How to Submit an Incident Report on Cayuse

Scribe

This guide provides a step-by-step process for submitting an incident report in Cayuse, specifically for unplanned events related to human subject research. It ensures that researchers understand the necessary procedures and documentation required for compliance and safety.

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

2 Locate the protocol that you'd like to submit an Incident Report for under **"Approved Studies"**

IRB-26-64	Example IRB Submission in Cayuse
IRB-26-60	Overview Sample 1

View All

IRB-26-63	Complete Submission
IRB-26-62	View Submission

View All

Approved Studies

IRB-26-66	Example IRB Submission in Cayuse
IRB-26-60	Overview Sample 1
IRB-25-35	Training Video
IRB-25-15	Workflow Example 3
IRB-FY2026-9	Workflow Example 1

View All

Studies Expiring in 30 days ▾

☺

No Expiring Studies

3 Click **"New Submission"**

80 Products ▾   👤 Irene Investigator ▾

+ New Submission

Submissions

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4 Click **"Incident"**

80 Products ▾   👤 Irene Investigator ▾

+ New Submission

Submissions   Incident

ization:
l of Professional   **Active**
ng   **Submissions:**
t Policy   Modification
2018 Rule   Renewal
                     Closure

                     Sponsors:
                     N/A

5 Click **"Edit"**

Studies / Study Details / Submission Details

| 1 | **In-Draft** Submission is with researchers | 2 | Awaiting Authorization Submission is awaiting certification or approval | 3 | Pre-Revie Submission |

Unsubmitted

Incident
IRB-26-66 - Example IRB Submission in Cayuse

✏️ Edit   PDF ▾   🗑 Delete

PI: **Current Analyst:**   **Decision:**   **Policy:**
Irene Investigator   N/A   N/A   Post-2018 Rule

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

Approvals   Task History   Attachments

6   Here is the initial page of the Incident Report Form.

Read the following instructions.

cayuse
Human Ethics

Dashboard   Studies   Submissions   Tasks

Products ▾   👤

SUBMISSION DETAILS
IRB NUMBER: **IRB-26-66**
Example IRB Submission in Cayuse - Incident

📄 CREATE PDF   ⬚ COMPARE

Sections   ‹
Incident Report

Incident Report

Use this form to report any unplanned event or incident related to human subject research.

Instructions:

- Submit a separate report for unrelated events.
- Select all applicable incident types; the form will adapt based on your choices.
- Attach supporting documentation where required.

* **Incident Type**

Select all categories that apply. If unsure, choose the best match and explain in comments.

☐ New or Increased Risk
Examples: Unanticipated problems, adverse events, SAE, FDA Black Box Warning, DSMB report, unauthorized disclosure, unanticipated adverse device effect.

☐ Protocol Deviation and/or Noncompliance
Examples: Events harming subjects, increased risk, serious or continuing noncompliance, deviations to avoid immediate hazard.

☐ Written Reports
Examples: Audits, inspections, inquiries by oversight agencies.

☐ Suspension or early Termination of the Study
Examples: Unplanned suspension or termination by sponsor, investigator, or institution.

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7   Next, review each incident type and **select the option** that best reflects your situation.

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☐ Written Reports
Examples: Audits, inspections, inquiries by oversight agencies.

☐ Suspension or early Termination of the Study
Examples: Unplanned suspension or termination by sponsor, investigator, or institution.

