

# How to Complete An IRB Review in Cayuse

Scribe<sup>™</sup>

This guide provides a step-by-step process for completing an IRB review in Cayuse, ensuring that reviewers can efficiently navigate submissions and provide necessary feedback. It highlights key features like commenting, checklist completion, and decision-making, which streamline the review process.

1

Navigate to your **Cayuse Dashboard!** <https://usm.app.cayuse.com/>

The Cayuse Dashboard is a comprehensive interface for managing research submissions and reviews. It includes the following sections:

- IRB Queue:** Shows 38 items, including "LW Test 12.12.2025" and "Workflow Example 2". A "View All" button is present.
- Renewal Queue:** Shows 6 items: Renewal, Initial, Modification, Incident, Withdrawal, Closure, and Legacy. A "View All" button is present.
- My Studies:** Shows 60 studies, including "Overview Sample 1", "Training Video", "Workflow Example 3", and "Workflow Example 1". A "View All" button is present.
- My Meetings:** Displays a monthly calendar for January 2026. The 12th is highlighted in grey, indicating an upcoming meeting. The calendar includes dates from 28 to 31 January, and 01 to 07 February.
- Upcoming Meetings:** Shows a message: "No Upcoming Meetings" with a sad face icon.

**2** Locate the area labeled as "**Submissions Where I Am the Primary Reviewer**" or the "**My Tasks**" to select a protocol.

**Note: You will also receive email notifications of each protocol that you are assigned to review.**

Human Ethics

Role: Reviewer Products

Dashboard Studies Submissions Tasks Meetings

Full Board Reviews ➔

Expedited Reviews ➔

Limited IRB Reviews ➔

Exempt Reviews ➔

Submissions where I am the Primary Reviewer ➔

IRB-26-66 Example IRB Submission in Cayuse

IRB-25-32 LW Test 12.12.2025

IRB-FY2026-10 Workflow Example 2

View All

My Tasks

IRB-26-66 Complete Expedited Review

View All

Submissions by Type

Renewal

Initial

Modification

Incident

Withdrawal

Closure

Legacy

Approved Studies

IRB-26-60 Overview Sample 1

Training Video

My Meetings

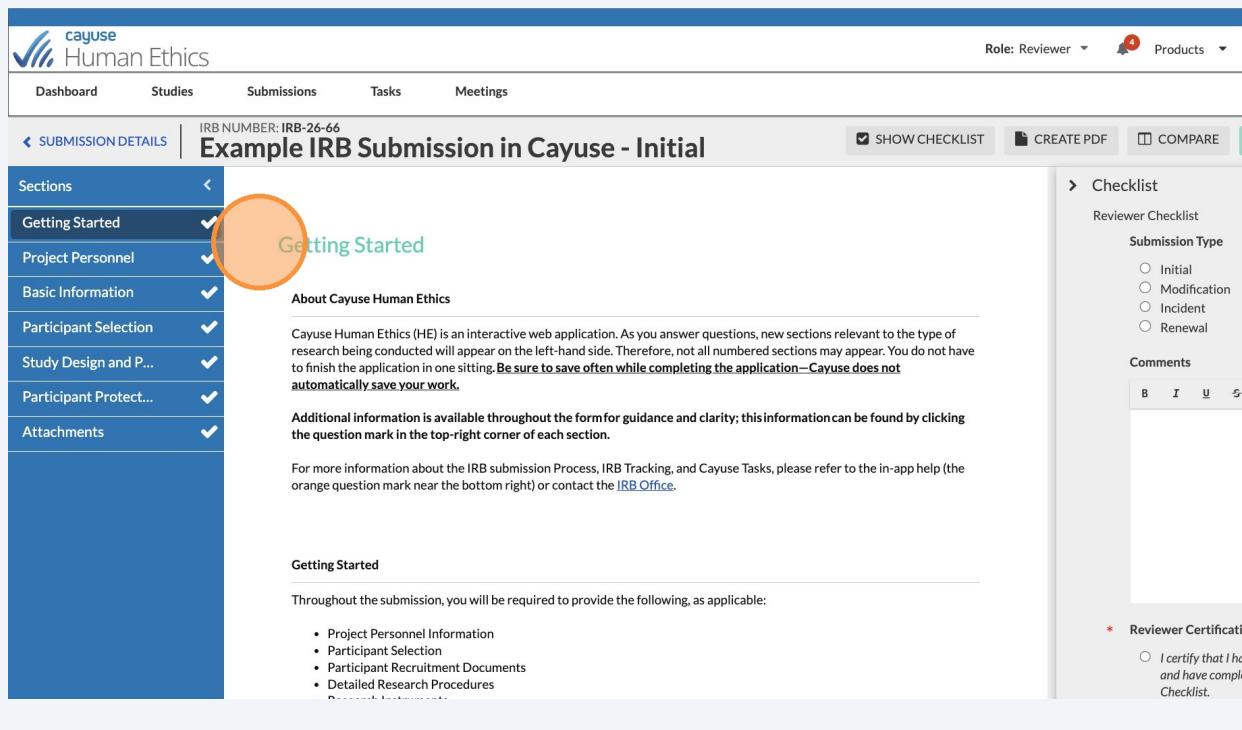
January 2026

Upcoming Meetings

### 3 Click "Review"

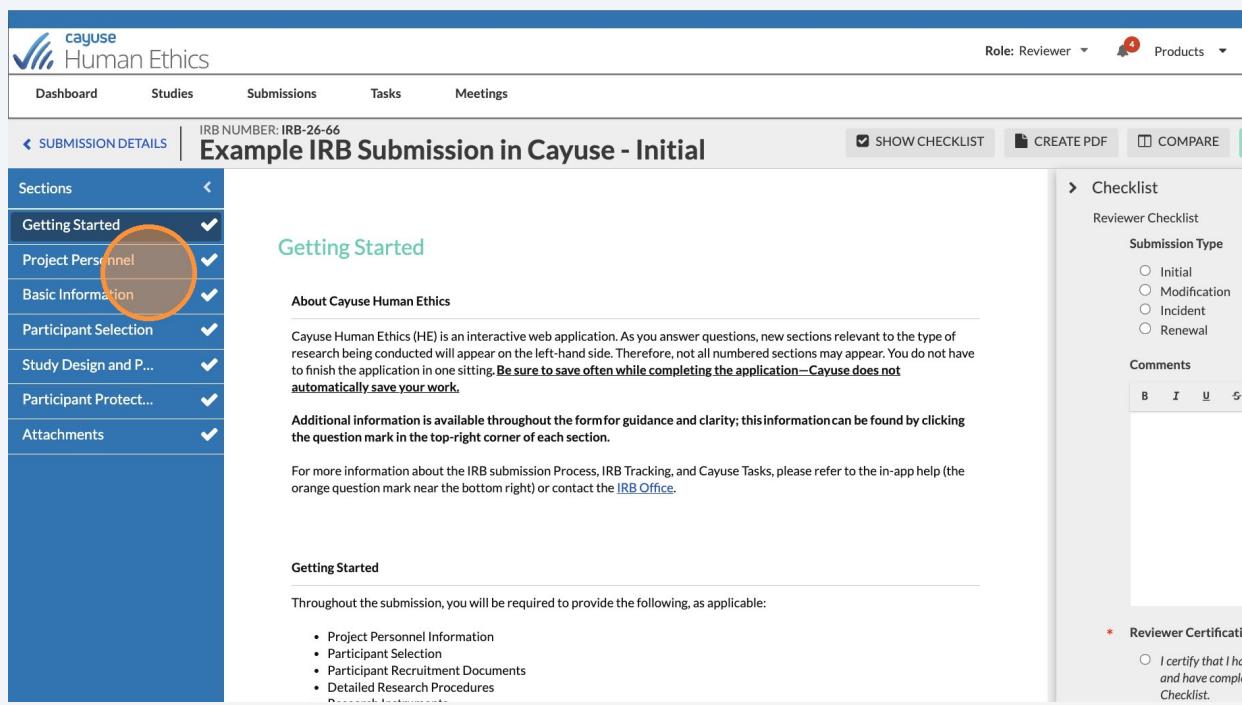
The screenshot shows the Human Ethics software interface. At the top, there is a navigation bar with the logo, 'Human Ethics', 'Role: Reviewer', a notification icon (4), and 'Products'. Below the navigation bar, there is a secondary navigation bar with links for 'Dashboard', 'Studies', 'Submissions', 'Tasks', and 'Meetings'. The main content area is titled 'Studies / Study Details / Submission Details'. Below this, there is a horizontal bar with four status indicators: 'In-Draft' (Submission is with researchers), 'Awaiting Authorization' (Submission is awaiting certification or approval), 'Pre-Review' (Submission is being prepared for review), and 'Under-Review' (Submission is with reviewers). The 'Under-Review' status is highlighted with a green checkmark and a count of 4. Below the status bar, there is a section for an 'Initial' submission titled 'IRB-20-001 Example IRB Submission in Cayuse'. This section includes a 'Review' button (which is highlighted with an orange circle), 'PDF', 'Delete', and 'Checklist' buttons. To the right, there is a 'Routing:' section with a 'Switch' button. Below the 'Initial' section, there is a table with details for the submission, including PI, Current Analyst, Decision, Policy, and Required Tasks. There are also sections for 'Review Type', 'Review Board', 'Meeting Date', and 'Attachments'. At the bottom, there is a 'Research Team' section with a table showing team members, their roles, results, and dates.

