Cayuse Human Ethics: Investigators Guide

WRIGHT STATE UNIVERSITY

Cayuse Orientation

Access

Home Screen

My Profile

Dashboard

Access to Cayuse Human Ethics

[Cayuse Human Ethics Link](#)

VPN Not Required!

- Request a Cayuse Access for Non-Wright State Users
  - https://www.wright.edu/research/research-and-sponsored-programs/cayuse-and-redcap-access-request-for-non-wright-state-users
  - Normally granted in one week

- Request Cayuse Access (have existing w-number)
  - https://www.wright.edu/research/research-and-sponsored-programs/cayuse-access-for-wsu-students-staff-and-faculty-form
  - Normally granted within two days

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Cayuse Home

➢ Assign tasks to yourself and research team
➢ Does not connect with individual products but will show up on this home task page and individuals assigned will receive e-mail notification to complete task.
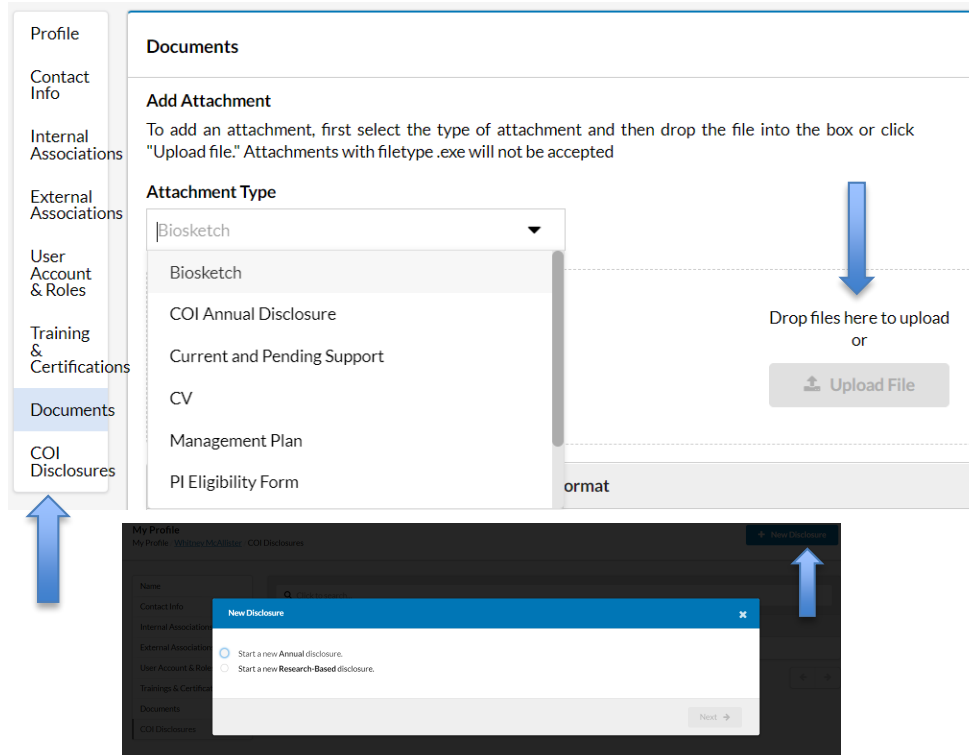
My Profile

- ➤ To Add a CV
  - ➤ Click My Profile
  - ➤ Click Documents
  - ➤ Select CV
  - ➤ Click the Upload button
- ➤ To add Annual COI:
  - ➤ Click My Profile
  - ➤ Click COI Disclosures
  - ➤ Click +New Disclosure
  - ➤ Select Research Based
  - ➤ Note: Annual only completed in January

Dashboard

- Role Switcher
- Notifications
- Product Switcher
- My Profile

Review Status

+ New Study

| 8 In-Draft | 0 Awaiting Authorization | 0 Pre-Review | 0 Under Review |

List of All Studies in Progress

List of All Approved Studies

My Studies

IRB-FY2020-	Test Study
IRB-FY2019-	Not HS Test
IRB-FY2019-	Overview Test
IRB-FY2019-	Title
IRB-FY2019-	link to proposal test

