CALIFORNIA STATE UNIVERSITY FULLERTON

Incident Notification

Cayuse IRB

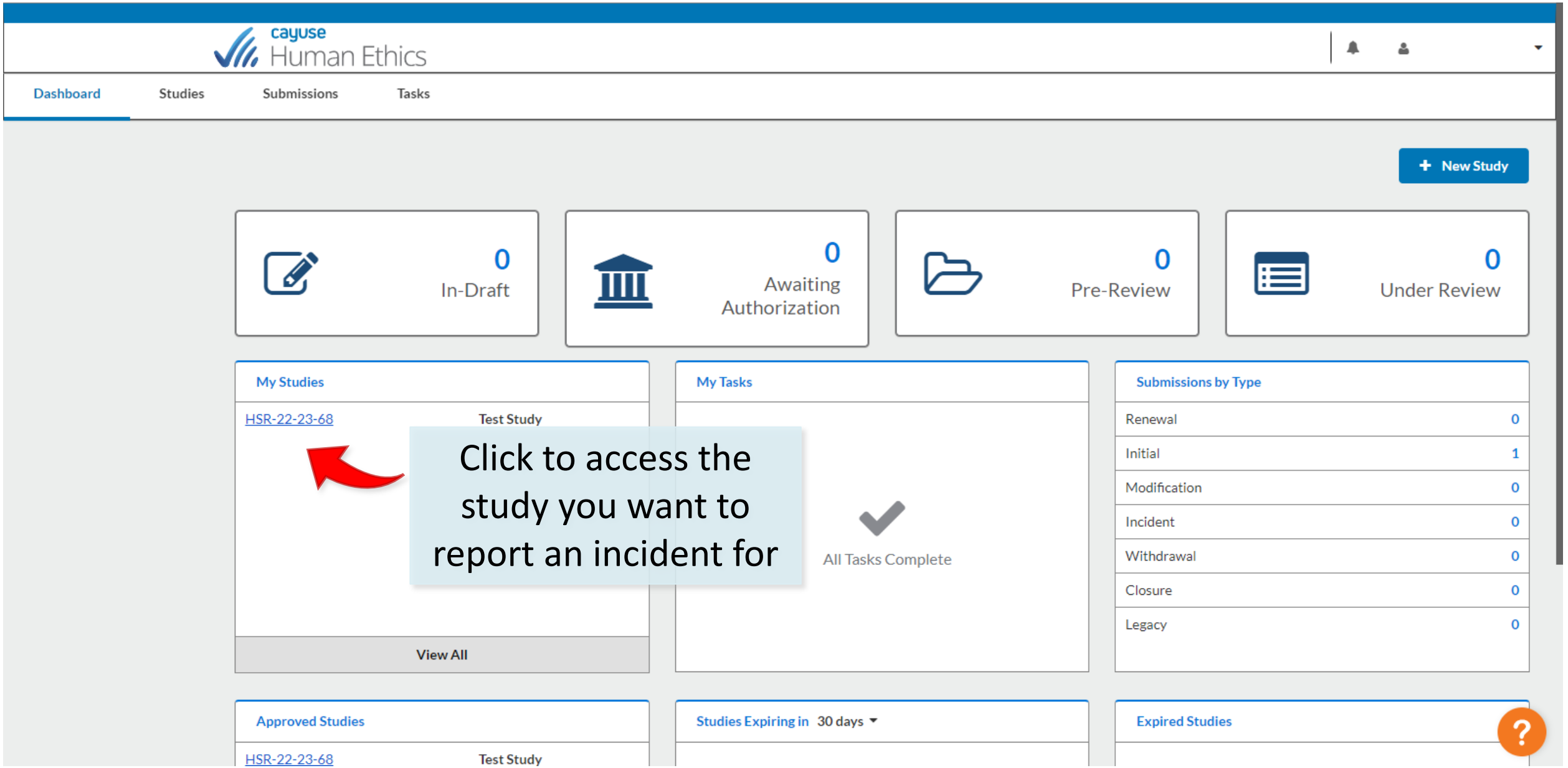
Office: 657-278-7719
Email: irb@fullerton.edu
Titan Hall ASC–232

Link: Cayuse IRB Log-In

Updated 10/2022

How to use this tutorial

- This tutorial is for researchers (PIs) who **already have an approved** IRB protocol and need to submit an Incident Report.



