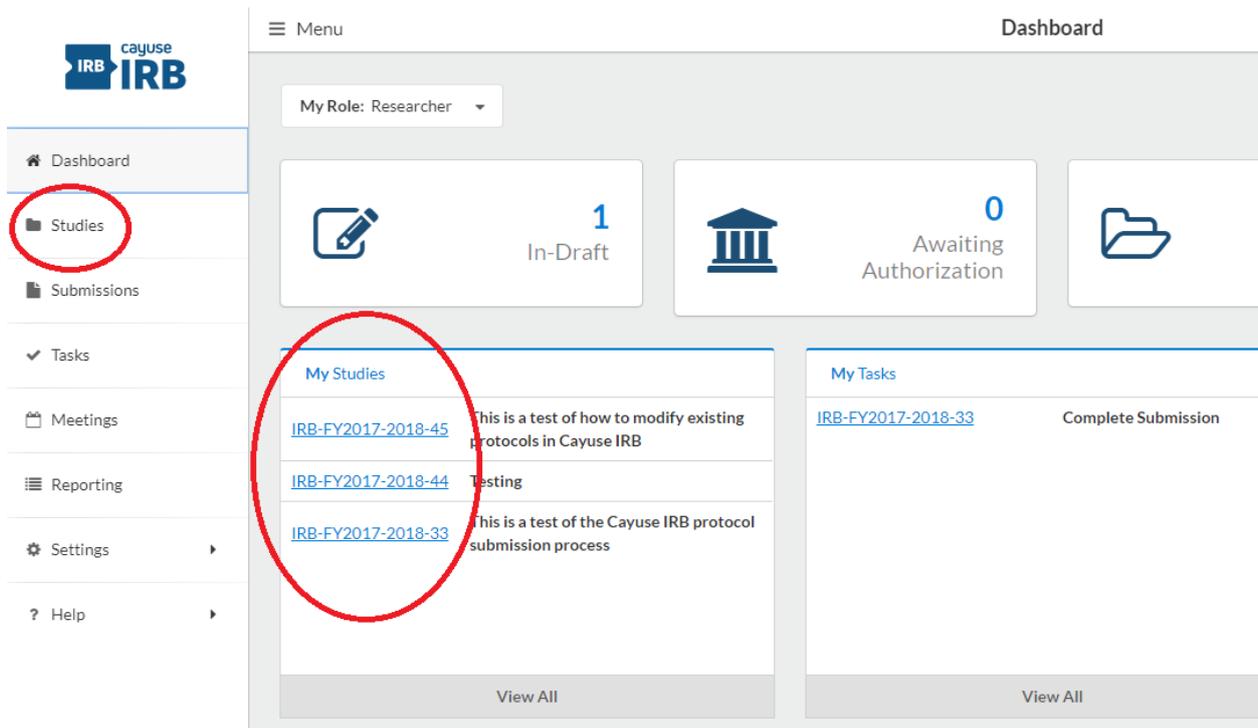
Log into the Cayuse Research Suite at the link: <https://uww.cayuse424.com>.

- Choose [Cayuse IRB]

On the Dashboard Page, if you have more than one role in Cayuse IRB, make sure your role is set at “Researcher”.

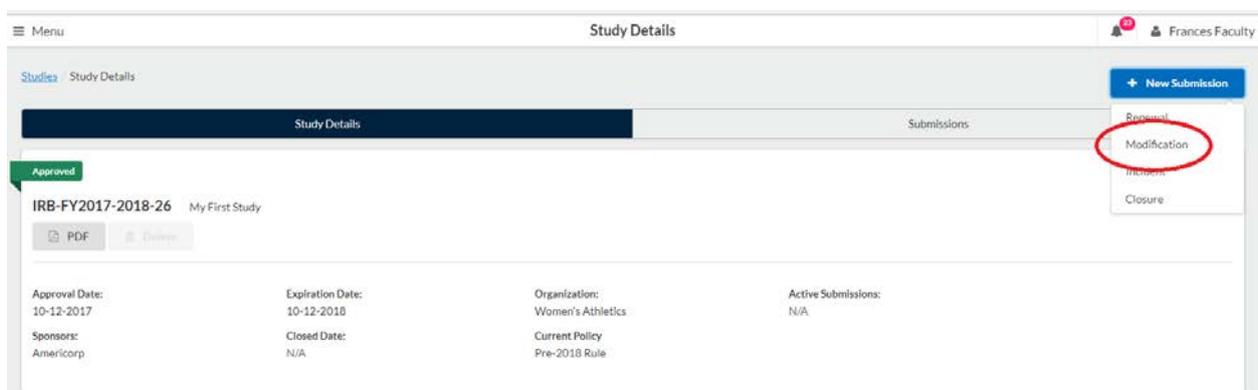
Under my studies,

- Choose [The study number you wish to modify]