View All

My Tasks

IRB-FY2020-	Complete Submission
IRB-FY2019-	Complete Submission
IRB-FY2019-	Complete Submission
IRB-FY2019-	Complete Submission
IRB-FY2019-	Complete Submission

View All

Submissions by Type

Renewal	0
Initial	10
Modification	0
Incident	0
Withdrawal	0
Closure	0
Legacy	0

Approved Studies

| IRB-FY2010- | Test Study |

Studies Expiring in 30 days ▼

Expired Studies

| IRB-FY2019- | Test Study 12/13/40 |

Assigned Tasks

List of Expired Studies: Submit Renewal or Closure

Interactive Help

Help Center ×

< Search for articles...

SUGGESTED ARTICLES

Creating a New Study
Creating an Initial Submission
Completing a Submission

N/A   06-17-2022

Submissions Tab

➢ Can filter and sort

Note about Assignment:
➢ Four Roles:
  ➢ Principal Investigator
  ➢ Primary Contact
  ➢ Co-Principal Investigator
  ➢ Investigator
    ➢ View Only Access

Each application will specify exact role in that study. It will not be reflected here.

Studies Tab

Study Details

PDF Button:
➢ Converts Application to PDF. Does not include attachments.

Letters Tab:
➢ If there are letters associated with the study, a letters tab will appear next to the attachment tab.

Submission Types

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

- **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 legacy submissions or work with studies that have been imported from other systems.

There are two additional submission types that are only available to IRB Analysts and Admins:

- **Admin Closure** - Allows a study to be administratively closed when needed, for example when the PI leaves the institution or chooses to let a study expire.
- **Admin Withdrawal** - Allows a study to be administratively withdrawn when needed, for example when the PI leaves the institution.

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Creating a New Protocol

Starting the Initial Submission

Question Types

Workflow

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Initial Submission

- **Save Often!!** Cayuse saves when you hit next arrow, not if you manually navigate sections.
- The person that starts the application is automatically assigned as Primary Contact (PC). This can be changed. You can have as many PC's as you need.
- You must designate <u>one</u> Primary Investigator (PI). This must be manually indicated in the application.

- Access Rights:
    - PI, Co-PI, PC: Edit Rights
    - Research Site Coordinators: Edit Rights
    - All Others: View Only Rights

Saving Your Changes

Sections that have unsaved changes have an asterisk next to the section name in the menu. To save your changes, click the Save button in the upper right.

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Simultaneous Users

More than one member of the research team (PI, Co-PI, Primary Contact, or another authorized Investigator) can be working on different sections of a submission at the same time. When another user is currently working on a section, that section will have a red lock icon in the section menu and you will not be able to make edits to that section. You can still work on other sections that are not locked. To see who is currently editing a locked section, hover over the lock icon in the section menu.

A submission cannot be completed while another user is still editing it.

Types of Questions

Radio Buttons

Select one of the available options.

* 1.0   What type of submission is this?   ❓

- ○ Research Study Involving Human Subjects (Exempt, Expedited, Full Board Review) oversight by the Cayuse University IRB
- ○ Research Study involving an Outside IRB of Record or NCI PCIRB
- ○ Emergency Use of Investigational Agent
- ○ Request for Determination of the Need for IRB Review

Check Boxes

Select one or more of the available options.

* 3.0   In which locations will the research take place? (Check all that apply.)

- ☐ Inpatient Location
- ☐ Outpatient Location
- ☐ Community Settings
- ☐ Subject's Home
- ☐ N/A (limited to review of records, data and analysis)

Text Box

A text box provides space for a short answer that does not require a lot of explanation. You can enter multiple lines of text here if needed; the box will expand to fit the text.

* 3.0   Create a SHORT title for your research protocol. (Five words maximum.)

Text Area

The multi-line text editor allows you to apply simple text formatting such as bold, italics, underline, strikethrough, bulleted lists, numbered lists, and hyperlinks.

