



Cayuse Human Ethics: Creating a New Protocol

Creating a New Protocol

Starting the Initial Submission

Question Types

Workflow

cayuse Human Ethics

Role: Researcher 5:00 PM

Dashboard Studies Submissions Tasks Meetings Reporting More

+ New Study

To begin a new protocol, click "New Study"

My Studies

IRB-FY2020-	Test Study	IRB-FY2019-	Complete Submission
IRB-FY2019-	New IRB Test	IRB-FY2019-	Complete Submission
IRB-FY2019-	Overview Test	IRB-FY2019-	Complete Submission
IRB-FY2019-	Title	IRB-FY2019-	Complete Submission
IRB-FY2019-	IRB to proposal test	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-FY2018-	Test Study
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Studies Expiring in 30 days

Expired Studies

IRB-FY2019-	Test Study 12/11/19
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6 ?

cayuse

Human Ethics

Role: Researcher

6

Dashboard

Studies

Submissions

Tasks

Meetings

Reporting

More

Studies

Study Details

+ New Submission

Study Details

Submissions

Enter study title here

Add Study Title here

PDF

Delete

Approval Date:
N/A

Expiration Date:
N/A

Admin Check-In Date:
N/A

Organization:
N/A

Current Policy

Active Submissions:

Sponsors:
N/A

Population Flags:

Additional Flags:

✓

✕

Click here to confirm creation of new study

6

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Human Ethics

Role: Researcher

Dashboard

Studies

Submissions

Tasks

Meetings

R

Studies

Study Details

Study Details

Unsubmitted

IRB-FY2021-

PDF

Delete

Approval Date:
N/A

Expiration Date:
N/A

Organization:

Active Submissions:
N/A

Population Flags:

Additional Flags:

Admin Check-In Date:
N/A

Closed Date:
N/A

Current Policy
Post-2018 Rule

Sponsors:
N/A

Key Contacts

Attachments

Flags

Team Member	Role	Number	Email
No Key Study Contacts.			

Begin Initial Submission

You've created a study! Click here to begin your initial submission to the IRB.

+ New Submission





Initial

Click here and select "Initial" to create the Initial submission for your study

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WRIGHT STATE UNIVERSITY

 Role: Researcher   

Dashboard Studies Submissions Tasks Meetings Reporting More

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

1 In-Draft
Submission is with researchers


2 Awaiting Authorization
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-FY2021 

Edit

PDF

Delete

PI:

Current Analyst:
N/A

Decision:
N/A

Policy:
Post-2018 Rule

Required Tasks:
[Assign PI](#)
[Assign PE](#)
[Complete Submission](#)

Review Type:
N/A

Review Board:
N/A

Meeting Date:
N/A

Approvals

Task History

Attachments

Research Team

Name

No entries.

Result

6 ?

Click here to begin editing your submission

Remaining tasks

cayuse Human Ethics Role: Researcher

Dashboard Studies Submissions Tasks Meetings Reporting More

IRB NUMBER: IRB-FY2021-
- Initial

Sections < ✓

Screening Questions

NYU Research Personnel

Project Information

Project Information II

Participants & Recruitment

Consent & Privacy

Data Confidentiality & Ris...

Review Type

Attachments

Once all required questions in a section are complete, a check will appear next to the section

* Primary Data Collection

Check all types of data collection that apply.

☒ Surveys, questionnaires, interviews, or focus groups

☐ one-on-one

☐ group

* Please submit a word document or PDF text of all p...

ATTACH

☐ Internet data collection, e.g., online survey

☐ Observation of participants (including field notes)

☐ Recordings of participants (video, image, audio)

☐ Collection of biological specimens for research purposes, e.g., blood, saliva, hair, nail clippings

☐ Devices, e.g., MRI, eye-tracking, EEG, galvanic skin response sensors

☐ Virtual reality device(s)

☐ Taste-testing

☐ Other

* Will data that may be clinically relevant to participants be collected?

Clinically relevant data includes individual results about which participants may wish to be informed, e.g., diagnostic assessment results, DNA sequencing, blood glucose levels, incidental findings from MRI, IQ test scores.