(Screen Shot 6)

- In the upper right corner, Choose [+ New Submission]
- From the drop down options, Choose [Modify]



(Screen Shot 7)

- On the left side of the screen, Choose [Edit]
- Complete the IRB Protocol Modification summary
- On the left section pane, select the section(s) you would like to modify.
- On the top ribbon, Choose [Save]
- On the left section pane, Choose [Complete Submission]
- Choose [Confirm], or you may cancel and make changes

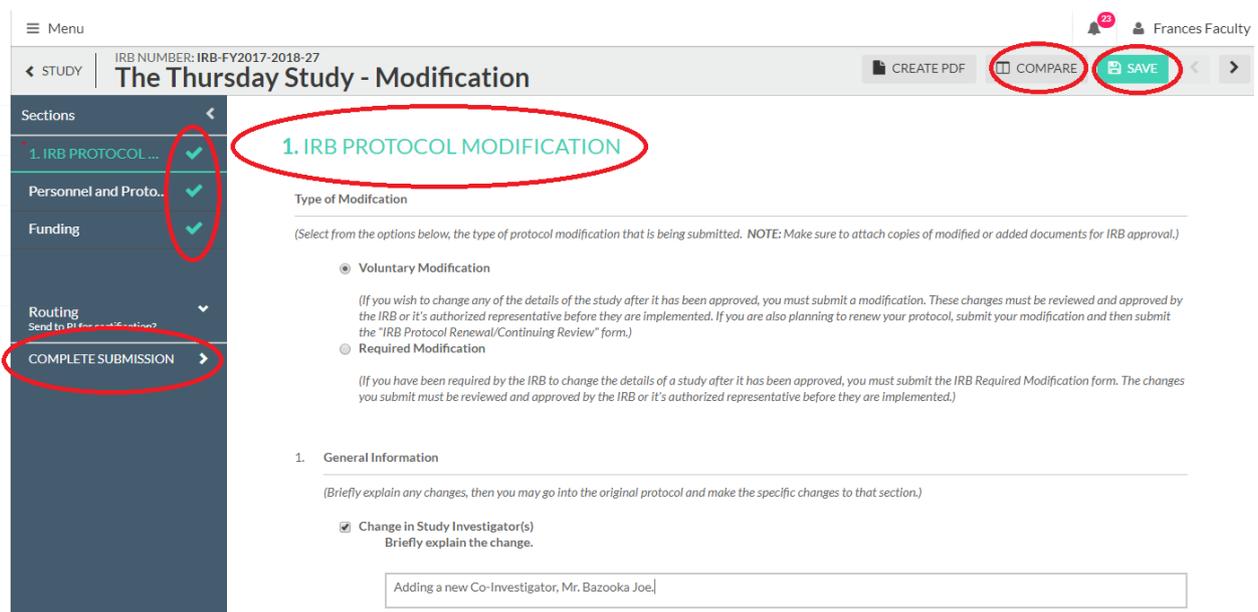
- Choose [Proceed]

You may also Choose [Compare] at any time to review your changes. To leave the 'compare' screen, Choose [View Submission] from the upper left corner of the screen.

Just as when you submitted your original protocol, the section you chose to modify is completed when it has a green checkmark next to it in the pane on the left of the screen.

- Choose [Complete Submission].

Refer to Screen Shot 7 for placement of all of the above mentioned links.



(Screen Shot 8)

An email will be sent to the P.I., Co-Investigators and Student' Investigators for certification. Each investigator must login to Cayuse IRB and certify that they agree to the Investigator's Certification Statement.

There is a link to Cayuse IRB in the email however, you may also;

Log into the Cayuse Research Suite at the link: <https://uww.cayuse424.com>.

- Choose [Cayuse IRB]
- On the of the "Dashboard" page, Choose [Awaiting Authorization]
- Choose [The number of the protocol you wish to Certify]
- On the right side of the screen, Choose [Certify].