* 2.0   What is the FULL title of the research protocol?

B *I* U S̶ ☰ ☰ ∞ 🖼

Types of Questions - Images

You can also add PNG or JPG images using the image browser. To add an image to the text area, click the 🖼 icon in the toolbar.

Add Image

Choose source:

- ⦿ Upload   **Choose File**
- ◯ Web URL
- ◯ Clipboard

Cance[l]

Depending on your browser, you have a choice of three possible image sources:

- **Upload** - Use the **Choose File** button to browse for an image on your computer or from a network location.
- **Web URL** - Paste the URL to an image that is hosted online.
- **Clipboard** - Paste an image that you have copied to your clipboard. Due to browser limitations, his option is only available to Chrome users.

Click **Confirm** to import the image.

Once the image is inserted, you can resize it as needed by clicking and dragging on the corners. When you hover over the image, an **Edit** button appears that opens a dialog where you can add a title for the image, turn the image into a hyperlink, or adjust the image position relative to the flow of text.

Edit   ✕

Title

Evisions logo

Link

www.evisions.com

☑ Open link in new tab

Position

Center ▾

Delete	Cancel	Save

Types of Questions:
Person & Sponsor Finder

Some fields require a single person, such as the Primary Contact for a study:

* 1.0   Who is the Primary Contact?

FIND PEOPLE

Click **Find People** to bring up the **Primary Contact** search dialog:

PRIMARY CONTACT

Name	Organization	Email	Phone	
Mark Williams	Biomedical	mwilliams@evisions.com	714 824 5678	+
Mark Klein	Biomedical	mklein@evisions.com	714 824 1234	+

Selected Records   * Select a single record.

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

⊘ CANCEL   💾 SAVE

Type the name or part of the name of the person you are looking for in the search box and click the **Search** icon. Locate the desired person in the list, then click the **+** button next to their name to add them to the selection. Click **Save** to return to the form.

Other People fields allow you to select more than one person. For example, when you click Find People, the **Investigator** search dialog allows you to select any number of investigators using the **+** buttons. When you add a person to the selection, the **+** button changes to a check mark.

INVESTIGATOR

Mark

Name	Organization	Email	Phone	
Mark Williams	Biomedical	mwilliams@evisions.com	714 824 5678	✓
Mark Klein	Biomedical	mklein@evisions.com	714 824 1234	✓

Selected Records

| Mark Williams | ✗ |
| Mark Klein | ✗ |

⊘ CANCEL   💾 SAVE

When you have added all the people you wish to include, click Save.

Sponsor finders work exactly the same way as Person finders, except that the search returns matching sponsors instead of people.

Types of Questions:
Attachments

Supported File Types

Cayuse IRB supports the following file types. Each file can be a maximum of 20 MB in size.

File Type	Extension
Text	txt
Adobe	pdf
Raster image formats	png, bmp, gif, tif, tiff, jpg, jpeg, jp2, jpx
Vector image formats	wmf, emf, svg
Microsoft Word	doc, docx, docm
Microsoft Excel	xls, xlsx, xlsm
Microsoft PowerPoint	ppt, pps, pptx, pptm, ppsx, ppsm, sldx, sldm

Deleting Attachments

To delete an attachment, click the **X** icon next to the attachment. You can also download file attachments by clicking on the filename.
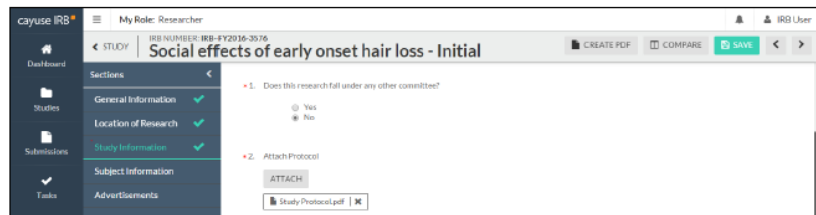
Attachments

Attachment fields allow you to upload one or more files to the study, or to include hyperlinks as "attachments".