Starred attachments must have something uploaded. If n/a, upload a Word doc stating such.

Questions marked with a red star are required

6 ?

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 one 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.

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.


The screenshot displays a user interface with a dark sidebar on the left containing three main categories: 'Studies' (with a folder icon), 'Submissions' (with a document icon), and 'Tasks' (with a checkmark icon). The 'Sections' menu is expanded, showing three items: 'Section 1 Assignme...' which has a red lock icon and a tooltip indicating it is 'Currently being edited by: IRBUser'; 'Section 2 Other Items' which has a green checkmark; and '3 Optional Form Ite...' which also has a green checkmark. In the background, a form titled 'Section 1 Ass...' is visible, featuring a question '1. PI and PC?' and a 'Yes' button.

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 ~~ABC~~    

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 ☐ Web URL ☐ Clipboard

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, this 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

Link

☒ Open link in new tab

Position

Center ▾

Types of Questions: Person & Sponsor Finder

[Person and Sponsor Finders](#)

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

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 * 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

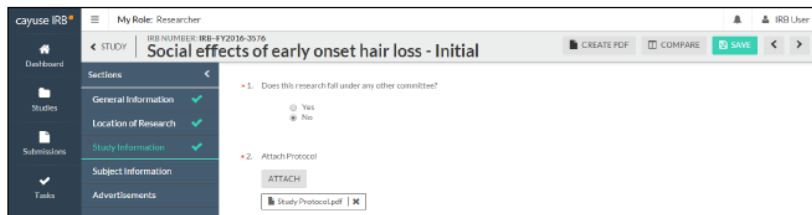
Supported File Types

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, xlsxm
Microsoft PowerPoint	ppt, pps, pptx, pptm, ppsx, pptsm, 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.



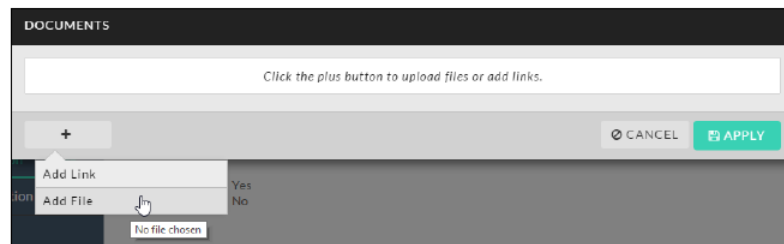
Attachments

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 title for the page:

DOCUMENTS

Add Link

Title: Google URL: http://www.google.com

CANCEL + ADD

Click the plus button to upload files or add links.

+ CANCEL APPLY

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?