- You may also choose to [Return] the protocol to the investigators to re-certify the protocol if changes were made by an investigator.
- Read Investigator's certification statement and Choose [Confirm].
 - The protocol will not proceed for the Administrative Review process until all investigators have certified their agreement.

Once all investigators have completed the certification process, they will receive an email notification that the study modification has been certified and sent to the IRB for review.

The Study is sent to an IRB Administrator (Analyst) for pre-view. You will be notified if any information is still required. If no additional information is required, the IRB Administrator will determine if the modification has changed the classification of the study. If the study is reclassified as "Exempt" or "Expedited" you will receive an email notice of status within approximately 10 working days. If the study was originally classified, or has been changed to a classification of "Full Board Review" you will be notified of the date and time of the IRB Meeting where it will be reviewed. Your attendance is encouraged, but not required at the meeting of the fully convened board.

Renewal/Continuing Review of an Existing Cayuse IRB Protocol

Policy Number: IRB103

Policy Date: 12/21/2017

Purpose of the Policy

This policy provides guidelines for the Renewal of existing IRB protocols in Cayuse IRB. The objective of this policy is to ensure proper and consistent renewal/continuing review of IRB protocols.

Procedures

You will be sent an email at 90, 60, and 30 days before an existing IRB protocol is up for renewal/continuing review. If you intend to continue your research, you must submit and receive an approval to continue a study BEFORE it has expired. If the study expires before an approval has been received, you must CEASE all study activity (unless doing so will adversely affect the study participants), until approval has been received. Studies that have not been submitted within 10 days of expiration will be administratively closed by ORSP. You will be required to submit and receive approval of a new study if you wish to continue your research.

NOTE: No protocol renewals/continuing reviews will be accepted if any added researchers have not completed the required CITI training. The protocol will be returned without review.

Log into the Cayuse Research Suite at the link: <https://uww.cayuse424.com>.

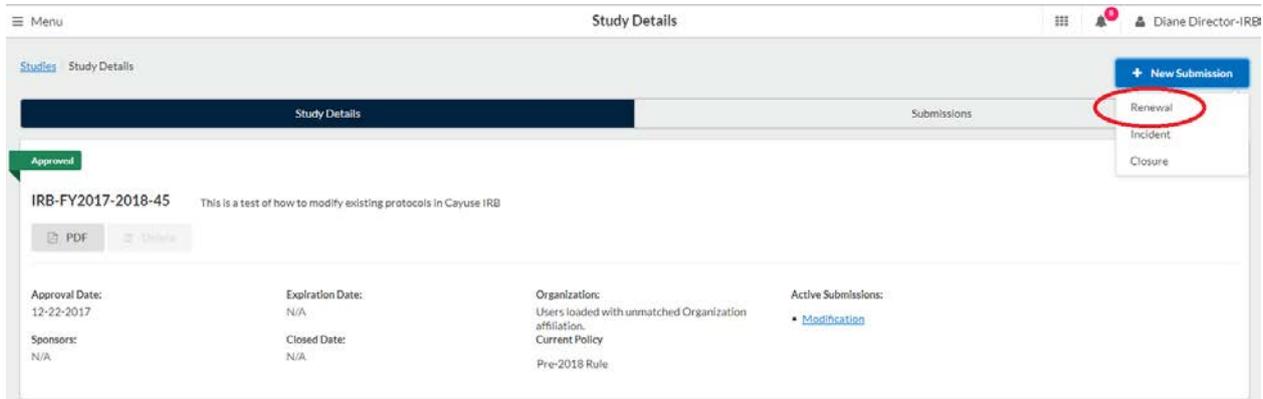
- Choose [Cayuse IRB]

On the Dashboard Page, if you have more than one role in Cayuse IRB, make sure your role is set at "Researcher".