4 Once you open the submission, you will see a page entitled "**Getting Started**".



The screenshot shows the Cayuse Human Ethics web application interface. At the top, there is a navigation bar with links for Dashboard, Studies, Submissions, Tasks, and Meetings. On the right side of the top bar, there are 'Role: Reviewer' and 'Products' dropdown menus. Below the navigation bar, the main content area has a header 'Example IRB Submission in Cayuse - Initial' with sub-links for 'SUBMISSION DETAILS', 'SHOW CHECKLIST' (with a checked checkbox), 'CREATE PDF', and 'COMPARE'. The main content area is titled 'Getting Started' and contains a sub-section 'About Cayuse Human Ethics'. A note in this section states: 'Cayuse Human Ethics (HE) is an interactive web application. As you answer questions, new sections relevant to the type of research being conducted will appear on the left-hand side. Therefore, not all numbered sections may appear. You do not have to finish the application in one sitting. Be sure to save often while completing the application—Cayuse does not automatically save your work.' Below this, another note says: 'Additional information is available throughout the form for guidance and clarity; this information can be found by clicking the question mark in the top-right corner of each section.' At the bottom of the 'Getting Started' section, there is a list of required items: 'Project Personnel Information', 'Participant Selection', 'Participant Recruitment Documents', and 'Detailed Research Procedures'. To the right of the main content area, there is a 'Checklist' sidebar with sections for 'Reviewer Checklist', 'Submission Type' (with radio buttons for 'Initial', 'Modification', 'Incident', and 'Renewal'), and a 'Comments' text area. At the bottom right of the sidebar, there is a 'Reviewer Certification' section with a radio button and a note: 'I certify that I have and have complete Checklist.'

5 To begin your review, please **navigate to each tab** on the left to review each section of the protocol submission.

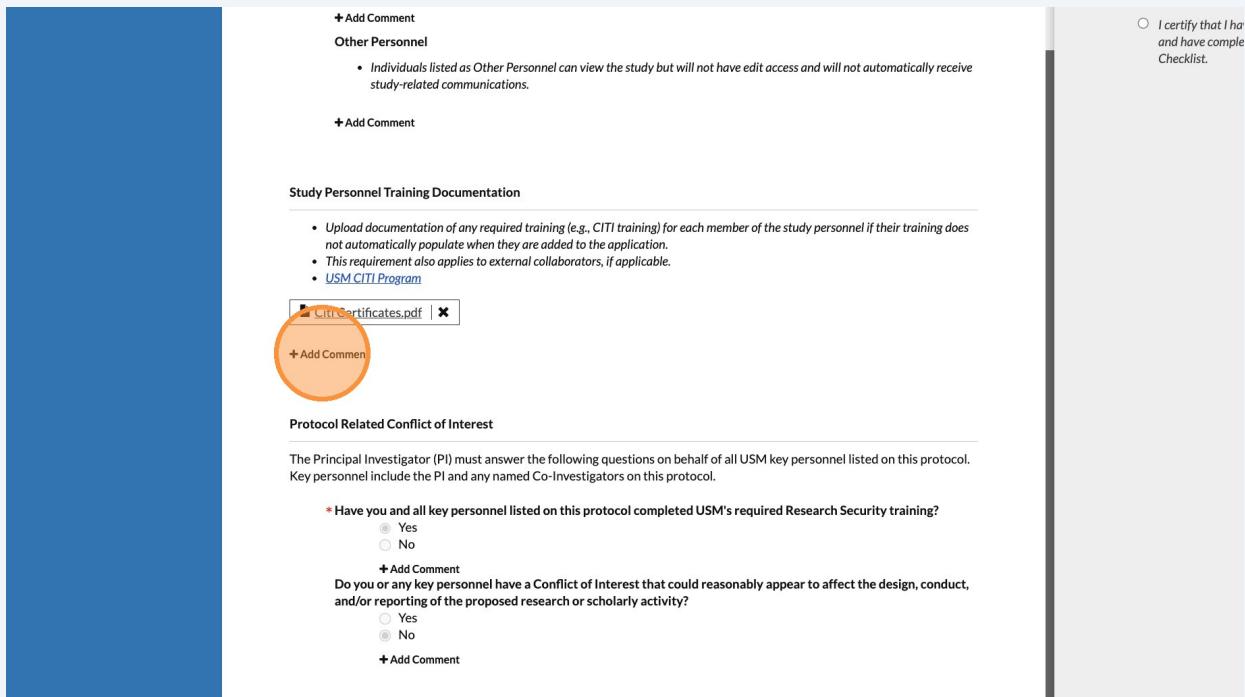


The screenshot shows the Cayuse Human Ethics web application interface, similar to the previous one but with a different section highlighted. The 'Project Personnel' section is now highlighted with a brown circle. The main content area is titled 'Getting Started' and contains a sub-section 'About Cayuse Human Ethics'. A note in this section states: 'Cayuse Human Ethics (HE) is an interactive web application. As you answer questions, new sections relevant to the type of research being conducted will appear on the left-hand side. Therefore, not all numbered sections may appear. You do not have to finish the application in one sitting. Be sure to save often while completing the application—Cayuse does not automatically save your work.' Below this, another note says: 'Additional information is available throughout the form for guidance and clarity; this information can be found by clicking the question mark in the top-right corner of each section.' At the bottom of the 'Getting Started' section, there is a list of required items: 'Project Personnel Information', 'Participant Selection', 'Participant Recruitment Documents', and 'Detailed Research Procedures'. To the right of the main content area, there is a 'Checklist' sidebar with sections for 'Reviewer Checklist', 'Submission Type' (with radio buttons for 'Initial', 'Modification', 'Incident', and 'Renewal'), and a 'Comments' text area. At the bottom right of the sidebar, there is a 'Reviewer Certification' section with a radio button and a note: 'I certify that I have and have complete Checklist.'

6

During your review, you may want to comment on the protocol.

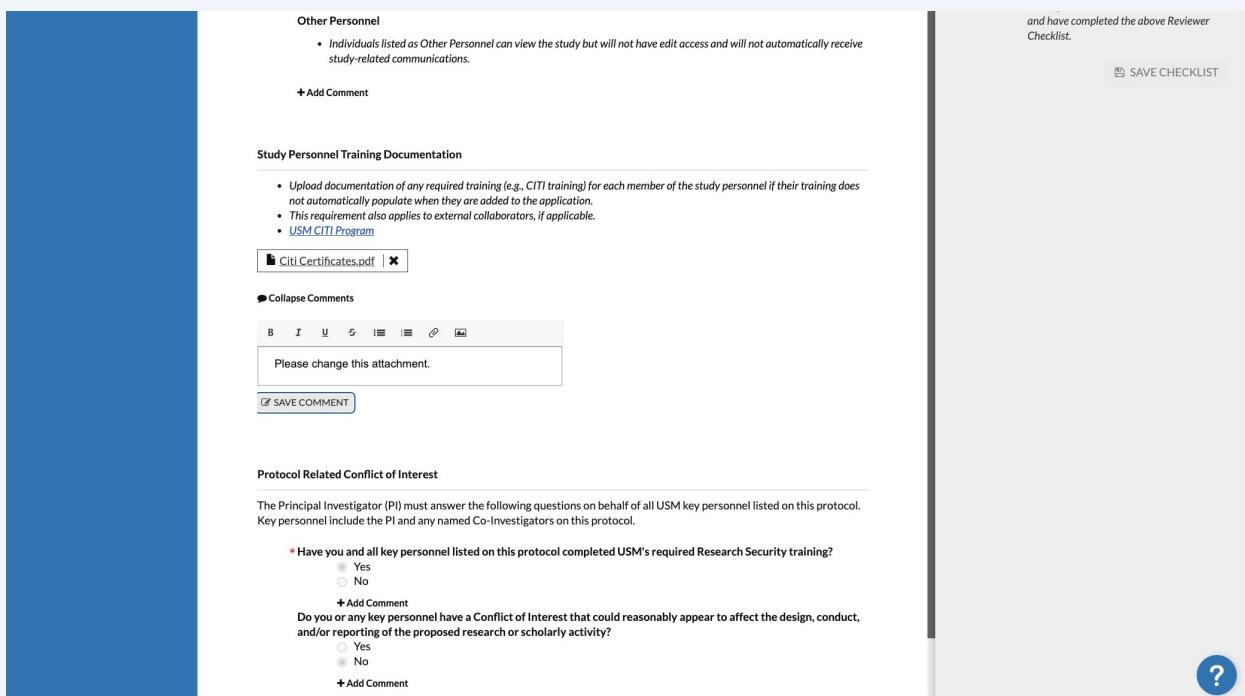
To comment on any section of a protocol, select "**+ Add Comment**"



The screenshot shows a portion of a web-based protocol review application. On the left, there is a large blue vertical bar. The main content area contains several sections: "Other Personnel" with a note about view-only access for other personnel; "Study Personnel Training Documentation" with a note about required training and a file attachment labeled "Citi Certificates.pdf"; "Protocol Related Conflict of Interest" with a note about PI responsibility and a question about research security training. A large orange circle highlights the "+ Add Comment" button in the "Protocol Related Conflict of Interest" section. In the top right corner, there is a checkbox for certifying completion of a checklist.