☐ Other
Examples: Unexpected incarceration, data/security breach, unresolved subject complaint.
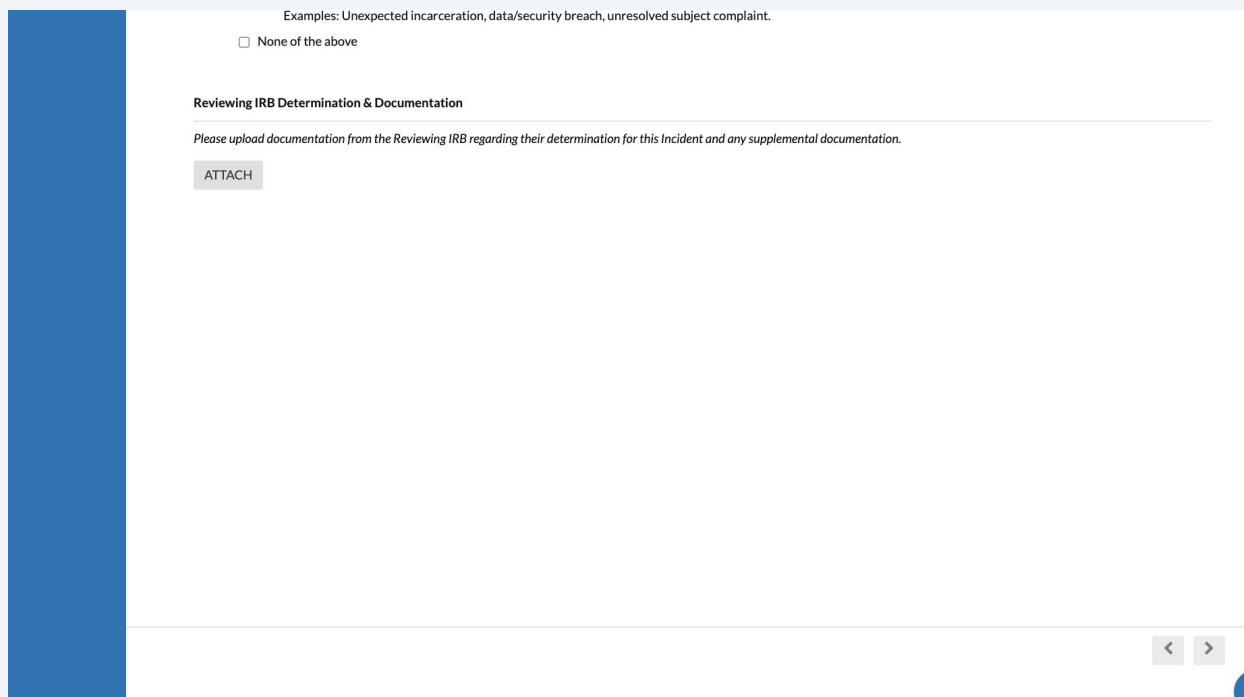
☐ None of the above

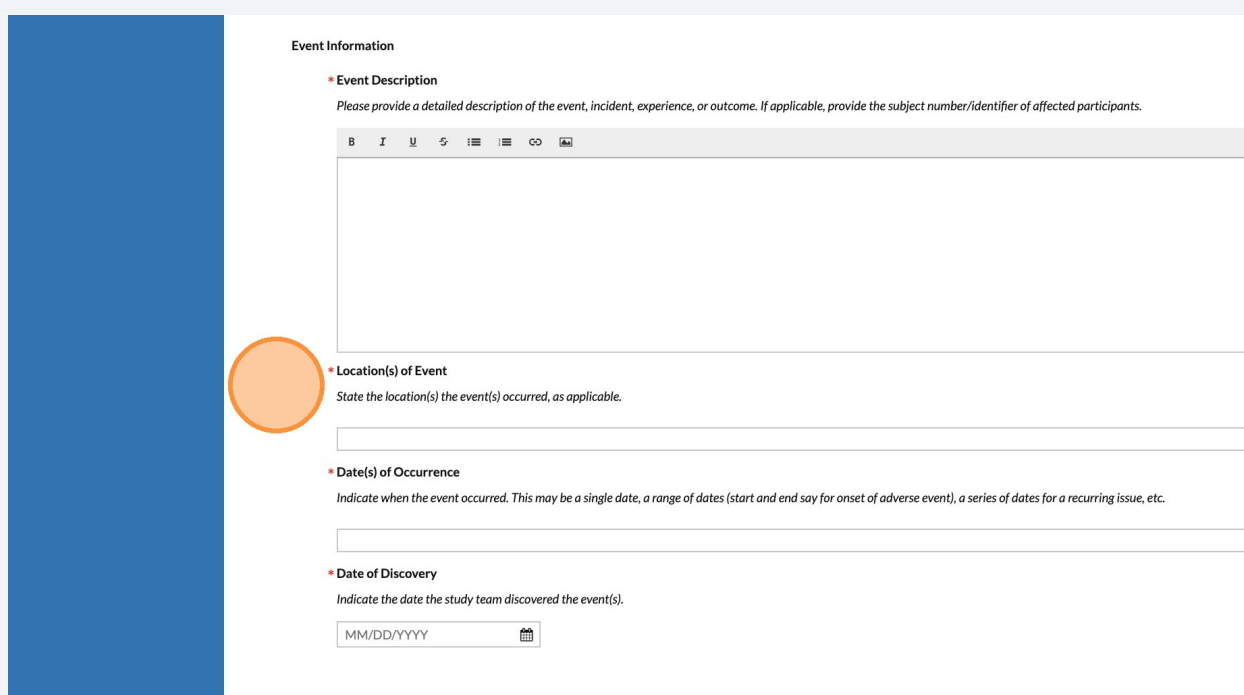**Reviewing IRB Determination & Documentation**

Please upload documentation from the Reviewing IRB regarding their determination for this Incident and any supplemental documentation.