Under my studies,

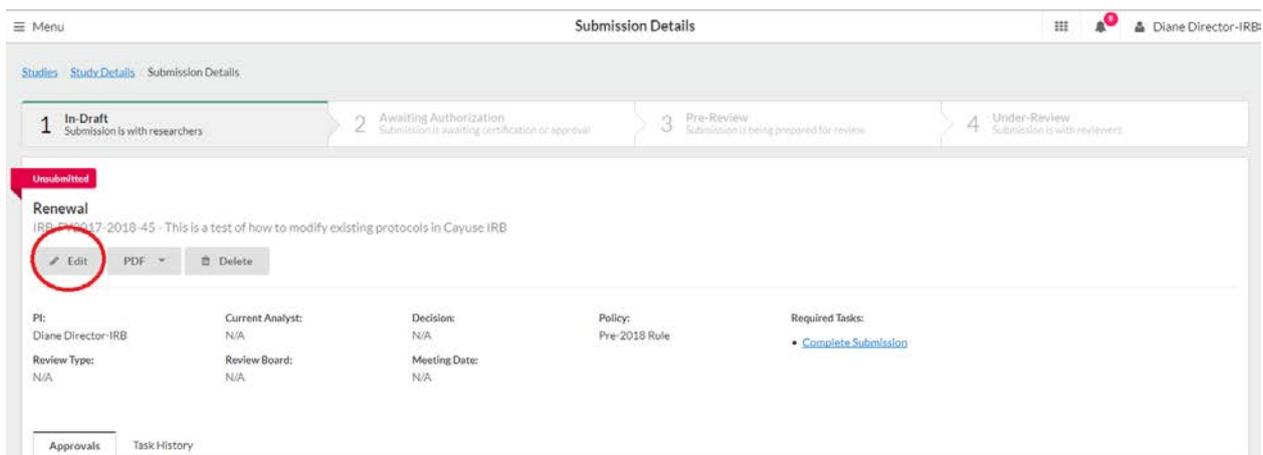
- Choose [The study number you wish to renew].

- In the upper right corner, Choose [+ New Submission].
- From the drop down options, Choose [Renew].



(Screen Shot 9)

- On the left side of the screen, Choose [Edit].



(Screen Shot 10)

- Complete the IRB Protocol Renewal/Continuing Review summary
- On the top ribbon, Choose [Save]
- On the left section pane, Choose [Complete Submission]
- Choose [Confirm], or you may cancel and make changes
- Choose [Proceed]

STUDY | IRB NUMBER: IRB-FY2017-2018-45 | This is a test of how to modify existing protocols in Cayuse IRB - Renewal | CREATE PDF | COMPARE | SAVE

Sections

- Renewal/Continu... ✓
- Routing and to PI for certification? ✓
- COMPLETE SUBMISSION >

Renewal/Continuing Review

Renewal Template - 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.

Briefly describe the progress on the completion of the study

We are still collecting data and recruiting new participants.

Have there been any unexpected reactions, findings, or complications in the study since the last approval?

There have been no unexpected reactions or complications. We do not anticipate any new findings until data analysis begins.

Approximately how many more participants will be required to complete the study?

We plan to recruit an additional 50 participants. These additional numbers are still within the participant numbers we anticipated in our original protocol submission.

(Screen Shot 11)

- Read Investigator's certification statement and Choose [Confirm].
 - The protocol will not proceed for the Administrative Review process until all investigators have certified their agreement.

Once all investigators have completed the certification process, they will receive an email notification that the study modification has been certified and sent to the IRB for review.

The Study is sent to an IRB Administrator (Analyst) for pre-view. You will be notified if any information is still required. If the study was originally classified as "Full Board Review" you will be notified of the date and time of the IRB Meeting where it will be reviewed for renewal. Your attendance is encouraged, but not required at the meeting of the fully convened board.

Withdrawal of an Unsubmitted Cayuse IRB Protocol

Policy Number: IRB104

Policy Date: 12/21/2017

Purpose of the Policy

This policy provides instructions for the Withdrawal of an un-submitted IRB protocol in Cayuse IRB. The objective of this policy is to ensure proper withdrawal of IRB protocols that are no longer being considered for submission.

Procedures

Only IRB protocols that have NOT been submitted to the IRB for review can be withdrawn. The researcher that has begun entry of the IRB submission that is being considered for withdrawal is the only person who has access to it, however ALL researchers that have been listed on the protocol must certify it's withdrawal – this will happen as part of the withdrawal procedure. No reminders or notifications will be sent regarding protocols that have been left un-submitted in the researchers Dashboard.