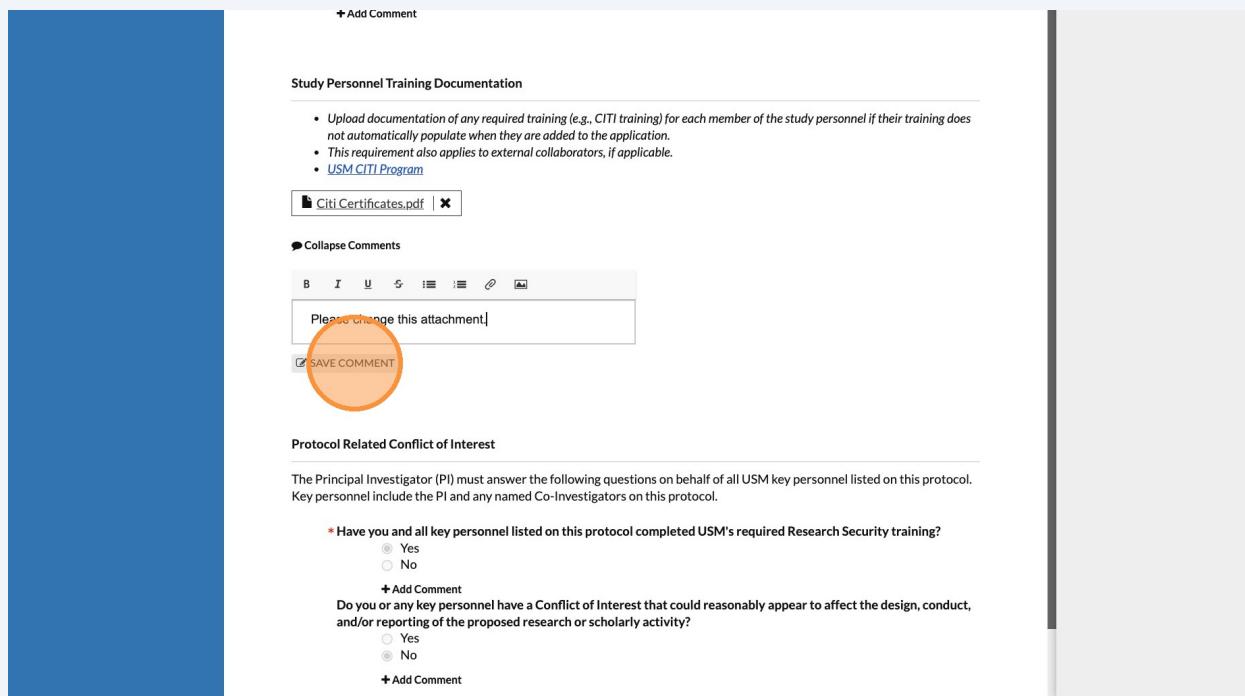
7

If you select, "**+Add Comment**", a text box will appear for you to describe any questions, comments or concerns you may have.



The screenshot shows the same protocol review interface as the previous one, but with a comment box open. The "Protocol Related Conflict of Interest" section is visible, and a comment box is open, containing the text "Please change this attachment." Below the comment box is a "SAVE COMMENT" button. The top right corner of the interface includes a "SAVE CHECKLIST" button and a help icon.

8 Enter your comment. Next, click "**Save Comment**"



+ Add Comment

Study Personnel Training Documentation

- Upload documentation of any required training (e.g., CITI training) for each member of the study personnel if their training does not automatically populate when they are added to the application.
- This requirement also applies to external collaborators, if applicable.
- [USM CITI Program](#)

**Citi Certificates.pdf** | x

**Comment**

Please change this attachment!

**SAVE COMMENT**

Protocol Related Conflict of Interest

The Principal Investigator (PI) must answer the following questions on behalf of all USM key personnel listed on this protocol. Key personnel include the PI and any named Co-Investigators on this protocol.

\* Have you and all key personnel listed on this protocol completed USM's required Research Security training?

Yes  
 No

**Add Comment**

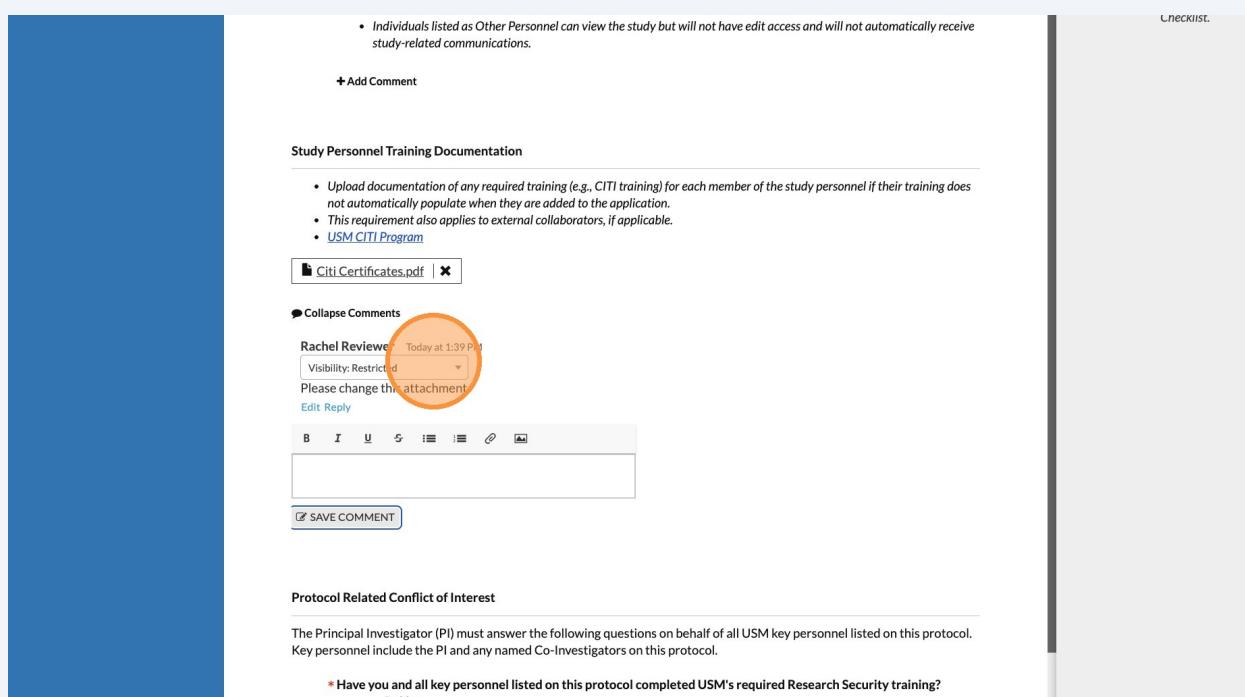
Do you or any key personnel have a Conflict of Interest that could reasonably appear to affect the design, conduct, and/or reporting of the proposed research or scholarly activity?

Yes  
 No

**Add Comment**

9 Note: The default option for your comment is reserved as "**Visibility: Restricted**".

**This means that only reviewers and analysts can access these comments.**



+ Add Comment

Study Personnel Training Documentation

- Upload documentation of any required training (e.g., CITI training) for each member of the study personnel if their training does not automatically populate when they are added to the application.
- This requirement also applies to external collaborators, if applicable.
- [USM CITI Program](#)

**Citi Certificates.pdf** | x

**Comment**

Rachel Reviewer Today at 1:39 PM

Visibility: **Restricted**

Please change this attachment!