> 4.0   Attach the Letters of Support from the respective Department/Division.
>
> ATTACH

Click **Attach** to open the **Documents** window. To add a file or link, click the **+** button and choose to add a URL or file.
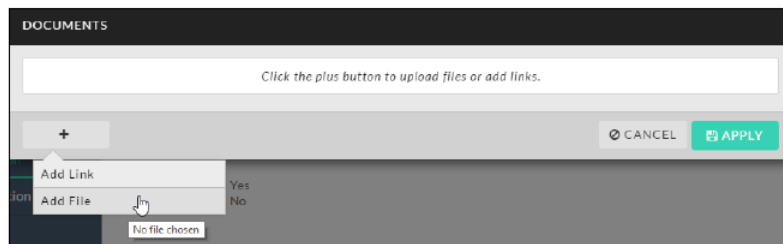
Choosing **Add File** launches the default file browser on your system. Choosing **Add Link** opens a text area where you can enter the URL and a title for the page:

Enter the desired URL or select the desired file, then click **Apply**.

Help with questions

A question may provide additional information in case you need assistance with that particular question. If there is help text for a question, you can click on the **(?)** button to the right of the question to view the additional information for that question.

＊ 1.0 What type of submission is this?

This is some help text.
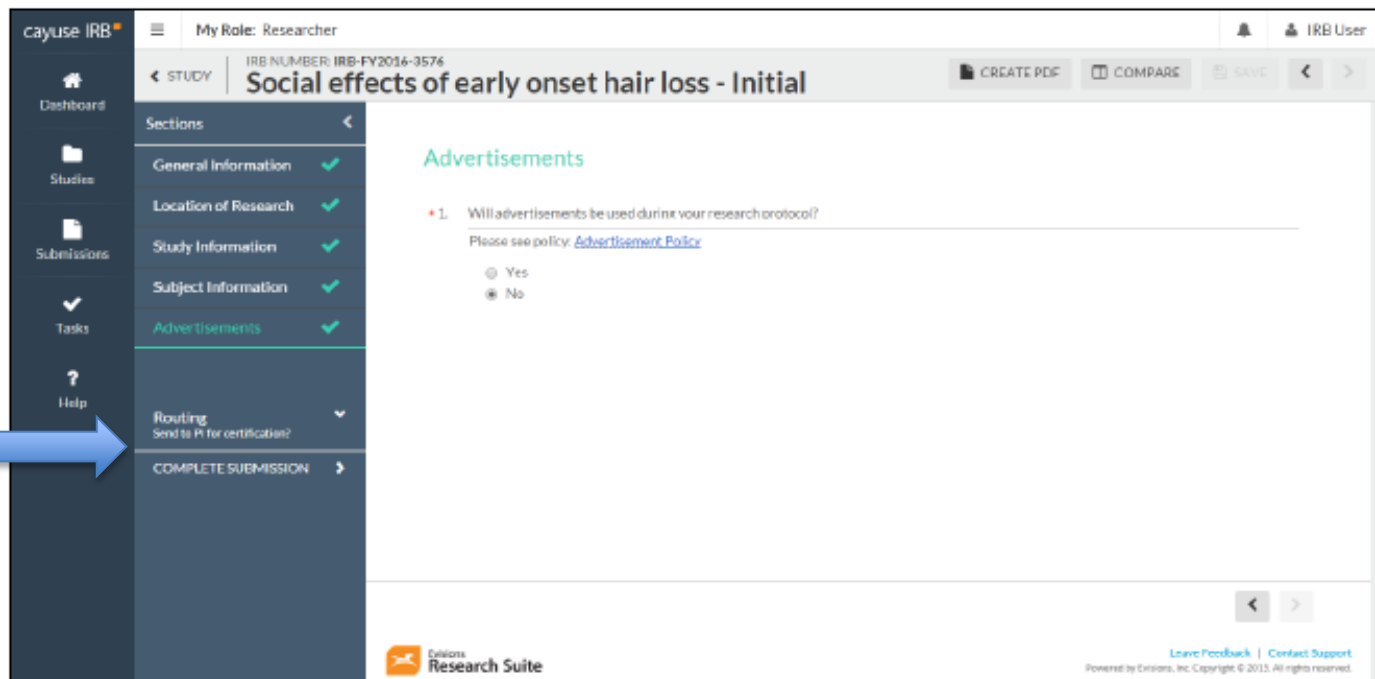
○ Research Study Involving Human Subjects (Exempt, Expedited, Full Board Review) oversight by the Cayuse University IRB

