

How to Complete An IRB Review in Cayuse

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 screenshot displays the Cayuse Dashboard interface. It features a top navigation bar with a search icon and a user profile icon. The main content area is divided into several sections:

- Example IRB Submission in Cayuse:** A table listing submissions with columns for ID, Title, and Status. The table includes entries like "LW Test 12.12.2025" and "Workflow Example 2". A "View All" button is at the bottom.
- Complete Expedited Review:** A section for reviewing expedited submissions, with a "View All" button.
- Renewal:** A sidebar menu with options: Initial, Modification, Incident, Withdrawal, Closure, and Legacy.
- My Meetings:** A calendar view for January 2026, showing dates from 28 to 07. A "View All" button is at the bottom.
- Upcoming Meetings:** A section showing no upcoming meetings, indicated by a sad face icon and the text "No Upcoming Meetings".

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.

The screenshot shows the Cayuse Human Ethics dashboard. The top navigation bar includes 'Dashboard', 'Studies', 'Submissions', 'Tasks', and 'Meetings'. The 'Submissions' section is active. Below the navigation bar, there are five main action buttons: 'Full Board Reviews', 'Expedited Reviews', 'Limited IRB Reviews', 'Exempt Reviews', and a list icon. The 'Submissions where I am the Primary Reviewer' section is highlighted with an orange circle. It contains a table with the following data:

Submission ID	Description
IRB-26-66	Example IRB Submission in Cayuse
IRB-25-39	LW Test 12.12.2025
IRB-FY2026-10	Workflow Example 2

Below the table is a 'View All' button. To the right, the 'My Tasks' section shows a task for 'IRB-26-66' with the description 'Complete Expedited Review'. Further right, the 'Submissions by Type' section lists various submission types: Renewal, Initial, Modification, Incident, Withdrawal, Closure, and Legacy. At the bottom, there are sections for 'Approved Studies', 'My Meetings', and 'Upcoming Meetings'.

3

Click **"Review"**

The screenshot shows the 'Under Review' page for submission IRB-26-66. The top navigation bar is the same as the previous screenshot. Below the navigation bar, there is a breadcrumb trail: 'Studies / Study Details / Submission Details'. The page is divided into four main sections: 'In-Draft', 'Awaiting Authorization', 'Pre-Review', and 'Under-Review'. The 'Under-Review' section is active and shows the submission details. The 'Initial' section is highlighted with an orange circle. It contains a table with the following data:

Field	Value
PI:	Irene Investigator
Current Analyst:	Andy Analyst
Decision:	N/A
Policy:	Post-2018 Rule
Required Tasks:	Make Decision
Review Type:	Expedited
Review Board:	IRB Board
Meeting Date:	N/A

Below the table, there are tabs for 'Approvals', 'Task History', 'Decisions', and 'Attachments'. The 'Approvals' tab is active. It shows a table with the following data:

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

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

The screenshot shows the Cayuse Human Ethics interface. The top navigation bar includes 'Dashboard', 'Studies', 'Submissions', 'Tasks', and 'Meetings'. The user's role is 'Reviewer'. The main heading is 'Example IRB Submission in Cayuse - Initial'. On the left, a 'Sections' sidebar lists various sections, with 'Getting Started' highlighted by an orange circle. The main content area displays the 'Getting Started' section, which includes information about Cayuse Human Ethics and a list of required information for the submission. The right sidebar contains a 'Checklist' section with a 'Reviewer Checklist' and a 'Reviewer Certification' section.

Getting Started

About Cayuse Human Ethics

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.**

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.

For more information about the IRB submission Process, IRB Tracking, and Cayuse Tasks, please refer to the in-app help (the orange question mark near the bottom right) or contact the [IRB Office](#).

Getting Started

Throughout the submission, you will be required to provide the following, as applicable:

- Project Personnel Information
- Participant Selection
- Participant Recruitment Documents
- Detailed Research Procedures

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 interface. The top navigation bar includes 'Dashboard', 'Studies', 'Submissions', 'Tasks', and 'Meetings'. The user's role is 'Reviewer'. The main heading is 'Example IRB Submission in Cayuse - Initial'. On the left, a 'Sections' sidebar lists various sections, with 'Getting Started' highlighted by an orange circle. The main content area displays the 'Getting Started' section, which includes information about Cayuse Human Ethics and a list of required information for the submission. The right sidebar contains a 'Checklist' section with a 'Reviewer Checklist' and a 'Reviewer Certification' section.