ATTACH

8   Next, you'll be asked to upload documents.

Select "**attach**" to append documents to this form.

Examples: Unexpected incarceration, data/security breach, unresolved subject complaint.
☐ None of the above

Reviewing IRB Determination & Documentation

Please upload documentation from the Reviewing IRB regarding their determination for this Incident and any supplemental documentation.

ATTACH

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9   Next, navigate to the **"Event Information"** section.

Scroll down to the **"Event Description"** section to provide a detailed description of the event, experience, etc.

Event Information

* **Event Description**

Please provide a detailed description of the event, incident, experience, or outcome. If applicable, provide the subject number/identifier of affected participants.

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* **Location(s) of Event**

State the location(s) the event(s) occurred, as applicable.

* **Date(s) of Occurrence**

Indicate when the event occurred. This may be a single date, a range of dates (start and end say for onset of adverse event), a series of dates for a recurring issue, etc.
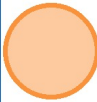
* **Date of Discovery**

Indicate the date the study team discovered the event(s).

MM/DD/YYYY   🗓

10 Next, please indicate the following:

- **Location of Event(s)**

- **Date(s) of Occurrence**

- **Date of Discovery**

* **Location(s) of Event**

State the location(s) the event(s) occurred, as applicable.

* **Date(s) of Occurrence**

Indicate when the event occurred. This may be a single date, a range of dates (start and end say for onset of adverse event), a series of dates for a recurring issue, etc.

* **Date of Discovery**

Indicate the date the study team discovered the event(s).

MM/DD/YYYY

New or Increased Risk Information

Expectedness

* **Expectedness Assessment**

Considering the research procedures described in the protocol and consent form AND the characteristics of the subject population being studied, is the event Unexpected in ANY of the following:
- *Nature of the event*
- *Severity of the event (more serious than expected)*

11 Following this, please navigate to the **"New or Increased Risk Information"** section.

Complete the Expectedness Assessment by:

1. **indicating whether the event was unexpected based on the reasons provided**

2. **elaborating on the selection in the text box provided.**
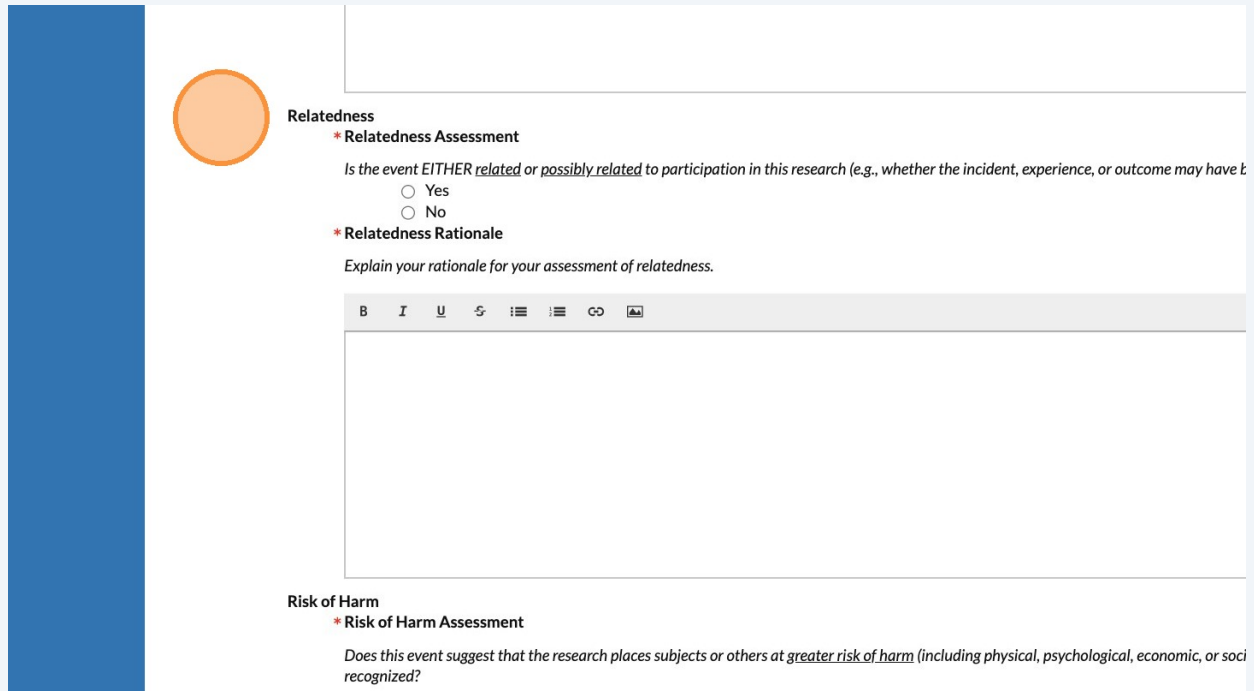
12 Next, navigate to the **"Relatedness"** section to complete the **Relatedness Assessment** by:

1. **Indicating if the incident is related to the research at hand.**

2. **Explaining the rationale for your selection in the text box provided.**

Relatedness
* **Relatedness Assessment**

Is the event EITHER related or possibly related to participation in this research (e.g., whether the incident, experience, or outcome may have b

○ Yes
○ No

* **Relatedness Rationale**

Explain your rationale for your assessment of relatedness.

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Risk of Harm
* **Risk of Harm Assessment**

Does this event suggest that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or soci recognized?

13 Following this, you will reach the **"Risk of Harm"** section where you will be prompted to complete the **Risk of Harm Assessment** by:

1. **Indicating if the incident suggests that the research places subjects or others at heightened risks of harm**

2. **Explaining the rationale for your selection in the text box provided.**

Risk of Harm

* **Risk of Harm Assessment**

Does this event suggest that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized?

NOTE: If the event is Serious, this answer should be Yes.

○ Yes
○ No

* **Risk of Harm Rationale**

Explain your rationale for your assessment of Risk of Harm.

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* **Is this a Reportable Event?**

○ Yes - (Expectedness, Relatedness, and Risk of Harm were ALL Yes)
○ No - (At least one was answered No for Expectedness, Relatedness, and/or Risk of Harm)

* **Prompt Reporting of Reportable Information**

Is this event being promptly reported per IRB Policy?

○ Yes

14 Scroll down to the next question.

"Is this a Reportable Event?"

Answer the question based on your previous responses.

15 Next, indicate if the event was promptly reported and describe if any corrective actions that were taken.

16 Finally, please use this section to identify any additional information that may be beneficial to this report.

You can also attach any relevant documentation by clicking **"Additional Documentation Attach"**

Additional Information

Additional Information or Comments

If applicable, you can provide additional information that you think to be beneficial to review of this Incident.

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Test.

Additional Documentation

If you have any additional documentation to provide for this Incident, upload it here (e.g., revised risk documentation, records on affected subject, Corrective Action Plan, etc.).

ADDITIONAL DOCUMENTATION ATTACH

< >

?