○ Research Study Involving an Outside IRB of Record or NCI PCIRB

○ Emergency Use of Investigational Agent

Routing

If there are available actions that you can perform, the **Routing** menu appears prompting you to perform the action. For example, when you finish filling out all parts of the submission, a "Complete Submission" link appears in the Routing menu. Completing the submission will send it to the PI for certification, which is the next step in the submission workflow.

Certification

After study is submitted, the PI, PC, and all Co-PI's must sign in to certify their involvement in the project.

The PI, Co-PI, and PC will receive:
➢ E-mail Message
➢ Notification Bubble
➢ Task
➢ Added to Awaiting Authorization Display Button

After all study personnel have certified it will be forwarded to the Organizational Approver (i.e., department chair).
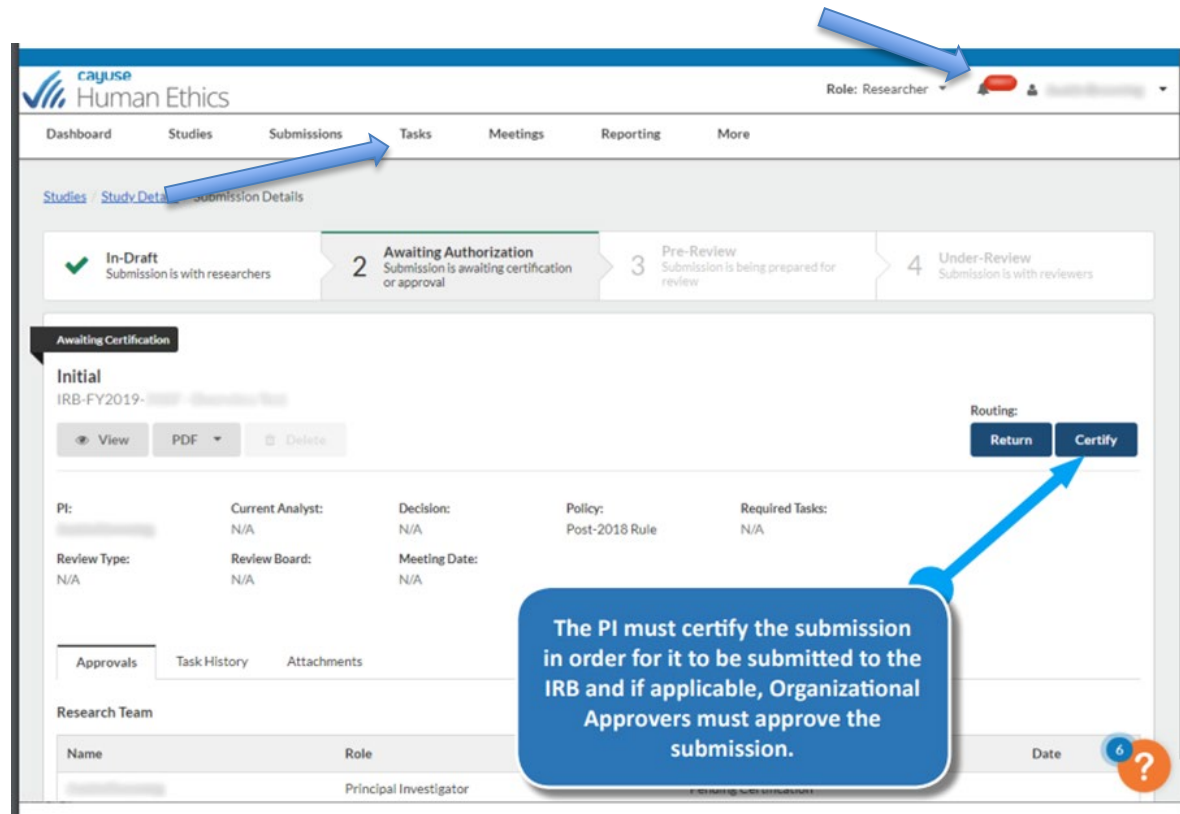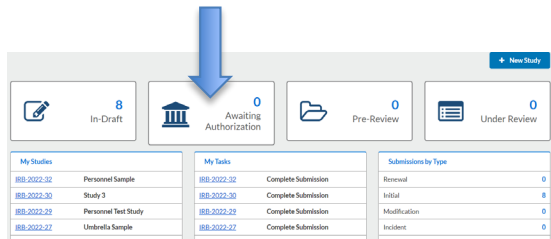
Note: No signature delegation ability in Cayuse.
Against IT policy to share passwords. Everyone must sign for themselves.