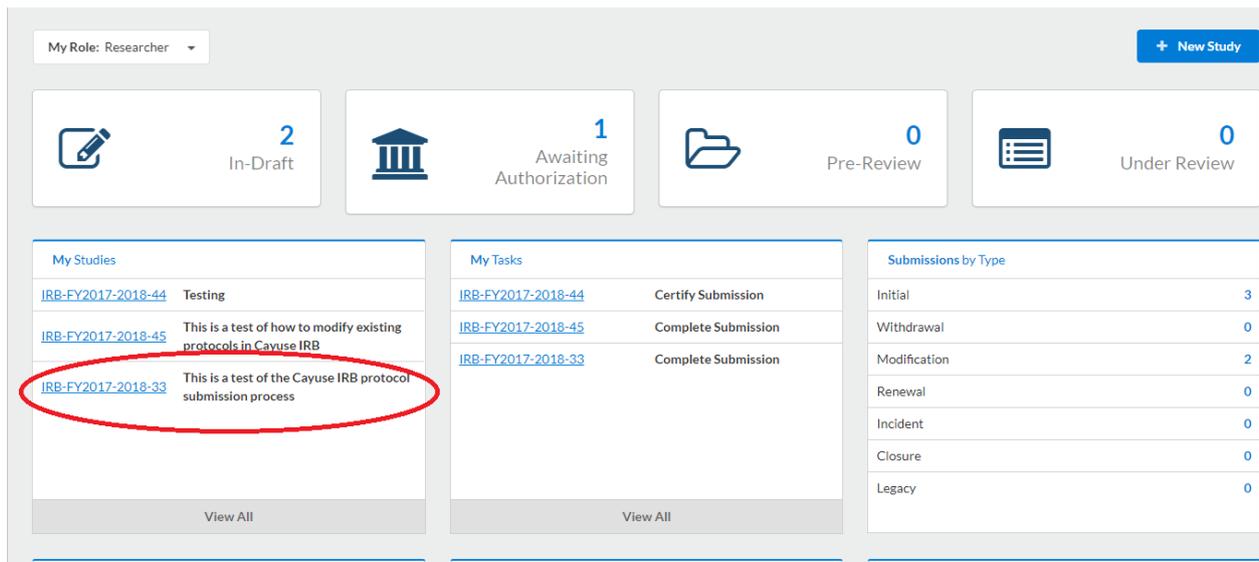
Log into the Cayuse Research Suite at the link: <https://uww.cayuse424.com>.

- Choose [Cayuse IRB]

On the Dashboard Page, if you have more than one role in Cayuse IRB, make sure your role is set at "Researcher".

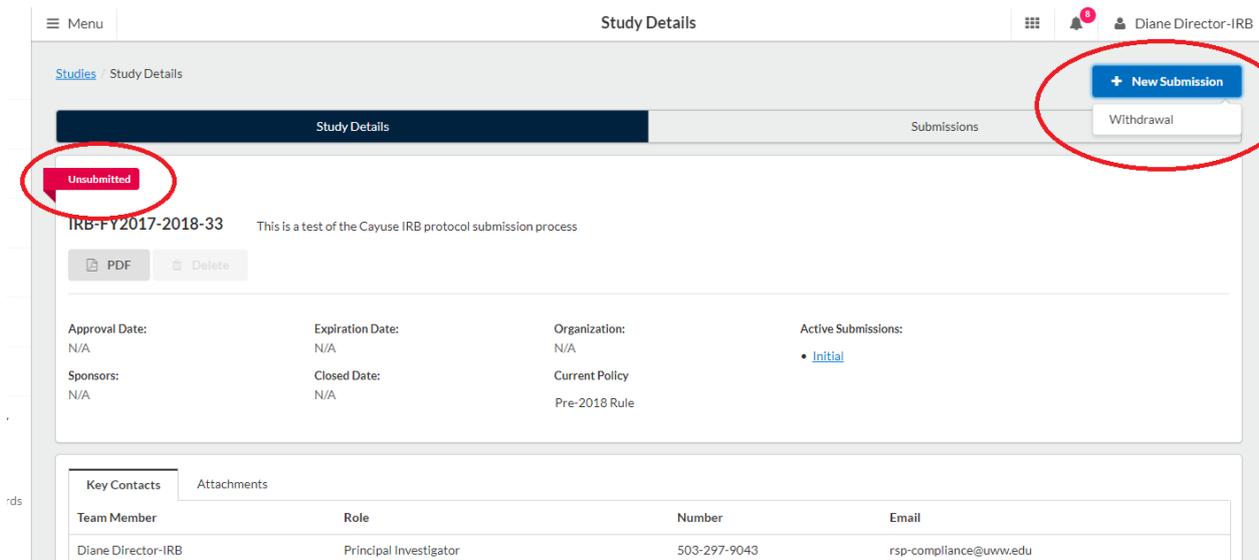
Under the Studies tab,

- Choose [The study number you wish to withdraw].