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Getting Started

Throughout the submission, you will be required to provide the following, as applicable:

- Project Personnel Information
- Participant Selection
- Participant Recruitment Documents
- Detailed Research Procedures

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

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

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

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

Collapse Comments

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.**

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.
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- [USM CITI Program](#)

Citi Certificates.pdf

Collapse Comments

Rachel Reviewer Today at 1:39 P

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 displays a web interface for adding a comment. At the top, there is a '+ Add Comment' button. Below it, the section 'Study Personnel Training Documentation' contains a list of instructions: '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.', and a link to 'USM CITI Program'. A file named 'Citi Certificates.pdf' is attached. A 'Collapse Comments' button is visible. The comment is authored by 'Rachel Reviewer' and is timestamped 'Today at 1:39 PM'. A dropdown menu for 'Visibility' is open, showing three options: 'Unrestricted' (highlighted with an orange circle), 'Restricted' (selected), and 'Restricted' (with a sub-label 'Researchers can not see comment'). Below the dropdown is a 'SAVE COMMENT' button. The section 'Protocol Related Conflict of Interest' follows, with a prompt for the Principal Investigator (PI) to answer questions on behalf of all USM key personnel. A specific question is listed: '* Have you and all key personnel listed on this protocol completed USM's required Research Security training?'. Below this question are radio buttons for 'Yes' and 'No'.

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 displays a web interface for reviewing study documentation. At the top, a note states: "Individuals listed as Other Personnel can view the study but will not have edit access and will not automatically receive study-related communications." Below this is a "+ Add Comment" button. 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," and a link to the "USM CITI Program". An attachment "Citi Certificates.pdf" is shown. A comment by "Rachel Reviewer" is displayed, with the text "Please change this attachment." and a "Feedback Requested" label. The comment's visibility is set to "Visibility: Unrestricted", which is highlighted with an orange circle. Below the comment is a rich text editor with a toolbar and a "SAVE COMMENT" button. A section titled "Protocol Related Conflict of Interest" follows, with instructions for the Principal Investigator (PI) to answer questions on behalf of all USM key personnel. A partially visible question at the bottom asks: "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

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

Name	Organization	Address	Phone	Email	Training
Irene Investigator	School of Professional Nursing			morgan.chapman+investigator@cayuse.com	View

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.

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.

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.
- [IJSM 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.

The screenshot shows the Cayuse web application interface for reviewing an IRB submission. The top navigation bar includes 'Studies', 'Submissions', 'Tasks', and 'Meetings'. The user is logged in as 'Rachel Reviewer'. The submission title is 'Example IRB Submission in Cayuse - Initial'. A sidebar on the left contains a list of submission items, each with a checkmark icon. The main content area displays details for the submission, including a table for 'Primary Contact' and sections for 'Co-Investigator(s)' and 'Other Personnel'. The 'SHOW CHECKLIST' button is highlighted with an orange circle.

IRB NUMBER: IRB-26-66

Example IRB Submission in Cayuse - Initial

SHOW CHECKLIST CREATE PDF COMPARE SAVE

Name	Organization	Address	Phone	Email	Trainings
Irene Investigator	School of 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's responsibilities.

+ 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

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+ Add Comment

Study Personnel Training Documentation

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14 Complete the checklist by answering the required questions.

First, **select** a submission type.

The screenshot shows the Cayuse web application interface for reviewing an IRB submission. The top navigation bar includes 'Studies', 'Submissions', 'Tasks', and 'Meetings'. The user is logged in as 'Rachel Reviewer'. The submission title is 'Example IRB Submission in Cayuse - Initial'. A sidebar on the left contains a list of submission items, each with a checkmark icon. The main content area displays details for the submission, including a table for 'Primary Contact' and sections for 'Co-Investigator(s)' and 'Other Personnel'. The 'SHOW CHECKLIST' button is highlighted with an orange circle. The 'Submission Type' dropdown menu is open, showing options: 'Initial', 'Modification', 'Incident', and 'Renewal'. The 'Reviewer Certification' section is also visible.

IRB NUMBER: IRB-26-66

Example IRB Submission in Cayuse - Initial

SHOW CHECKLIST CREATE PDF COMPARE SAVE

Name	Organization	Address	Phone	Email	Trainings
Irene Investigator	School of Professional Nursing			morgan.chapman+investigator@cayuse.com	View

+ Add Comment

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+ Add Comment

Checklist

Reviewer Checklist

Submission Type

- ☐ Initial
- ☐ Modification
- ☐ Incident
- ☐ Renewal

Comments

B I U S L R

* 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

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Name	Organization	Address	Phone	Email	Training
Irene Investigator	School of Professional Nursing			morgan.chapman+investigator@cayuse.com	View

+ Add Comment

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- USM CITI Program

Reviewer Checklist

Submission Type

☒ Initial

☐ NHSR/Not Engaged/118 Determination
 ☐ Full application (e.g., research study, clinical trial, etc.)

☐ Modification
 ☐ Incident
 ☐ Renewal

Comments

B I U ↺ ↻ ⌵ ⌶ 🖼

* 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."

✓

✓

RESPONSIBILITIES

Name	Organization	Address	Phone	Email	Training
Irene Investigator	School of Professional Nursing			morgan.chapman+investigator@cayuse.com	View

+ Add Comment

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- USM CITI Program

Citi Certificates.pdf

×

⌵

Collapse Comments

Rachel Reviewer Today at 1:39 PM

Visibility: Restricted

▼

Please change this attachment.

Edit Reply

☐ Renewal

Comments

B I U ↺ ↻ ⌵ ⌶ 🖼

Test.

Reviewer Certification

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

SAVE CHECKLIST

17 Click "Save Checklist"

Investigator
Nursing

+ Add Comment

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Citi Certificates.pdf

Collapse Comments

Rachel Reviewer Today at 1:39 PM

Visibility: Restricted

Please change this attachment.