**Edit Reply**

**SAVE COMMENT**

Protocol Related Conflict of Interest

The Principal Investigator (PI) must answer the following questions on behalf of all USM key personnel listed on this protocol. Key personnel include the PI and any named Co-Investigators on this protocol.

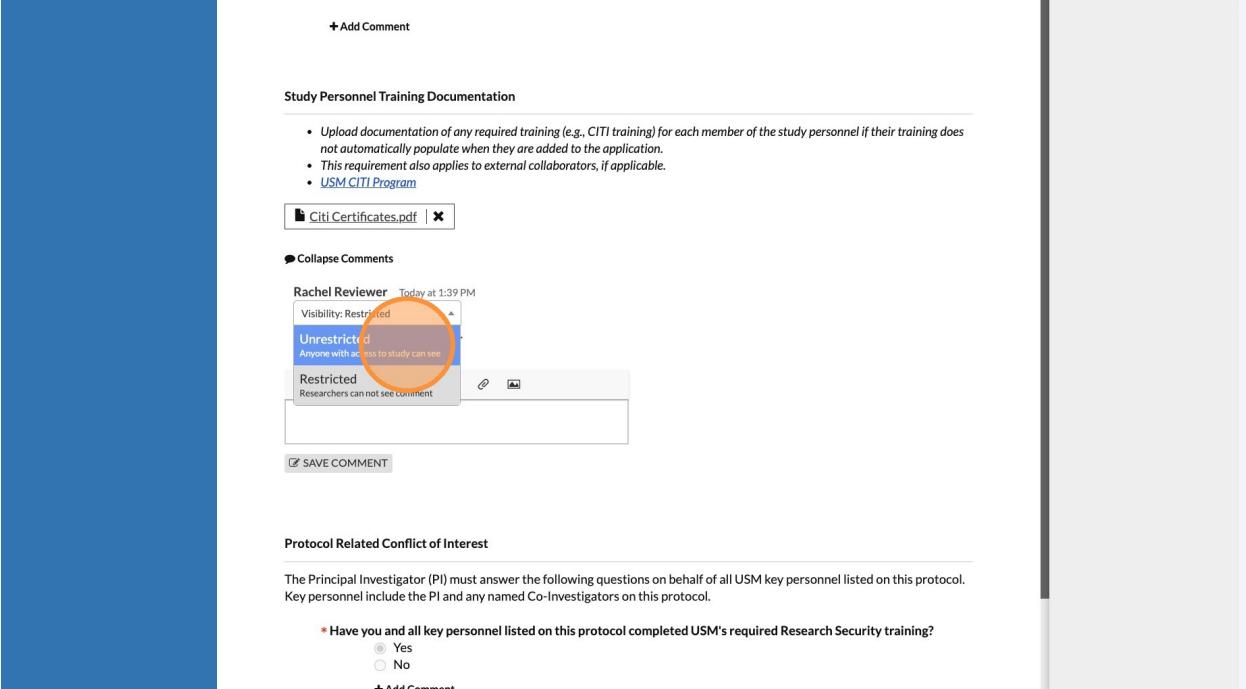
\* Have you and all key personnel listed on this protocol completed USM's required Research Security training?

Yes

10

**Since comments are automatically restricted, you will need to manually unrestrict your comment to make them visible to investigators.**

To do this, you **MUST** click "**Unrestricted: Anyone with access to study can see**" to allow all investigators to view your comments.



The screenshot shows a user interface for managing study personnel training documentation. At the top, there is a button to '+ Add Comment'. Below it, a section titled 'Study Personnel Training Documentation' contains a list of requirements:

- Upload documentation of any required training (e.g., CITI training) for each member of the study personnel if their training does not automatically populate when they are added to the application.
- This requirement also applies to external collaborators, if applicable.
- [USM CITI Program](#)

Below this is a file upload area for 'Citi Certificates.pdf' with a delete button. A 'Collapse Comments' button is present. A comment by 'Rachel Reviewer' is shown, timestamped 'Today at 1:39 PM'. The comment has a dropdown menu with two options: 'Unrestricted' (highlighted with an orange circle) and 'Restricted'. The 'Unrestricted' option is described as 'Anyone with access to study can see'. The 'Restricted' option is described as 'Researchers can not see comment'. There are edit and delete icons for the comment. At the bottom of the comment area is a 'SAVE COMMENT' button.

Below the comment section, there is a section titled 'Protocol Related Conflict of Interest'. It states: 'The Principal Investigator (PI) must answer the following questions on behalf of all USM key personnel listed on this protocol. Key personnel include the PI and any named Co-Investigators on this protocol.' A question is listed: '\* Have you and all key personnel listed on this protocol completed USM's required Research Security training?' with 'Yes' and 'No' radio button options. At the bottom of this section is a '+ Add Comment' button.

11

After selecting **"Unrestricted: Anyone with access to study can see,"** the comment label will update to **"Visibility Unrestricted."**

Please ensure that this setting is applied to **every comment** you submit during your review.

The screenshot shows a web-based application for managing study personnel training documentation. On the left, a large blue sidebar is visible. The main content area has a white background with a dark grey header bar at the top.

**Study Personnel Training Documentation**

• *Individuals listed as Other Personnel can view the study but will not have edit access and will not automatically receive study-related communications.*

**+ Add Comment**

**Study Personnel Training Documentation**

• *Upload documentation of any required training (e.g., CITI training) for each member of the study personnel if their training does not automatically populate when they are added to the application.*

• *This requirement also applies to external collaborators, if applicable.*

• [USM CITI Program](#)

**Citi Certificates.pdf** | **x**

**Collapse Comments**

**Rachel Reviewer** Today at 1:39 PM

Visibility: Unrestricted

Please change this attachment.

[Edit](#) [Reply](#)

**Feedback Requested**

**B** **I** **U** **S** **≡** **≡** **⊕** **⊕**

**SAVE COMMENT**

**Protocol Related Conflict of Interest**

The Principal Investigator (PI) must answer the following questions on behalf of all USM key personnel listed on this protocol. Key personnel include the PI and any named Co-Investigators on this protocol.

\* Have you and all key personnel listed on this protocol completed USM's required Research Security training?

12

## While completing your review, you can also access several key features:

- **Show Checklist** – Displays your reviewer checklist.
- **Create PDF** – Generates a PDF copy of the submission.
- **Compare** – Allows you to view and cross-reference previous submissions side by side.

IRB NUMBER: IRB-26-66

**Example IRB Submission in Cayuse - Initial**

**Primary Contact**

- The Primary Contact is the main point of communication for the study. This role does not replace the Principal Investigator responsibilities.

Name	Organization	Address	Phone	Email	Training
Irene Investigator	School of Professional Nursing			morgan.chapman+investigator@cayuse.com	<a href="#">View</a>

[+ Add Comment](#)

**Co-Investigator(s)**

- Individuals listed as Co-Investigators will have edit access to the study, can submit follow-on submissions after initial approval, and will automatically receive all study-related communications.

[+ Add Comment](#)

**Other Personnel**

- Individuals listed as Other Personnel can view the study but will not have edit access and will not automatically receive study-related communications.

[+ Add Comment](#)

**Study Personnel Training Documentation**

- Upload documentation of any required training (e.g., CITI training) for each member of the study personnel if their training does not automatically populate when they are added to the application.
- This requirement also applies to external collaborators, if applicable.
- [IISN CITI Program](#)

**Checklist**

Reviewer Checklist

Submission Type

- Initial
- Modification
- Incident
- Renewal

Comments

**Reviewer Certification**

I certify that I have reviewed this submission and have completed the above Reviewer Checklist.

13

Click **"SHOW CHECKLIST"** to view your reviewer checklist.

IRB NUMBER: IRB-26-66

## Example IRB Submission in Cayuse - Initial

Irene Investigator Professional Nursing morgan.chapman+investigator@cayuse.com [View](#)

[SHOW CHECKLIST](#) [CREATE PDF](#) [COMPARE](#) [SAVE](#)

**+ Add Comment**

**Primary Contact**

- Anyone listed as **Primary Contact (PC)** will have edit access to the study, can create follow-on submissions after initial approval, and will receive all study-related communications.
- All students (undergraduate or graduate) should list themselves as the Primary Contact.
- The Primary Contact is the main point of communication for the study. This role does not replace the Principal Investigator's responsibilities.

Name	Organization	Address	Phone	Email	Trainings
Irene Investigator	School of Professional Nursing			morgan.chapman+investigator@cayuse.com	<a href="#">View</a>

**+ Add Comment**

**Co-Investigator(s)**

- Individuals listed as Co-Investigators will have edit access to the study, can submit follow-on submissions after initial approval, and will automatically receive all study-related communications.