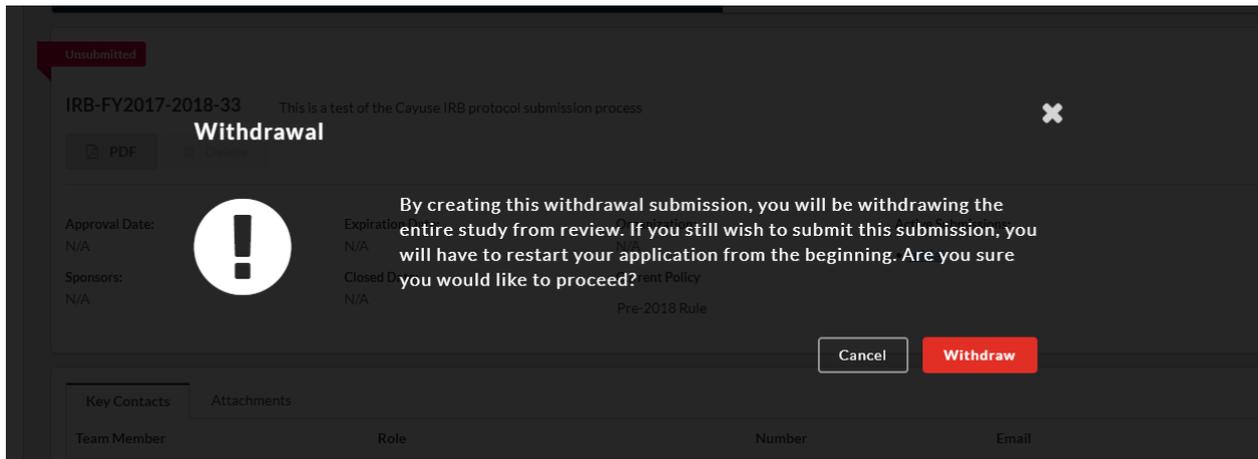
(Screen Shot 12)

- In the upper right corner, Choose [+ New Submission]
- From the drop down options, Choose [Withdraw]



(Screen Shot 13)

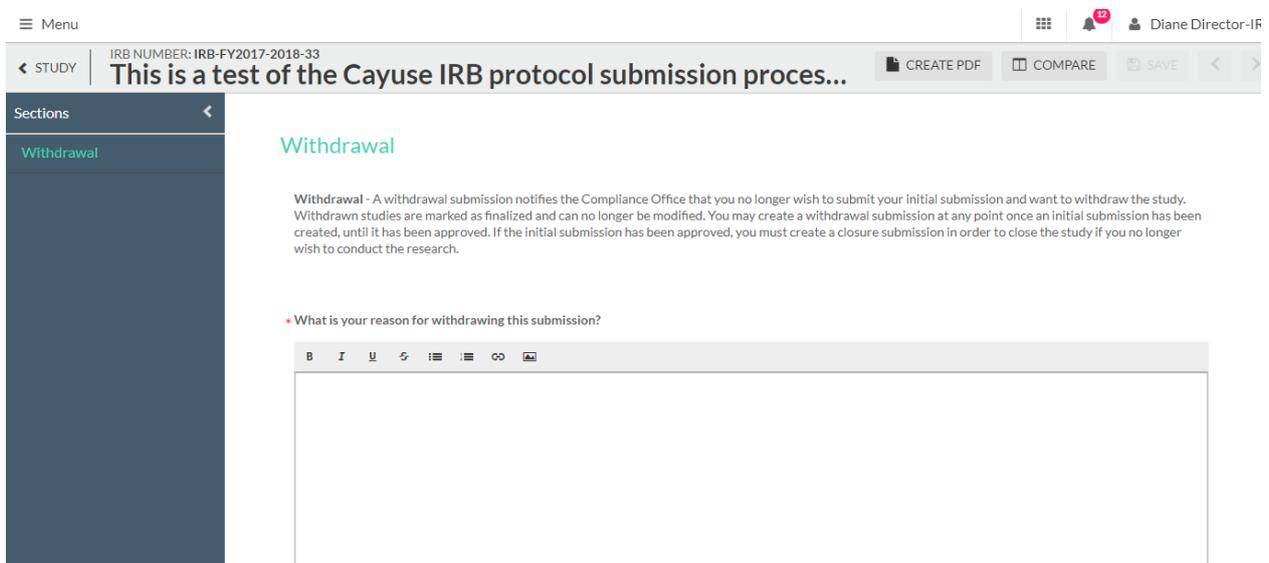
You will receive a warning screen notifying you that if you withdraw the submission, you must reenter the protocol.