Edit Reply

B I U

Test.

Reviewer Certification

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

SAVE CHECKLIST

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."**

cayuse
Human Ethics

Role: Reviewer
Products

Dashboard
Studies
Submissions
Tasks
Meetings

SUBMISSION DETAILS

IRB NUMBER: IRB-26-66

Example IRB Submission in Cayuse - Initial

SHOW CHECKLIST
CREATE PDF
COMPARE

Sections
Getting Started
Project Personnel
Basic Information
Participant Selection
Study Design and P...
Participant Protect...
Attachments

Name	Organization	Address	Phone	Email	Training
Irene Investigator	School of Professional Nursing			morgan.chapman+investigator@cayuse.com	View

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Name	Organization	Address	Phone	Email	Training
Irene Investigator	School of Professional Nursing			morgan.chapman+investigator@cayuse.com	View

+ Add Comment

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+ Add Comment

Other Personnel

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Checklist
Reviewer Checklist
Submission Type

- Initial
 - NHSR/ Determ
 - Full app study, c
- Modification
- Incident
- Renewal

Comments

B I U

Test.

19 You should land on this page.

Click **"Make Decision"**.

/ Submission Details

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

able IRB Submission in Cayuse

PDF ▾

Delete

Checklist

Routing:

Switch

Review Complete

Current Analyst:
Andy Analyst

Review Board:
IRB Board

Decision:
N/A

Meeting Date:
N/A

Policy:
Post-2018 Rule

Required Tasks:
[Make Decision](#)

Task History Decisions Attachments

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

20

This window will now appear.

Click **"Select a decision"**

cayuse
Human Ethics

Role: Reviewer ▾ Products ▾

Dashboard Studies Submissions Tasks Meetings

Studies / Study ID: IRB-26-61234

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 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 modification 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 10 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 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) unannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a substance 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 swabs; (j) urine; (k) stool; (l) sputum; (m) nasal mucus; (n) tears; (o) sweat; (p) vaginal secretions; (q) semen; (r) saliva; (s) hair; (t) nails; (u) skin cells; (v) blood; (w) bone marrow; (x) bone; (y) fat; (z) other biological specimens.

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 displays a web application interface with a navigation bar at the top containing links for Dashboard, Studies, Submissions, Tasks, and Meetings. The main content area is titled 'Studies / Study' and shows a 'Pending' status for a review by 'Rachel Reviewer'. A dropdown menu is open, showing the following options: 'Select a decision', 'Not Approved', 'Not Expedited', 'Rely on External IRB', 'Rely on NCI-CIRB', 'Return to PI' (highlighted with an orange circle), and 'Voided'. To the right of the dropdown, there is a 'Result Date' field with a calendar icon and a 'Today' button. Below the dropdown, the text 'Initial IRB-26-6' is visible. The main content area also contains a 'Review Type' dropdown set to 'Expedited' and a 'Research' section with a 'Name' field and a 'Research' button. The background text is partially obscured but includes information about a new drug application (21 CFR Part 312) and an investigational device exemption application (21 CFR Part 812).

22

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 Products Rachel

Board Studies Submissions Tasks Meetings

Cancel

Pending Rachel Reviewer

Decision
Return to PI Clear

Result Date
MM-DD-YYYY Today

Categories
Select the applicable categories for this decision.

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23

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 interface. At the top, there's a navigation bar with 'Dashboard', 'Studies', 'Submissions', 'Tasks', and 'Meetings'. Below this, a sidebar on the left shows a list of studies, including 'Initial IRB-26-4'. The main content area is titled 'Pending Rachel Reviewer'. It features a 'Decision' dropdown menu set to 'Return to PI' and a 'Result Date' field set to '01-12-2026'. Below these, there's a section titled 'Categories' with the instruction 'Select the applicable categories for this decision.' This section contains four numbered categories, each with a checkbox and a description. An orange circle highlights the 'Categories' section.

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 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 being 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) unannulated 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, 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 by buccal 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 interface, similar to the previous one. The 'Categories' section is visible, and the 'Save' button is highlighted with an orange circle. The 'Save' button is located at the top right of the main content area, next to a 'Cancel' button. The 'Save' button has a small icon of a document with a checkmark.

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 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 being 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) unannulated 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, 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 by buccal

25 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 displays the Cayuse IRB Submission interface. At the top, the user is logged in as 'Rachel Reviewer' with the role of 'Reviewer'. The navigation bar includes 'Studies', 'Submissions', 'Tasks', and 'Meetings'. The main section is titled 'Submission Details' and shows a progress bar with four stages: 'Awaiting Authorization' (green checkmark), 'Pre-Review' (green checkmark), and 'Under-Review' (number 4). Below the progress bar, there are buttons for 'PDF', 'Delete', and 'Checklist'. The 'Required Tasks' section shows 'Make Decision' with a line through it. The 'Review Complete' button is highlighted with an orange circle. Below the submission details, there is a table with columns 'Role', 'Result', and 'Date'.

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"**