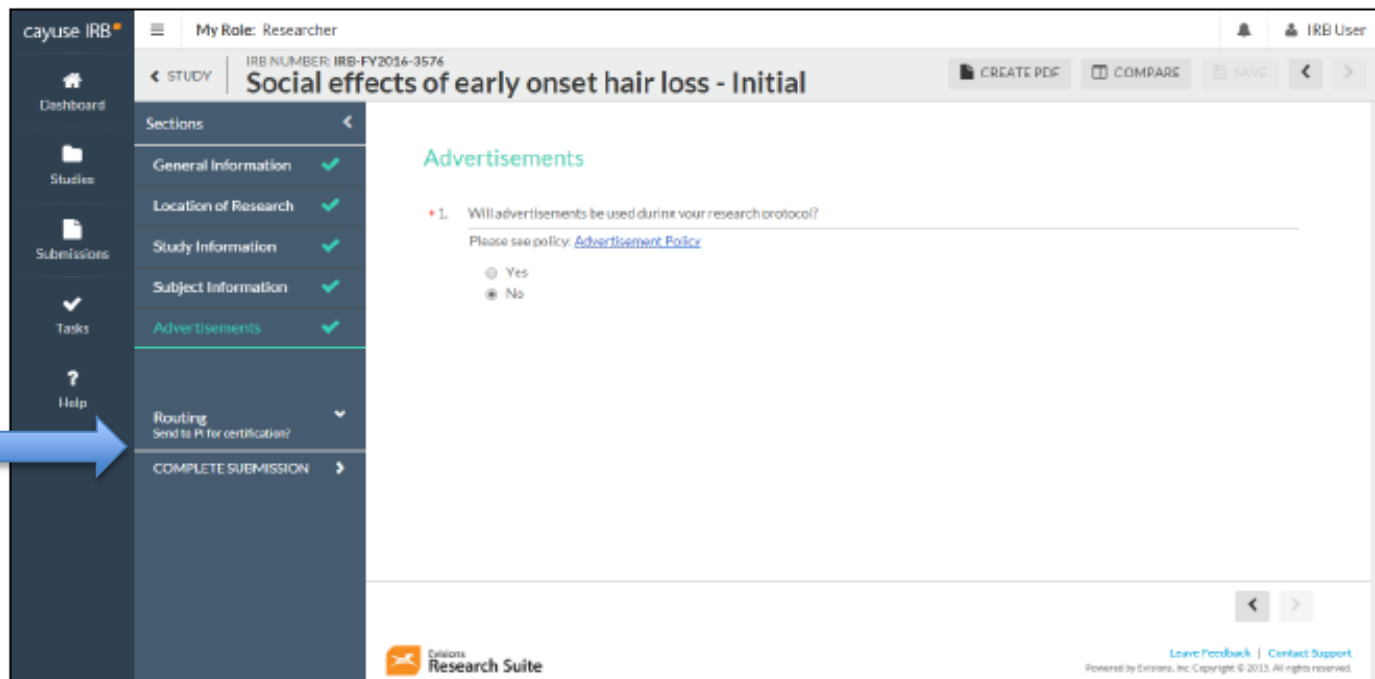
This is some help text.



- ☐ 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.



The screenshot displays the cayuse IRB web application interface. On the left is a dark blue sidebar with navigation links: Dashboard, Studies, Submissions, Tasks, Help, and a 'Routing' section. A large blue arrow points to the 'Routing' section in the sidebar. The 'Routing' section is expanded, showing a list of actions: 'Send to PI for certification?' and 'COMPLETE SUBMISSION'. The main content area shows the 'Advertisements' section of a study titled 'Social effects of early onset hair loss - Initial'. The study number is IRB-FY2016-3574. The 'Advertisements' section contains a question: '1. Will advertisements be used during your research protocol?' with radio button options for 'Yes' and 'No'. The 'Yes' option is selected. The interface also includes a top navigation bar with 'My Role: Researcher', a notification bell, and a user profile icon labeled 'IRB User'. At the bottom, there is a footer with the 'Evident Research Suite' logo and copyright information.