Return to Investigator during Certification

Alternatively, if the PI decides that changes need to be made, they can send the submission back to the research team by clicking **Return to Investigators**. The research team members will receive an email notification of the change in status so they can make the necessary edits before marking it complete again.

Once the PI has certified the submission, it goes to the departmental approver for review, and from there goes down the chain to the IRB analyst and members. At any point the submission may be returned to the investigation team to answer questions or to make changes.
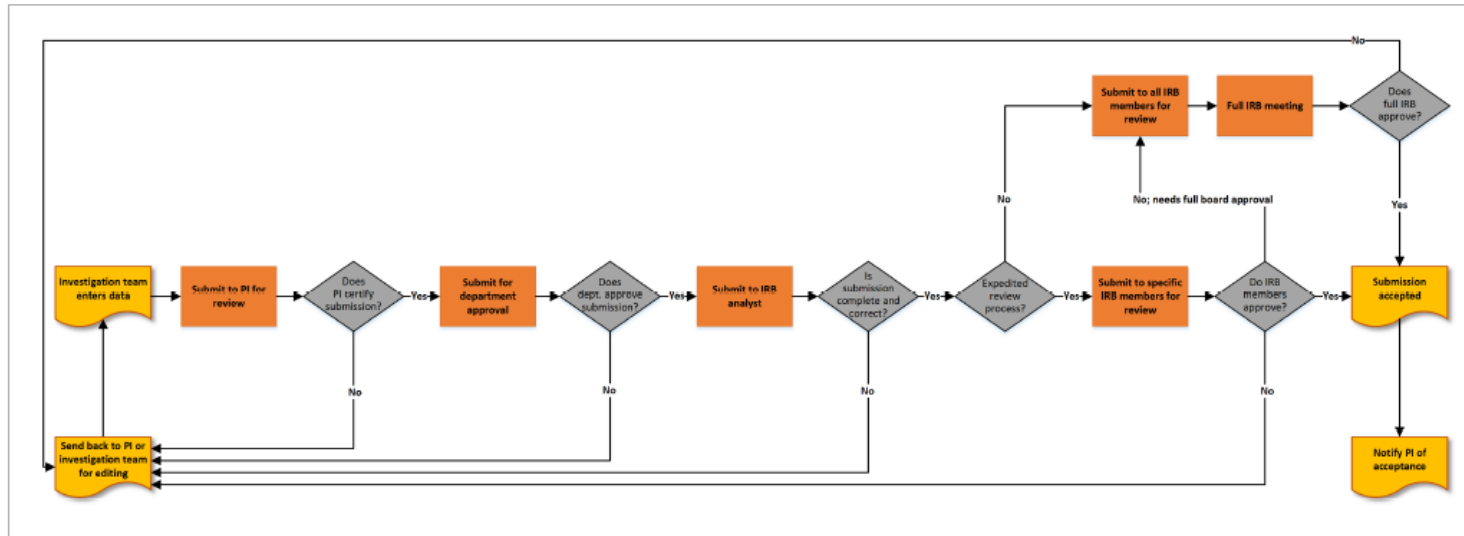
IRB recommends using the **Task** feature on the Cayuse Home screen to communicate requested changes.