(Screen Shot 14)

- Choose [Withdraw] or you may cancel.
- Choose [Complete Submission]

You will be taken to the 'Withdrawal page', where you will need to submit a reason for withdrawing the submission.



(Screen Shot 15)

- Choose [Complete Submission] from the left pane.
- Choose [Confirm] or you may cancel.
- Choose [Certify]

- Read Investigator's certification statement and Choose [Confirm].
- The protocol will not proceed for the Administrative Review process until all investigators have certified their agreement.

Once all investigators have completed the certification process, they will receive an email notification that the study withdrawal has been completed.

Closure of a Completed Cayuse IRB Protocol

Policy Number: IRB105

Policy Date: 12/21/2017

Purpose of the Policy

This policy provides instructions for the Closure of a completed IRB protocol in Cayuse IRB. The objective of this policy is to ensure proper and required closure documentation of IRB protocols that are no longer in progress.

Procedures

You will be sent an email at 90, 60, and 30 days before an existing IRB protocol is up for renewal/continuing review. If you do not intend to continue your research, you must submit a closure report to inform the IRB of the status and any unanticipated results and/or findings from the completed study. Closure reports are a required as part of the IRB process. Failure to provide a closure report may have adverse effects or may create delays in the approval of new studies.

Log into the Cayuse Research Suite at the link: <https://uww.cayuse424.com>.

- Choose [Cayuse IRB]

On the Dashboard Page, if you have more than one role in Cayuse IRB, make sure your role is set at "Researcher".

On your Cayuse IRB Dashboard, or from the Studies tab,

- Choose [The study number you wish to close].

- In the upper right corner, Choose [+ New Submission]
- From the drop down options, Choose [Closure]

The screenshot shows the 'Study Details' page for 'IRB-FY2017-2018-45'. The status is 'Approved'. A dropdown menu is open in the top right corner, showing options for 'Incident' and 'Closure', with 'Closure' circled in red. The page also displays a table of key contacts and a list of active submissions.

Team Member	Role	Number	Email
Diane Director-IRB	Principal Investigator	503-297-9043	rsp-compliance@uww.edu
Diane Director-IRB	Primary Contact	503-297-9043	rsp-compliance@uww.edu

(Screen Shot 16)

- On the left side of the screen, Choose [Edit].
- On the Closure screen, specify why the study is being closed.
- Give a brief summary of the research results.
- You may attach a Final Report Summary.
- You may attach any additional documents.

Refer to Screen Shot 17 for a preview of the Protocol Closure form.

IRB NUMBER: IRB-FY2017-2018-31
Test Study - CAK - Closure CREATE PDF COMPARE SAVE

Sections

- 1. IRB PROPOSAL C... ✓
- Routing
Send to PI for certification?
- COMPLETE SUBMISSION ▶

1. IRB PROPOSAL CLOSURE

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.

Reason for Closure

- Loss of funding
- Research has been completed
- Other

Final Report Summary

(Provide a summary of your study results.)

ATTACH

Additional Attachments for IRB protocol records

(Briefly describe and attach any additional information you wish to keep with this protocol record.)

(Screen Shot 17)

- In the upper right corner, Choose [Save].
- In the left hand pane, Choose [Complete Submission].
- Choose [Confirm] or you may cancel and make changes.
- On the right side of the screen, Choose [Certify]
- Choose, [Confirm].
- On the right side of the screen, Choose [Proceed].

You will receive an email notification that the protocol has been submitted to the IRB Administrator for closure. Once it has been closed, you will also receive a notification indicating the process is complete.

Reporting an Incident in Cayuse IRB

Policy Number: IRB106

Policy Date: 12/21/2017

Purpose of the Policy

This policy provides instructions for reporting incidents, adverse effects, and unanticipated problems involving risks to subjects or others during a research study. Federal Guidelines require adverse effects must be reported and reviewed by the institutional IRB for review and determination of the steps to be taken.