**+ Add Comment**

**Other Personnel**

- Individuals listed as Other Personnel can view the study but will not have edit access and will not automatically receive study-related communications.

**+ Add Comment**

**Study Personnel Training Documentation**

- Upload documentation of any required training (e.g. CITI training) for each member of the study personnel if their training does not automatically populate when they are added to the application

14

Complete the checklist by answering the required questions.

First, **select** a submission type.

Role: Reviewer Products Rachel Reviewer

Studies Submissions Tasks Meetings

IRB NUMBER: IRB-26-66

## Example IRB Submission in Cayuse - Initial

SHOW CHECKLIST  CREATE PDF  COMPARE  SAVE

Name	Organization	Address	Phone	Email	Training
Irene Investigator	School of Professional Nursing			morgan.chapman+investigator@cayuse.com	<a href="#">View</a>

**+ Add Comment**

**\* Primary Contact**

- Anyone listed as a Primary Contact (PC) will have edit access to the study, can create follow-on submissions after initial approval, and will receive all study-related communications.
- All students (undergraduate or graduate) should list themselves as the Primary Contact.
- The Primary Contact is the main point of communication for the study. This role does not replace the Principal Investigator responsibilities.

Name	Organization	Address	Phone	Email	Training
Irene Investigator	School of Professional Nursing			morgan.chapman+investigator@cayuse.com	<a href="#">View</a>

**+ Add Comment**

**Co-Investigator(s)**

- Individuals listed as Co-Investigators will have edit access to the study, can submit follow-on submissions after initial approval, and will automatically receive all study-related communications.

**+ Add Comment**

**Other Personnel**

- Individuals listed as Other Personnel can view the study but will not have edit access and will not automatically receive study-related communications.

**Checklist**

Reviewer Checklist

Submission Type

- Initial
- Modification
- Incident
- Renewal

Comments

B I U S : : :

**\* Reviewer Certification**

I certify that I have reviewed this submission and have completed the above Reviewer Checklist.

15

Next, enter comments, if necessary.

✓ Irene Investigator Professional Nursing morgan.chapman+investigator@cayuse.com [View](#)

[+ Add Comment](#)

**\* Primary Contact**

- Anyone listed as a Primary Contact (PC) will have edit access to the study, can create follow-on submissions after initial approval, and will receive all study-related communications.
- All students (undergraduate or graduate) should list themselves as the Primary Contact.
- The Primary Contact is the main point of communication for the study. This role does not replace the Principal Investigator responsibilities.

Name	Organization	Address	Phone	Email	Training
Irene Investigator	School of Professional Nursing			morgan.chapman+investigator@cayuse.com	<a href="#">View</a>

[+ Add Comment](#)

**Co-Investigator(s)**

- Individuals listed as Co-Investigators will have edit access to the study, can submit follow-on submissions after initial approval, and will automatically receive all study-related communications.

[+ Add Comment](#)

**Other Personnel**

- Individuals listed as Other Personnel can view the study but will not have edit access and will not automatically receive study-related communications.

[+ Add Comment](#)

**Study Personnel Training Documentation**

- Upload documentation of any required training (e.g., CITI training) for each member of the study personnel if their training does not automatically populate when they are added to the application.
- This requirement also applies to external collaborators, if applicable.
- [USM CITI Program](#)

Reviewer Checklist

Submission Type

Initial

NCSR/Not Engaged/118 Determination

Full application (e.g., research study, clinical trial, etc.)

Modification

Incident

Renewal

Comments

[B](#) [I](#) [U](#) [S](#) [≡](#) [≡](#) [≡](#)

**\* Reviewer Certification**

I certify that I have reviewed this submission and have completed the above Reviewer Checklist.

[SAVE CHECKLIST](#)

16

Finally, complete the certification.

Select "**I certify that I have reviewed this submission and have completed the above Reviewer Checklist.**"

✓ Irene Investigator Professional Nursing morgan.chapman+investigator@cayuse.com [View](#)

[+ Add Comment](#)

**Co-Investigator(s)**

- Individuals listed as Co-Investigators will have edit access to the study, can submit follow-on submissions after initial approval, and will automatically receive all study-related communications.

[+ Add Comment](#)

**Other Personnel**

- Individuals listed as Other Personnel can view the study but will not have edit access and will not automatically receive study-related communications.

[+ Add Comment](#)

**Study Personnel Training Documentation**

- Upload documentation of any required training (e.g., CITI training) for each member of the study personnel if their training does not automatically populate when they are added to the application.
- This requirement also applies to external collaborators, if applicable.
- [USM CITI Program](#)

[Citi Certificates.pdf](#) [X](#)

[Collapse Comments](#)

Rachel Reviewer Today at 1:39 PM

Visibility: Restricted

Please change this attachment.

[Edit](#) [Reply](#)

Reviewer Checklist

Renewal

Comments

[B](#) [I](#) [U](#) [S](#) [≡](#) [≡](#) [≡](#)

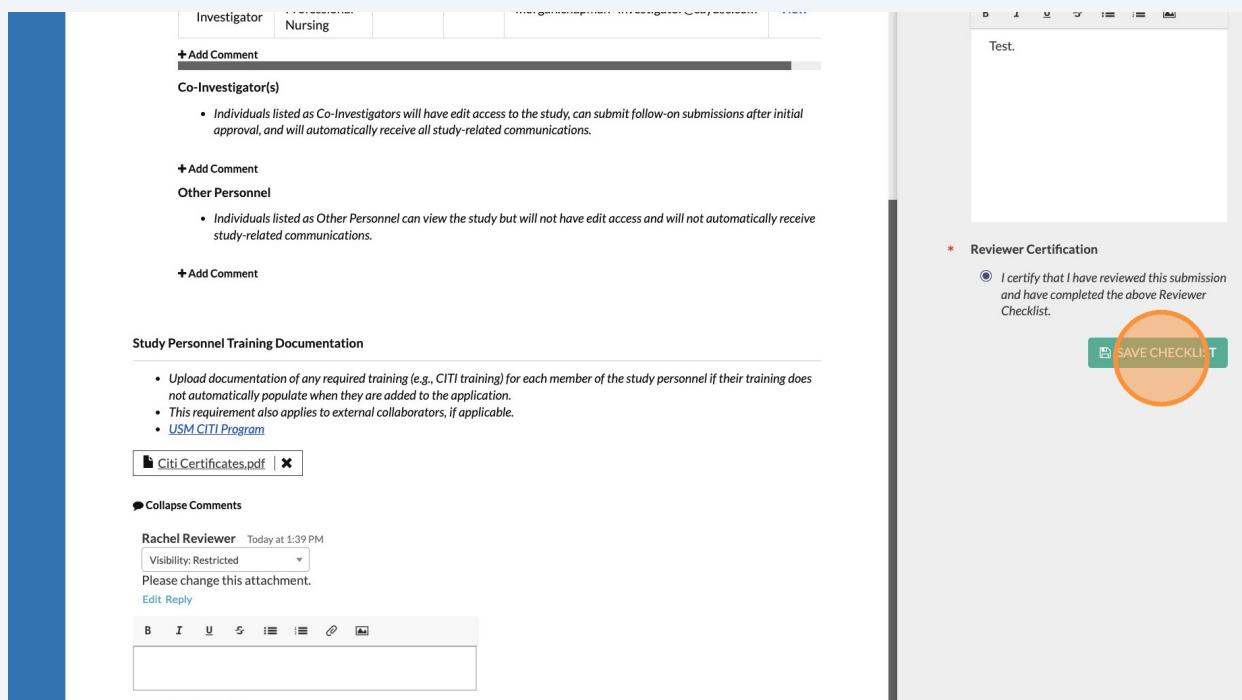
Test.

**\* Reviewer Certification**

I certify that I have reviewed this submission and have completed the above Reviewer Checklist.