17 Click **"+"**

18 Click **"add file"**
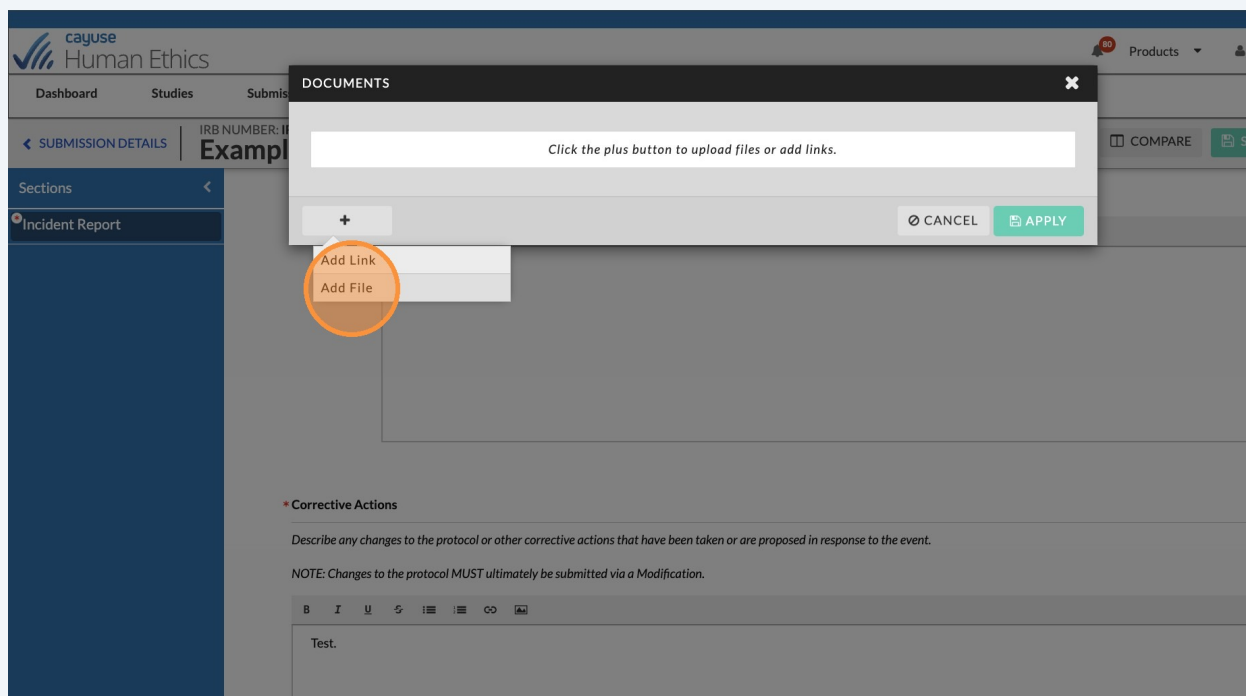
19 The attachment should populate onto the protocol.

Additional Information

Additional Information or Comments

If applicable, you can provide additional information that you think to be beneficial to review of this Incident.

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Test.

Additional Documentation

If you have any additional documentation to provide for this Incident, upload it here (e.g., revised risk documentation, records on affected subject, Corrective Action Plan, etc.).

ATTACH

📄 Attachments.pdf ✖

20 To submit this form, click **"Complete Submission"**

‹ SUBMISSION DETAILS

IRB NUMBER: **IRB-26-66**
Example IRB Submission in Cayuse - Incident

Sections ‹
⊛ Incident Report ✔

Routing ∨
Send to PI for certification?

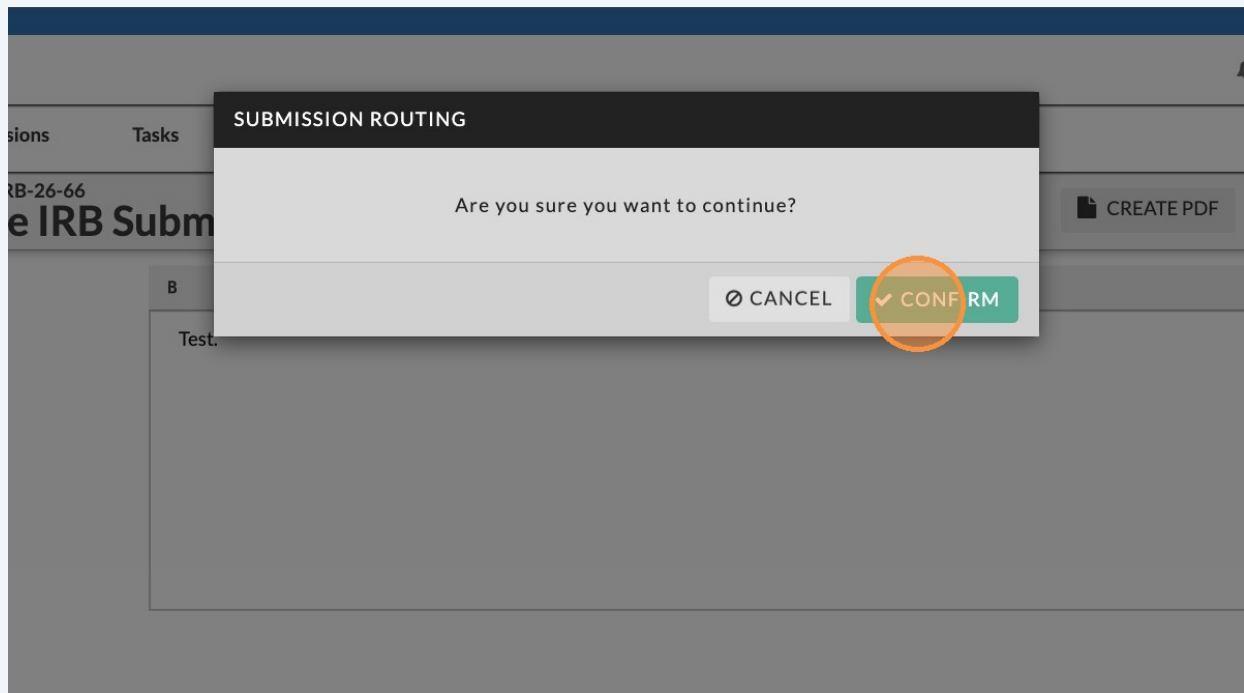COMPLETE SUBMISSION ›

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Test.