Pre-Review

➢ IRB Quick Overview Occurs

- ➢ Correct Application Type Completed
  - ➢ Quick confirmation of review path
- ➢ Required Documents Attached
- ➢ Investigator Credentialing
  - ➢ CV's
  - ➢ CITI Training
  - ➢ Project-Specific SFI
  - ➢ Annual COI
- ➢ Identification of required ancillary review & regulatory determinations needed

Under Review

The IRB has accepted the study and it is starting the review process.

Step 1:
- ➢ Risk Management Pre-Review (WSU)
  - ➢ Conflicts of Interest
  - ➢ Export Control

Step 2:
- ➢ Premier Health HIRC Committee
- ➢ VAMC Research Committee

Step 3:
- ➢ Wright State IRB Review

Step 4:
- ➢ Risk Management Post-Review (WSU)
  - ➢ Biosafety
  - ➢ Laser/Radiation Safety
  - ➢ Institutional Research/Registrar
  - ➢ CoNNECT MRI Center

Note: Contact the IRB for an update if your study is in the same status for more than two weeks.

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Legacy Studies

Study Shell

Initial Submission

Working with Legacy Studies

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

Legacy Study Shell

➤ Basic Study Details will be imported into Cayuse for **Approved** Studies Only

➤ Cannot import application details or documents, just basic study information.

➤ Will be listed under RSP Gateway study number.

Click View All under "My Studies" for a list of all your protocols.

Click the IRB number of the protocol you are interested in.

Click + New Submission Select Legacy

Legacy Study Conversion

➢ Must complete the legacy initial application and submit.

  ➢ Needs to be completed and approved before you can complete a modification or renewal (CR).

  ➢ If you do not need to submit a Mod or CR, then no action is required.

➢ The Legacy Initial Application is identical to the initial application BUT no required fields.

If you only need to close the study, this option will bypass the legacy initial application.

Exempt & Expedited Conversion

➢ When processing the Legacy Study Conversion, all exempt and *qualifying* Expedited studies will be converted to an Administrative Check-In process.
  ➢ Removes renewal (CR) requirement.
  ➢ Add annual e-mail reminders.

Note: Exempt with limited review and Expedited studies are subject to post-approval monitoring.

➢ Contact IRB Office to:
  ➢ Set up individual appointments to assist with legacy transfer
  ➢ Obtain copies of previously approved applications to assist with data transfer

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Checking the Status of an Existing Protocol

Navigation

Study Statuses

Left panel callout: Click View All under "My Studies" for a list of all your protocols.

Right panel callout: Click the IRB number of the protocol you are interested in.

Left panel:

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Role: Researcher

Dashboard | Studies | Submissions | Tasks | Meetings | Reporting | More

Studies / Study Details

Study Details | Submissions

Under Review

IRB-FY2019-

PDF | Delete

Approval Date: N/A	Expiration Date: N/A	Organization: PROVOST - Vice Provost for Research (VPR)	Active Submission:	Population Flags:	Additional Flags:
Admin Check-In Date: N/A	Closed Date: N/A			

Click "Submissions" on the Study Details page for a list of submissions related to the protocol

Key Contacts | Attachm...

Team Member		Number	Email
	Principal Investigator		
	Primary Contact		

Right panel:

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Role: Researcher

Dashboard | Studies | Submissions | Tasks | Meetings | Reporting | More

Studies / Study Details

Study Details | Submissions

Submission Type	Review Type	Status	Decision
Initial	Full	● Under Review	--
Withdrawal	Unassigned	● Under Review	--

1-2 of 2

1

25 per page

Click the link for the submission you are interested in

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Status

Task History
Indicate where in the process the study is currently in queue.