[SAVE CHECKLIST](#)

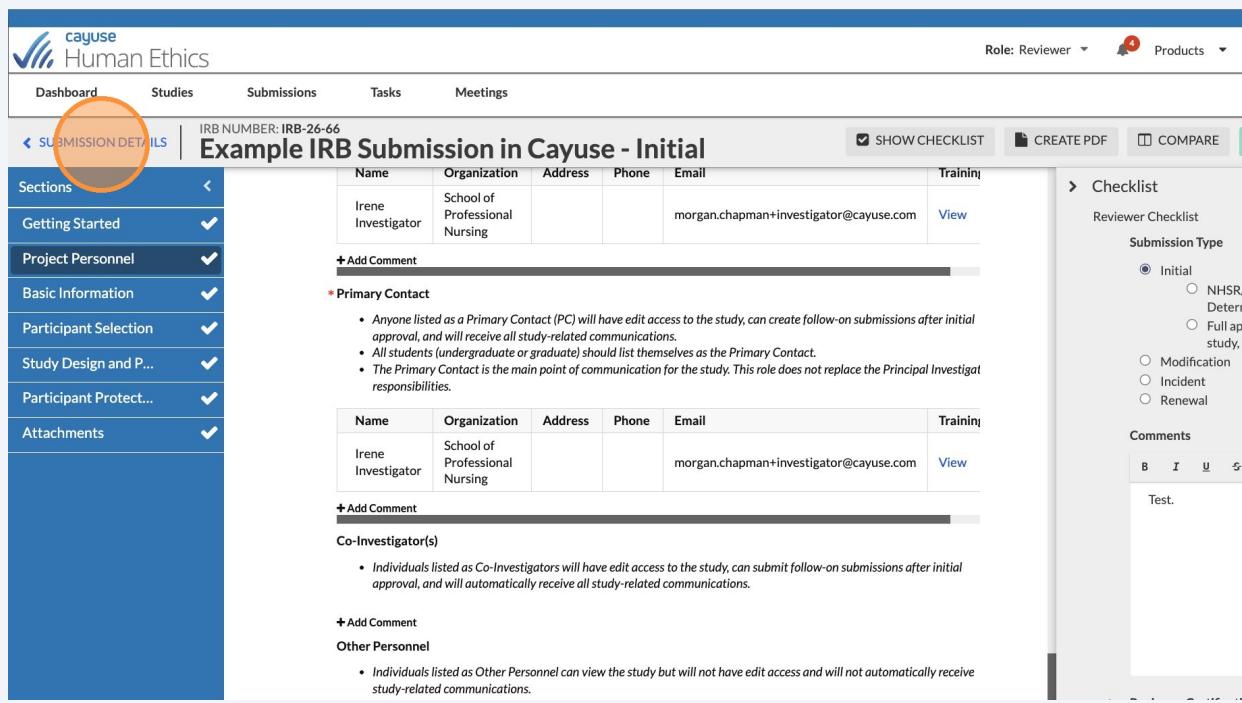
17 Click "Save Checklist"



The screenshot shows the 'Study Personnel Training Documentation' section. It includes a list of requirements, a PDF attachment named 'Citi Certificates.pdf', and a comment from 'Rachel Reviewer' with a 'Collapse Comments' button. On the right, there is a 'Reviewer Certification' section with a radio button and a statement. The 'SAVE CHECKLIST' button is highlighted with an orange circle.

18 After completing your review/checklist, you will need to record a decision on the proposal (e.g., approve, require revisions, etc.).

To navigate to the decision page, select "**Submission Details.**"



The screenshot shows the 'Example IRB Submission in Cayuse - Initial' page. The 'SUBMISSION DETAILS' section is highlighted with an orange circle. The page displays sections like 'Sections', 'Getting Started', 'Project Personnel', 'Basic Information', 'Participant Selection', 'Study Design and P...', 'Participant Protect...', and 'Attachments'. It also shows 'Primary Contact' and 'Co-Investigator(s)' sections with their respective details. On the right, there is a 'Checklist' section with a 'Reviewer Checklist' and 'Submission Type' (set to 'Initial'), and a 'Comments' section with a 'Test.' note.

19 You should land on this page.

Click **"Make Decision"**.

The screenshot shows the 'Submission Details' page for an IRB submission. At the top, there are three status boxes: 'Awaiting Authorization' (with researchers), 'Pre-Review' (with reviewers), and 'Under-Review' (with reviewers). The 'Under-Review' box is highlighted with an orange circle around the 'Make Decision' button. Below the status boxes, there is a section for 'Role IRB Submission in Cayuse' with buttons for 'PDF', 'Delete', and 'Checklist'. To the right, there are 'Routing' buttons for 'Switch' and 'Review Complete'. Underneath, there is a table with submission details: Current Analyst: Andy Analyst, Decision: N/A, Policy: Post-2018 Rule; Review Board: IRB Board, Meeting Date: N/A. At the bottom, there are tabs for 'Task History', 'Decisions', and 'Attachments', followed by a table of decision results.

Role	Result	Date
Principal Investigator	Certified	01-12-2026 9:24 AM

20 This window will now appear.

Click "Select a decision"

The screenshot shows a software interface for 'cayuse Human Ethics'. At the top, there is a navigation bar with links for 'Dashboard', 'Studies', 'Submissions', 'Tasks', and 'Meetings'. On the right side of the top bar, there are 'Role: Reviewer' and 'Products' dropdown menus, and a notification icon with a '4' badge. The main content area is titled 'Studies / St...' and shows a list of studies. One study is highlighted with a yellow background and the text 'Initial IRB-26-6'. To the right of this study, there is a 'Pending' status indicator and the name 'Rachel Reviewer'. Below this, a modal window is open. The modal has a header 'Pending Rachel Reviewer'. It contains two sections: 'Decision' (with a dropdown menu showing 'Select a decision' and a circled orange highlight) and 'Result Date' (with a date input field showing 'MM-DD-YYYY' and a 'Today' button). Below these sections is a 'Categories' section with the sub-instruction 'Select the applicable categories for this decision.' and a list of checkboxes for research categories. At the bottom of the modal, there is a note about examples of biological specimens and a 'Close' button.

Pending Rachel Reviewer

Decision

Select a decision

Result Date

MM-DD-YYYY

Today

Categories

Select the applicable categories for this decision.

1a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the benefits associated with the use of the product is not eligible for expedited review.)

1b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the use is in accordance with its cleared/approved labeling.

2a. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 50 ml in an 8 week period and collection may not occur more frequently than 2 times per week.

2b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount drawn, the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

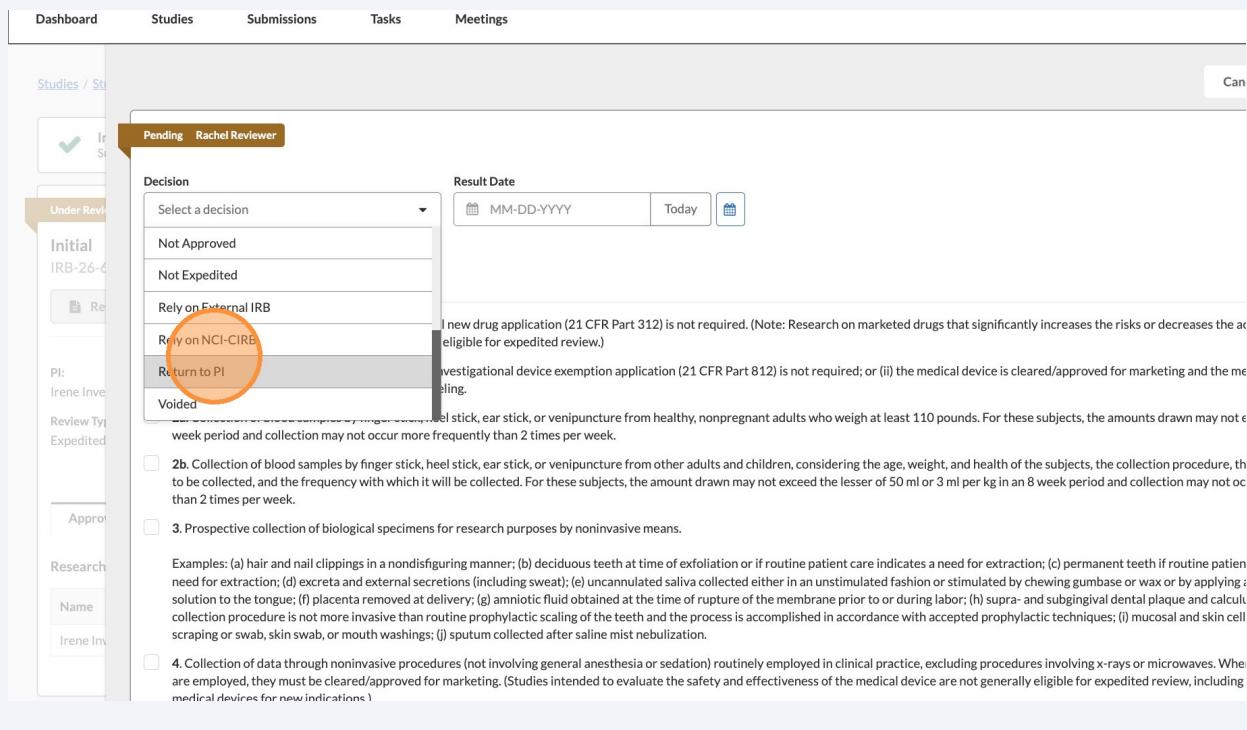
3. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a topical solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus; (i) mucosal and skin cell collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (j) mucosal and skin cell

## 21 A dropdown menu will appear.

**The dropdown menu provides several decision options that you can utilize to make your decision.**

- If revisions are required for the protocol, select **"Return to PI"** here.
- If the protocol is acceptable as submitted, you can select **"APPROVED"** here.