✱ **Corrective Actions**

Describe any changes to the protocol or other corrective actions that have been taken or are proposed ir

NOTE: Changes to the protocol MUST ultimately be submitted via a Modification.
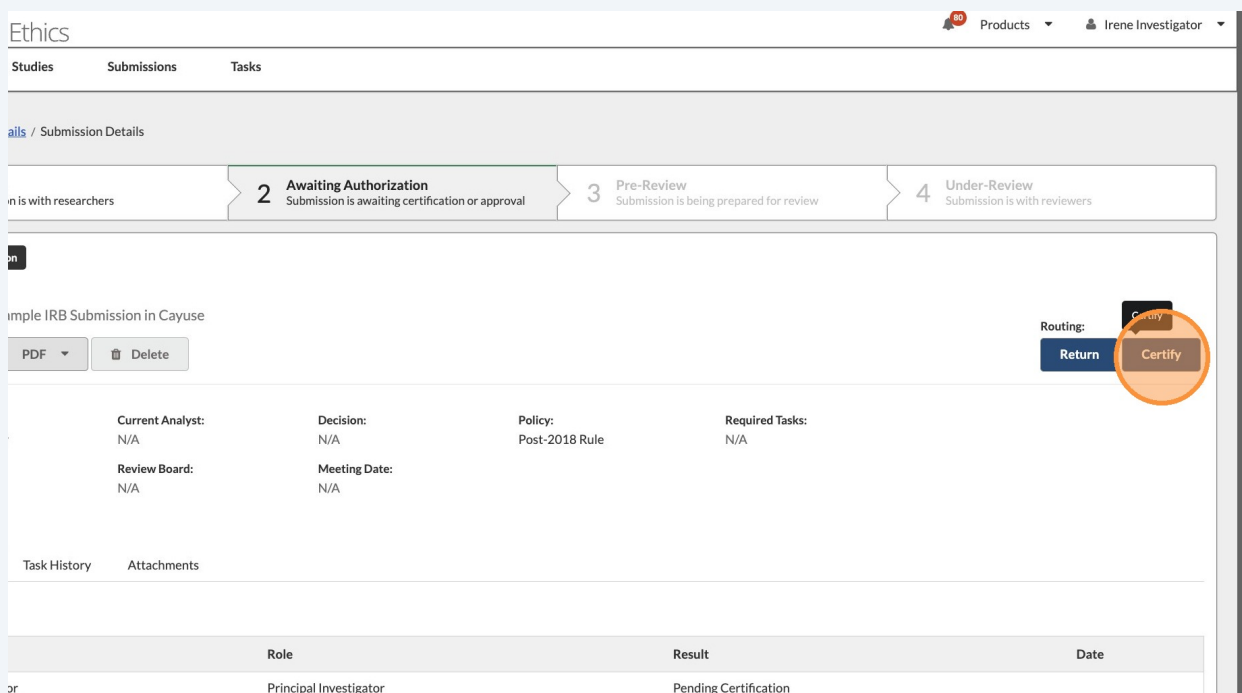
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21 Click **"Confirm"**

SUBMISSION ROUTING

Are you sure you want to continue?

⊘ CANCEL   ✓ CONFIRM

CREATE PDF

22 You will be redirected to this page.

To submit, Click **"Certify"**

If you want to make changes to this protocol, **click "Return"**

Ethics

Products ▾   👤 Irene Investigator ▾

Studies   Submissions   Tasks

ails / Submission Details

| | 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 |

n is with researchers

mple IRB Submission in Cayuse

PDF ▾   🗑 Delete

Routing: Certify

Return   Certify

| | Current Analyst: N/A | Decision: N/A | Policy: Post-2018 Rule | Required Tasks: N/A |
| Review Board: N/A | Meeting Date: N/A | | |

Task History   Attachments

| | Role | Result | Date |
| or | Principal Investigator | Pending Certification | |

23 After pressing **"Certify"**, this message will appear.

Click **"Confirm"** if you agree to the statements below.