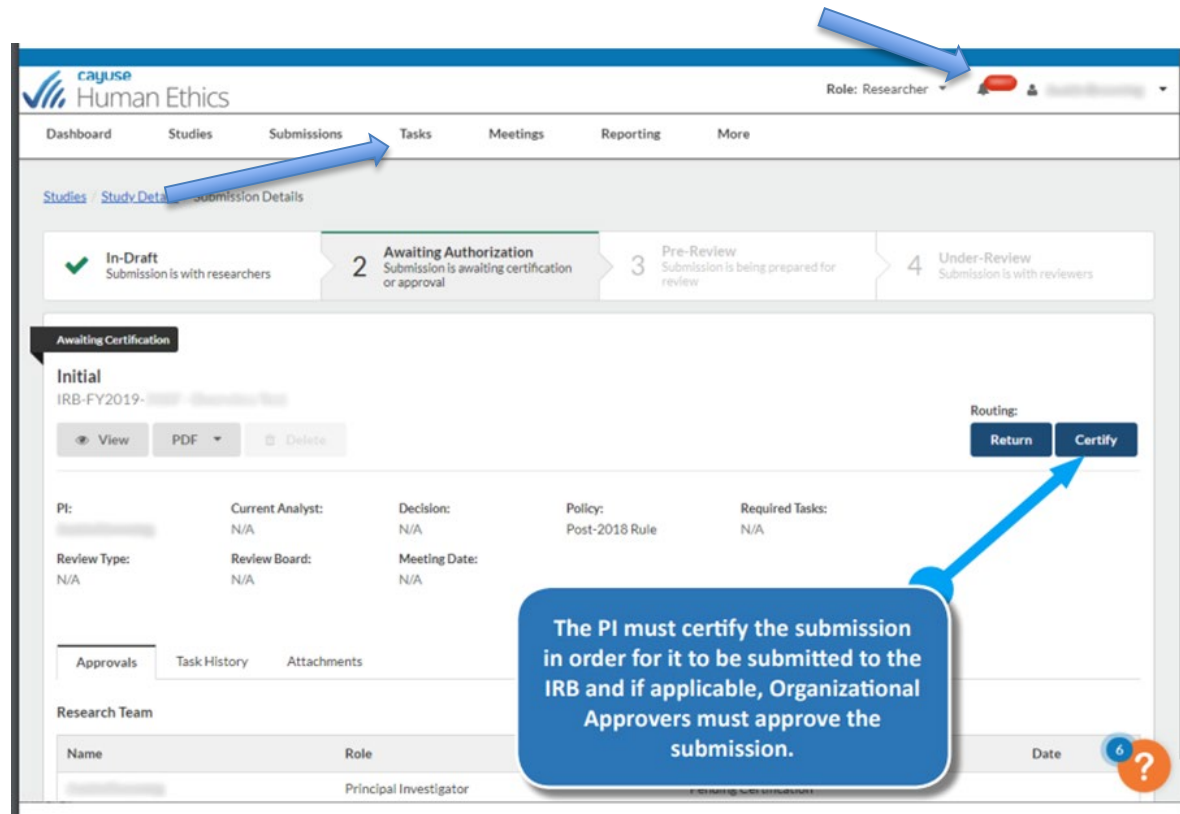
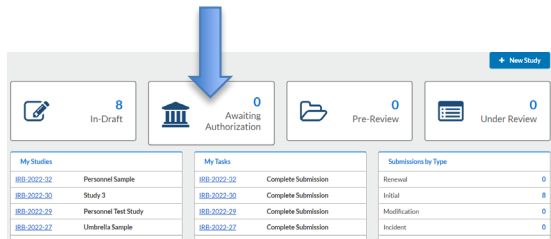
Certification

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).