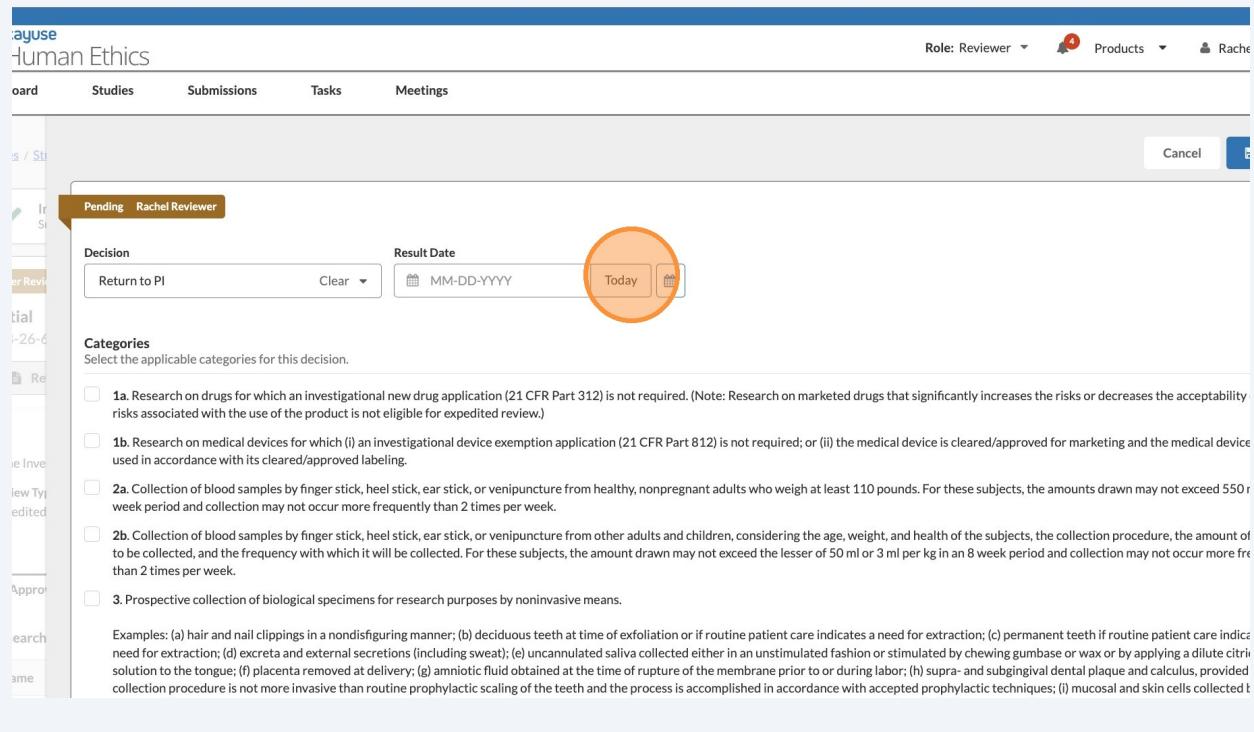
The screenshot shows a software interface for protocol review. The top navigation bar includes links for Dashboard, Studies, Submissions, Tasks, and Meetings. The main content area is titled "Studies / St..." and shows a list of protocols. One protocol, "Initial IRB-26-6", is highlighted with a yellow background and has a "Review Type" of "Expedited". A dropdown menu titled "Pending Rachel Reviewer" is open, listing several decision options: "Select a decision", "Not Approved", "Not Expedited", "Rely on External IRB", "Rely on NCI-CIRB", "Return to PI", and "Voided". The "Return to PI" option is circled in orange. To the right of the dropdown, there are fields for "Result Date" (with a date picker showing "MM-DD-YYYY" and "Today") and a "Comments" text area. Below the dropdown, there is a detailed description of the protocol and a list of numbered requirements (2a, 2b, 3, 4) with checkboxes. The requirements are as follows:

- 2a. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- 2b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed the lesser of 30 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- 3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus; (i) collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (j) mucosal and skin cell scraping or swab, skin swab, or mouth washings; (k) sputum collected after saline mist nebulization.
- 4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. When employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including medical devices for new indications.)

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If you select "Return to PI", "APPROVED" or any other decision, the next step will be adding a date to your decision.

Add a date by Clicking "**Today**".



ayuse  
Human Ethics

Role: Reviewer 4 Products Rachel

oard Studies Submissions Tasks Meetings

Cancel Save

Pending Rachel Reviewer

Decision: Return to PI Clear

Result Date: Today MM-DD-YYYY

Categories: Select the applicable categories for this decision.

1a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability risks associated with the use of the product is not eligible for expedited review.)

1b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device used in accordance with its cleared/approved labeling.

2a. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.

2b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

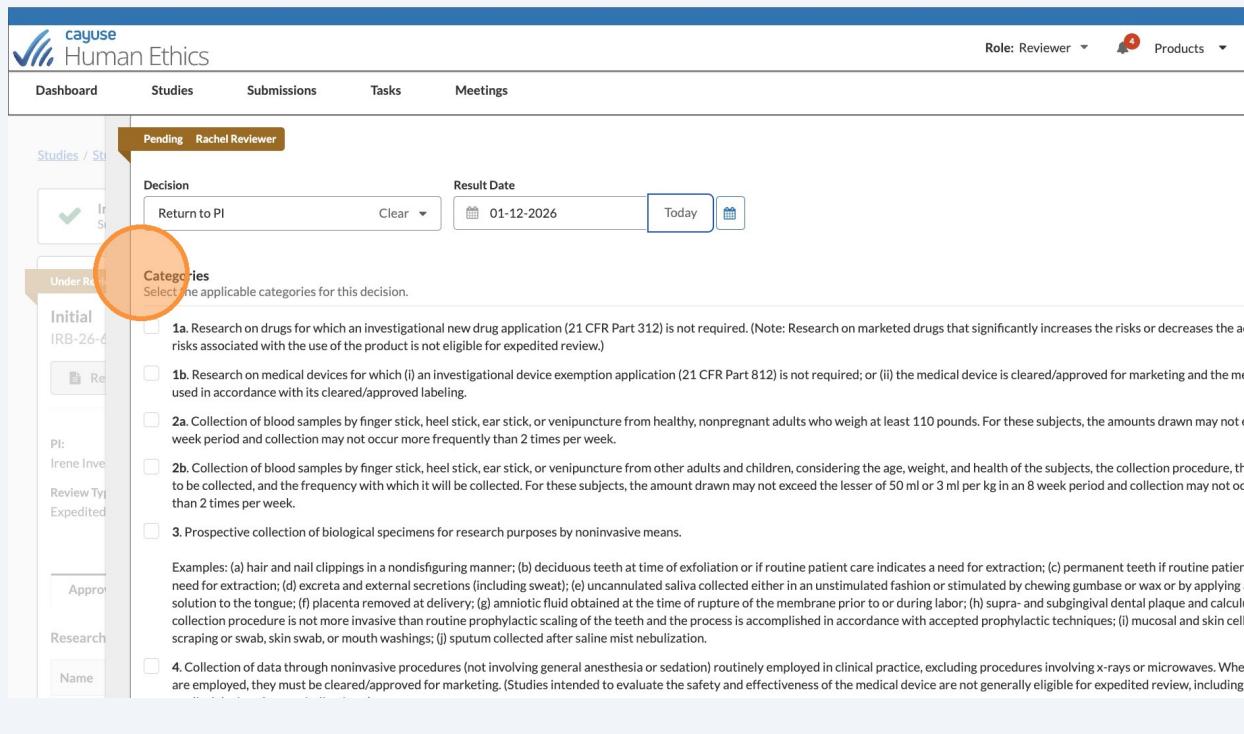
3. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric acid solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected from the oral mucosa.

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Below the decision options, you will see categories that correspond to various decision types.

If applicable, you may select a category that aligns with the appropriate federal regulation. However, selecting a category is **optional**—you may submit your decision **without** choosing one.