Review Board:
Indicates which Committee is reviewing
➤ Dayton VAMC Research Committee
➤ Premier Health HIRC Committee
➤ Risk Management Review (WSU)
  ➤ Conflicts of Interest
  ➤ Biosafety
  ➤ Laser/Radiation Safety
➤ Wright State IRB

Note: Risk Management is generally first.
Wright State IRB is generally LAST.

Study Status Descriptions

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.

Editing and Re-submitting a Reopened Submission

How to address changes requested by the IRB

Requires Changes

➢ Click on the Active Submission Type
  ➢ Initial
  ➢ Modification
  ➢ Renewal
  ➢ Incident
  ➢ Closure

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Comments

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

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

The PI, Co-PI, and PC will receive:
➢ E-mail Message
➢ Notification Bubble
➢ Task
➢ Added to Awaiting
   Authorization Display Button

Where to find your approval documents

Documents

Letters

Modifications/Amendments

Create & Submit a modification

Revising the application

Comparison Tool

Creating & Submitting a Modification

Note: You are only able to have one modification in process at any given time.

> Complete Amendment Details Section

Note: A copy of your last approved version of the application is generated.

➤ Make all changes.
➤ This ensures proper version control.

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Comparison Tool

➢ Select COMPARE on Menu Bar
➢ Shows the changes made between this application version and previous one
➢ Can be used for uploaded documents
➢ Number indicators for number of differences
➢ Green for additions
➢ Red for deletions

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Updated Documents:
- Add Date or Version Number to Title.
- Keep unchanged documents
- Add New Documents

The PI will receive:
➢ E-mail Message
➢ Notification Bubble
➢ Task
➢ Added to Awaiting
  Authorization Display Button

The PI can Certify the Modification by clicking here (refer to the start of the Modification guide for directions on navigating to this page)

Continuing Review/Administrative Check-In

Starting a submission

Submission requirements

Procedure Change

Creating & Submitting a Renewal

Click "New Submission" then select "Renewal"

Click "Edit" to begin working on your Renewal

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Human Ethics

Dashboard   **Studies**   **Submissions**   **Tasks**   **Meetings**   **Reporting**   **More**

‹ SUBMISSION DETAILS | IRB NUMBER: IRB-2022-18
Sample_06.14.2022_TK1 -...

☑ SHOW CHECKLIST   📄 CREATE PDF   ⊞ COMPARE   💾 SAVE   ‹   ›

Sections	‹
Continuing Review	✔
Study Summary	✔
Study Monitoring	✔

Please answer all questions in each section.

Continuing Review

This form is to be submitted for studies with an expiration date. If your study ~~only~~ has a check-in date, it is not required to submit this form.

Note: Modification to study procedures cannot be made via this form. If you need to change study procedures, please complete an modification request form.

* **Protocol Lapse**

   * Is the study past its expiration date?
      ○ Yes
      ● No

* **Local Subject Enrollment**

   Please select the appropriate designation:
   ● Research Study
   ○ Humanitarian Use Device Treatment Protocol

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Incidents/Reportable Events

What needs to be reported

How to create and submit an incident

On the Dashboard, click here to view your studies

Click on the Study for which an Incident will be entered

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Click "New Submission" then click "Incident"

Click here to begin editing the Incident report

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Incident Report

➢ Complete all questions

➢ When finished, click COMPLETE SUBMISSION

➢ Recommend submitting all minor study deviations once per year for Exempt/Expedited studies

Closure Request

How to create and submit an closure request

On the Dashboard, click here to view your studies

Click on the Study which will be Closed

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Click "New Submission" then click "Closure"

Click here to begin editing the submission

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Study Closures

➢ Complete all sections on the left menu

➢ Submit when complete

➢ Will follow same process as modifications, renewals, and incidents by being routed to the PI for certification prior to review by the IRB.

➢ Once closed, there is no re-opening the study.

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Get Help – IRB Staff Consultations

➢ Virtual Office Hours
  ➢ Wednesdays at 11am – 12:30pm
  ➢ By appointment
➢ IRB Chat via Teams
➢ IRB Help Line:
  ➢ 937-775-4462
➢ Email: irb-rsp@wright.edu