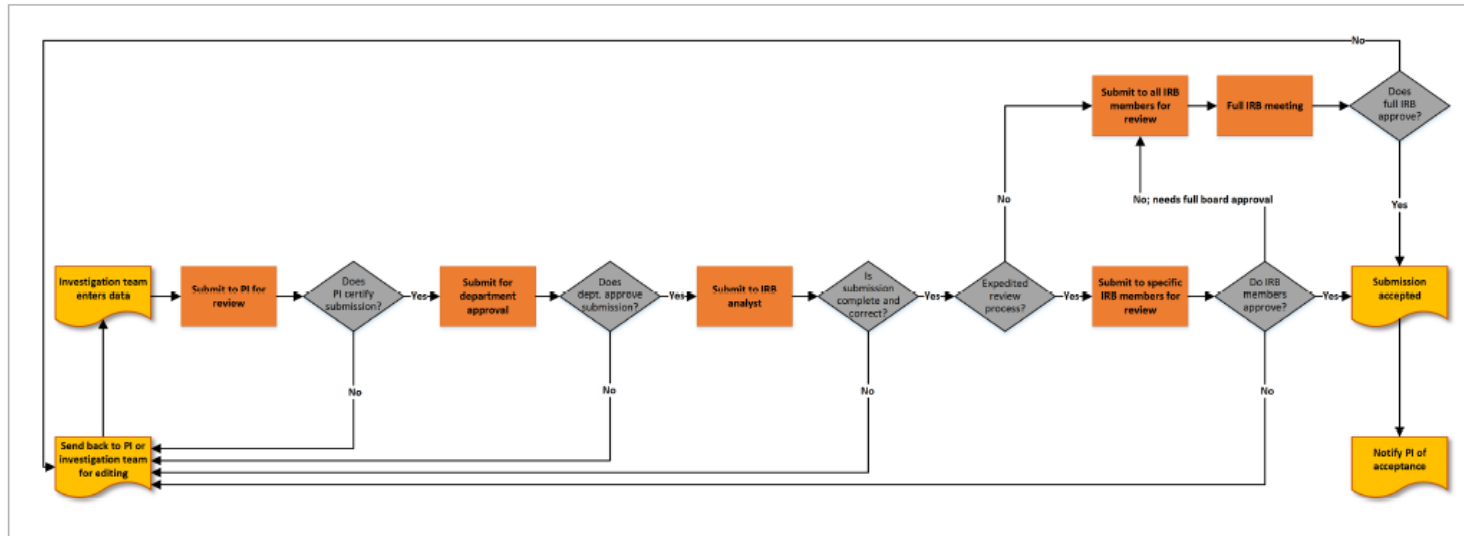


Note: No signature delegation ability in Cayuse.
Against IT policy to share passwords. Everyone must sign for themselves.

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

The screenshot displays the Cayuse Human Ethics submission details page. At the top, the navigation bar includes links for Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, and More. The user's role is set to 'Researcher'. 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 Authorization (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. Below the progress bar, a blue arrow points from the 'Under Pre-Review' status to the 'Initial' submission details. The details include fields for PI, Current Analyst, Decision, Policy, Review Type, Review Board, and Meeting Date. A 'Routing' section shows 'Post-2018 Rule' and a link to 'Assign Analyst'. A blue callout box states: 'Once certified by the PI (and approved by Organizational Approvers, if applicable), the application is submitted to the IRB and placed in Pre-Review'. At the bottom, a 'Research Team' table lists the Principal Investigator as 'Certified'. A red notification bubble with a question mark is visible in the bottom right corner.

Role: Researcher

Dashboard Studies Submissions Tasks Meetings Reporting More

Studies / Study Details / Submission Details

✓ In-Draft Submission is with researchers

✓ Awaiting Authorization 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
IRB-FY2019-

Review PDF Delete

Routing: Proceed

PI: Current Analyst: N/A Decision: N/A Policy: Post-2018 Rule Required Tasks: Assign Analyst

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

Approvals Task History Attachments

Research Team

Name	Role	Result	Date
	Principal Investigator	Certified	

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
 - CoNECT MRI Center

The screenshot displays the Cayuse Human Ethics interface. At the top, the user is logged in as Whitney McAllister with the role of Admin. The navigation bar includes links to Dashboard, Studies, Submissions, Tasks, Meetings, Reporting, and More. The breadcrumb trail shows the path: Studies / Study Details / Submission Details. A progress bar at the top of the submission details section shows four stages: In-Draft (Submission is with researchers), Awaiting Authorization (Submission is awaiting certification or approval), Pre-Review (Submission is being prepared for review), and 4 Under-Review (Submission is with reviewers). A blue arrow points to the 'Under-Review' stage. Below the progress bar, the submission is identified as 'Initial' with ID 'IRB-2022-21 - Sample_06.17.2022 - Expedited1'. Action buttons include Review, PDF, Delete, and Checklist. The Routing section contains buttons for Return, Change, and Review Complete. The submission details section lists: PI: Irene Investigator, Current Analyst: Whitney McAllister, Decision: N/A, Policy: Post-2018 Rule, Review Type: Full Board, Review Board: Wright State IRB, Meeting Date: 07-18-2022, and Required Tasks: Assign to Meeting, Make Decision, and Manage Letters. A blue arrow points to the 'Current Analyst' field.

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

Get Help – IRB Staff Consultations

- Virtual Office Hours
 - Wednesdays at 11am –12:00pm
 - By appointment
- IRB Chat via Teams
- IRB Help Line:
 - 937-775-4462
- Email: irb-rsp@wright.edu