The screenshot shows the Cayuse Human Ethics software interface. At the top, there is a navigation bar with links for Dashboard, Studies, Submissions, Tasks, and Meetings. The user is identified as 'Role: Reviewer' and 'Products'. Below the navigation bar, a sub-menu for 'Studies / Study' is open, showing 'Pending' and 'Rachel Reviewer'. The main content area is titled 'Decision' and shows a dropdown menu set to 'Return to PI' with a 'Clear' button. A 'Result Date' field is set to '01-12-2026' with a 'Today' button and a calendar icon. Below this, a section titled 'Categories' is shown with the instruction 'Select the applicable categories for this decision.' An orange circle highlights this section. A list of categories follows, each with a checkbox:

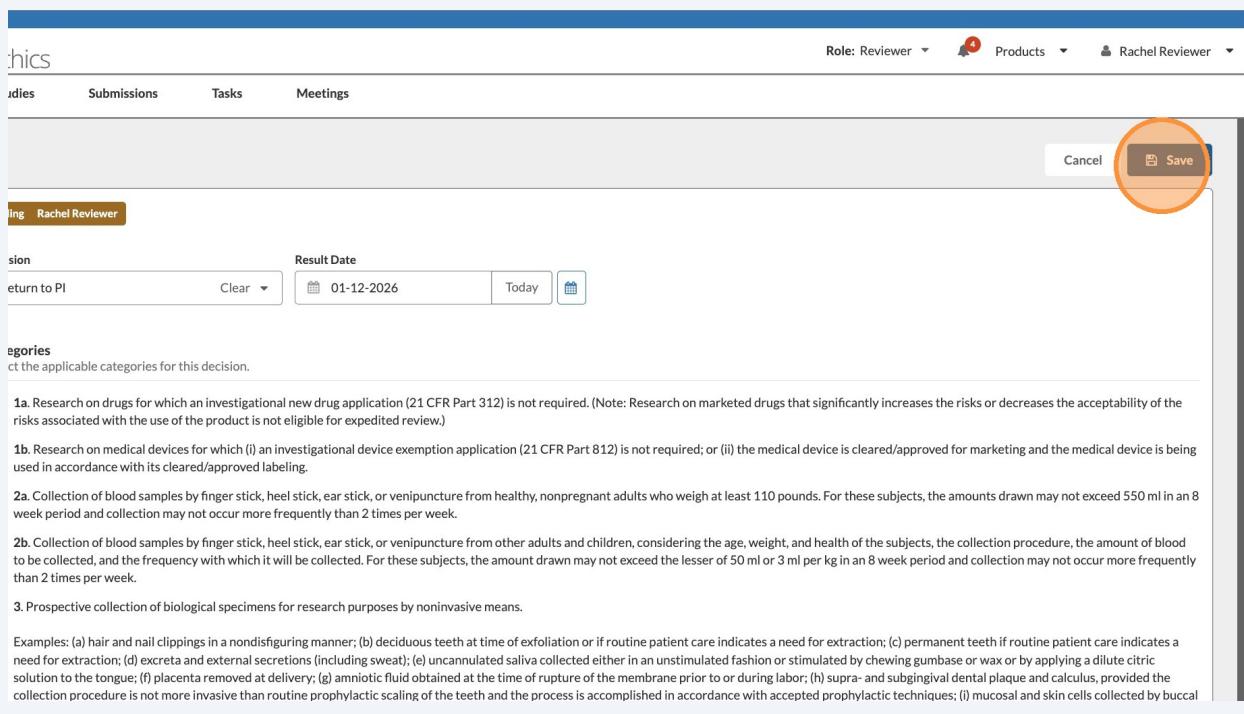
- 1a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
- 1b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is used in accordance with its cleared/approved labeling.
- 2a. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.
- 2b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
- 3. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus; (i) mucosal and skin cell scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. When employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including

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Next, click "**Save**" to save your decision.



The screenshot shows the Cayuse Human Ethics software interface. At the top, there is a navigation bar with links for Studies, Submissions, Tasks, and Meetings. The user is identified as 'Role: Reviewer' and 'Products'. Below the navigation bar, a sub-menu for 'Studies / Study' is open, showing 'Pending' and 'Rachel Reviewer'. The main content area is titled 'Decision' and shows a dropdown menu set to 'Return to PI' with a 'Clear' button. A 'Result Date' field is set to '01-12-2026' with a 'Today' button and a calendar icon. Below this, a section titled 'Categories' is shown with the instruction 'Select the applicable categories for this decision.' An orange circle highlights the 'Save' button in the bottom right corner of the decision form. A 'Cancel' button is also visible.

The 'Categories' section contains the same list of items as the previous screenshot, each with a checkbox. The examples and notes are identical.

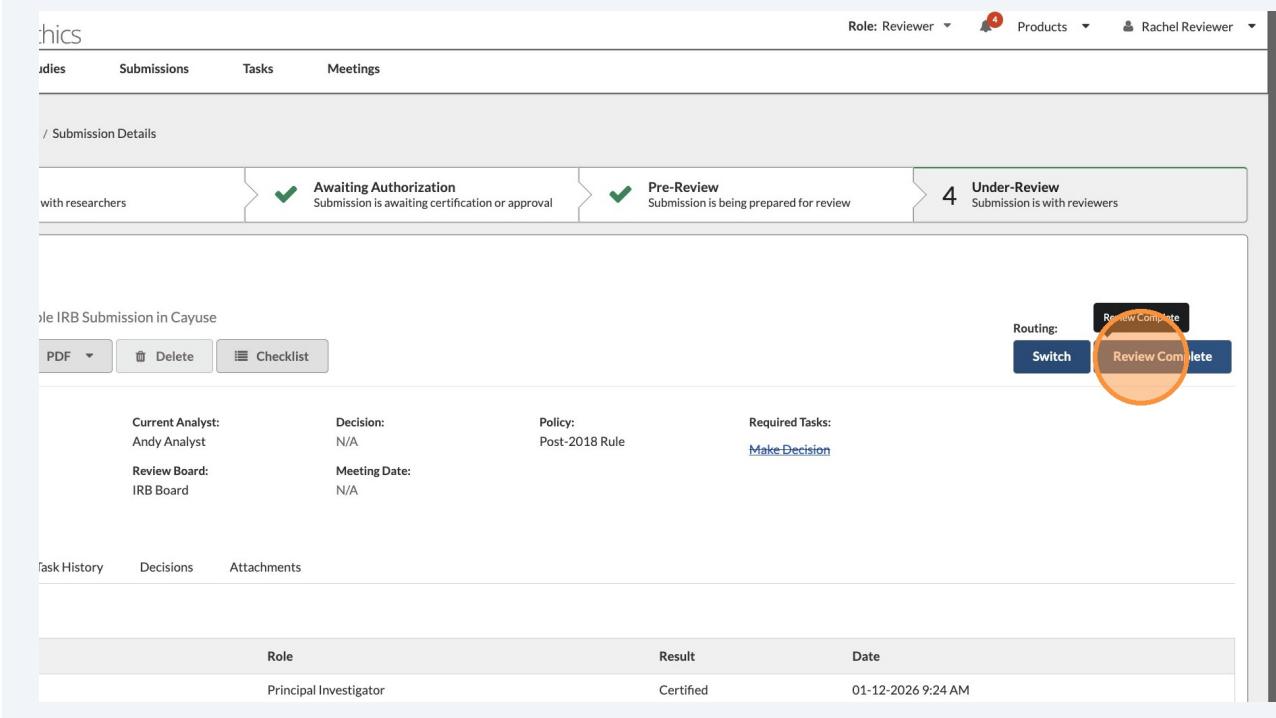
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Following your selection, this page will reappear.

Notice that under Required Tasks, "**Make Decision**" now has a line through it, indicating the task has been completed.

**Important: (If the "Make Decision" section does NOT have a line through it, this means that you must complete this step to submit your review. If you attempt to submit your review without this task being handled, an error message will populate on your screen).**

When all necessary information has been completed, select "**Review Complete**" to submit your review.



The screenshot shows the Cayuse submission interface. At the top, there are tabs for 'Studies', 'Submissions', 'Tasks', and 'Meetings'. The 'Submissions' tab is active, showing a list of submissions. The first submission in the list is highlighted. The submission details are as follows:

- with researchers**
- Awaiting Authorization**  
Submission is awaiting certification or approval
- Pre-Review**  
Submission is being prepared for review
- 4 Under-Review**  
Submission is with reviewers

Below the submission details, there are buttons for 'PDF', 'Delete', and 'Checklist'. To the right, there is a 'Routing:' section with 'Switch' and 'Review Complete' buttons. The 'Review Complete' button is highlighted with an orange circle. The submission information table includes:

Current Analyst: Andy Analyst	Decision: N/A	Policy: Post-2018 Rule	Required Tasks: <del>Make Decision</del>
Review Board: IRB Board	Meeting Date: N/A		

At the bottom, there are tabs for 'Task History', 'Decisions', and 'Attachments'. The 'Task History' table shows:

Role	Result	Date
Principal Investigator	Certified	01-12-2026 9:24 AM

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A confirmation message will appear to ensure that you are ready to submit your review.

Click "**Confirm**"