Procedures

Serious Incidents:

If a serious incident such as a life-threatening illness, injury, or death occurs during the course of the study, the study investigators must immediately seek the appropriate medical treatment for the participant(s) and cease all study activities, unless stopping activities will be life-threatening to participants. The incident must be reported to the UW-Whitewater IRB via the Cayuse IRB Incident report within **three (3) days**. The IRB will assign an investigator to the incident who may contact the P.I. for additional information. A determination will be made on the proper procedures for next steps. Federal Guidelines require that serious incidents may need to be reported to the OHRP (Office for Human Research Protections) and any research sponsors. Research activities may not resume until notified by the UW-Whitewater IRB and may be terminated or suspended indefinitely as a result of the incident.

Non-Serious Incidents:

In the event of a non-serious incident, the study may continue but must be reported to the UW-Whitewater IRB within **seven (7) days** via the Cayuse IRB incident report. The IRB Administrator and IRB Chair will review the incident report and depending upon the incident and severity, determine if the entire IRB needs to be consulted and if an investigator needs to be assigned to the incident for further review. They will also determine if the study needs to be suspended until the investigation has been completed. No studies will be suspended if suspension will create further complications for the participants. The investigators will be instructed on how to proceed and given deadlines as appropriate for changes and corrections.

Federal Guidelines for reporting the incident will be reviewed by the IRB and completed as appropriate.

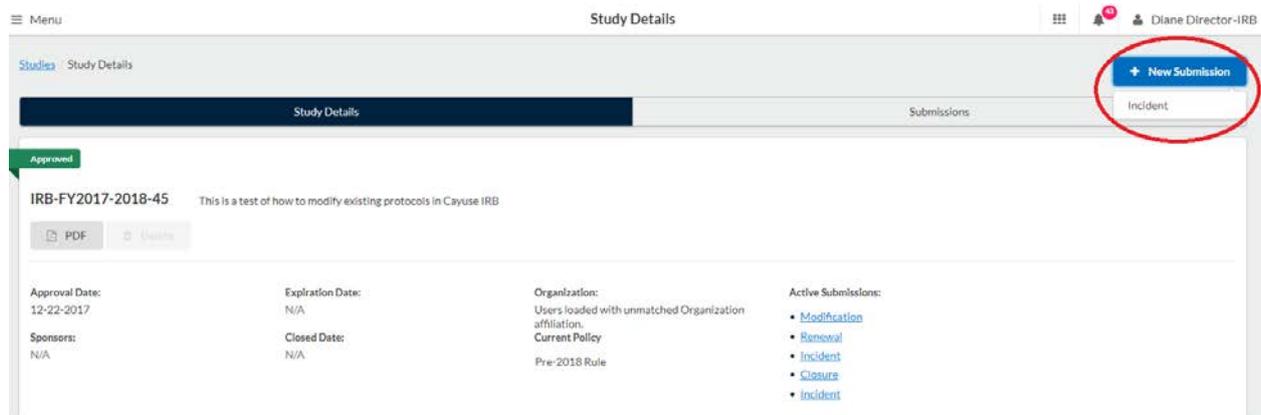
Log into the Cayuse Research Suite at the link: <https://uww.cayuse424.com>.

- Choose [Cayuse IRB]

On the Dashboard Page, if you have more than one role in Cayuse IRB, make sure your role is set at “Researcher”.

On your Cayuse IRB Dashboard, or from the Studies tab,

- Choose [The study number for which you are reporting the incident].
- In the upper right corner, Choose [+ New Submission]
- From the drop down options, Choose [Incident]



(Screen Shot 18)

- Under the study title, Choose [Edit]

Complete the Incident form to the best of your ability. Some of the fields are required.

- Once completed, Choose [Affirmation of Investigator] from the left side pane.
- Choose, [Your name] from the drop down selection.
- Choose, [Save] on the upper right side of your screen.

Menu

STUDY | IRB NUMBER: IRB-FY2017-2018-44 | Testing - Incident

CREATE PDF | COMPARE | SAVE

Sections

1. ADMINISTRATIVE DATA

2. AFFIRMATION O... ✓

2. AFFIRMATION OF INVESTIGATOR

As the Principal Investigator I am confirming that the information I have provided in this report is accurate and true.

Principal Investigator

Name	Organization	Address	Phone	Email	
Carol Katch	Users loaded with unmatched Organization affiliation.	800 West Main Street, Whitewater, WI 53190-1790		katchc@uww.edu	✕

(Screen Shot 19)

- Choose, [Complete Submission]
- On the Submissions page, Choose [Certify].
- Choose, [Confirm].

The P.I. is the only research team member who is required to certify the submission of an incident report.

Your submission will be reviewed by the IRB Administrator and you will be contacted with any further instructions.