Click to access the study you want to report an incident for

cayuse Human Ethics

Dashboard Studies Submissions Tasks

Studies / Study Details

+ New Submission

Study Details | Submissions

Approved

HSR-22-23-68 Test Study

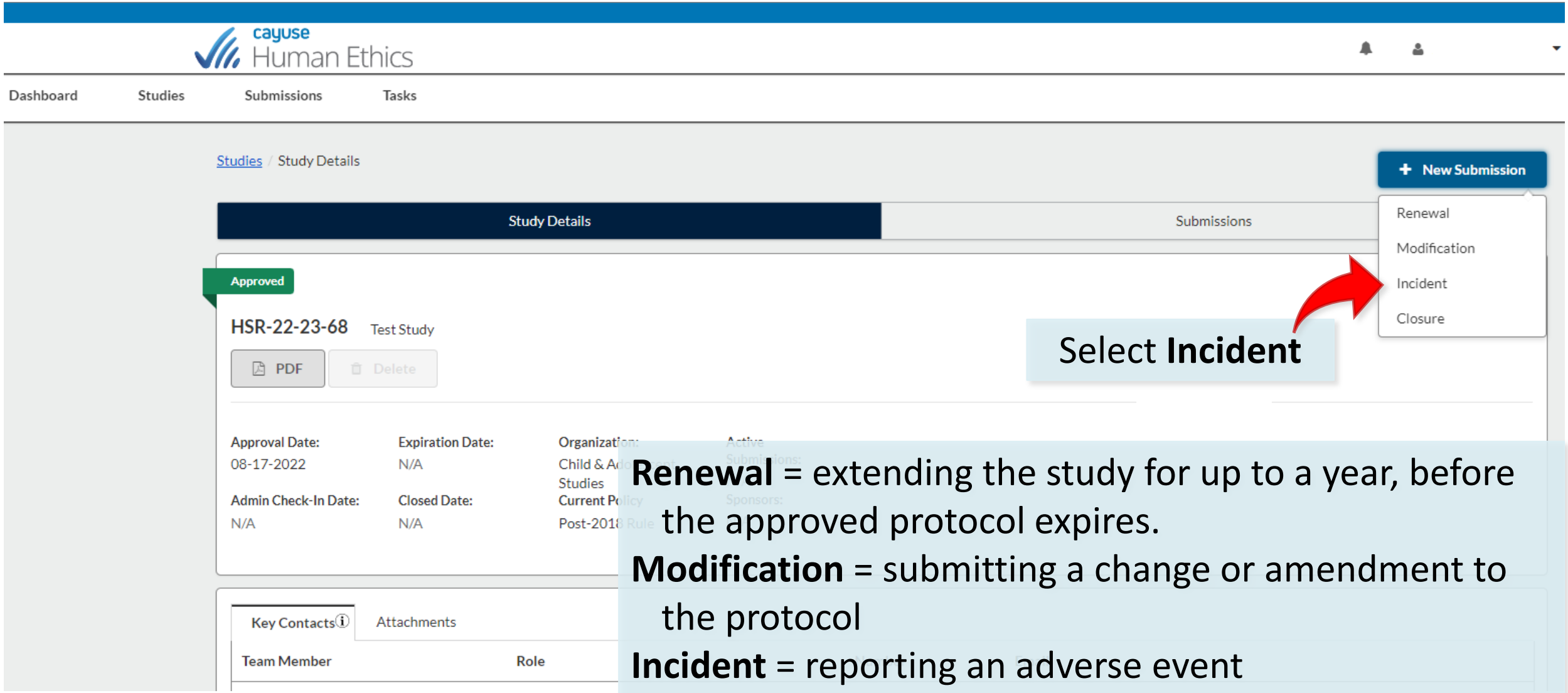
PDF Delete

Approval Date:	Expiration Date:	Organization:	Active Submissions:
08-17-2022	N/A	Child & Adolescent Studies	N/A
Admin Check-In Date:	**Closed Date:**	**Current Policy**	**Sponsors:**
N/A	N/A	Post-2018 Rule	N/A

Key Contacts ⓘ Attachments

Team Member	Role	Number	Email

You'll be taken to this page. Click on the blue button for "**+ New Submission**"



Select **Incident**

Renewal = extending the study for up to a year, before the approved protocol expires.

Modification = submitting a change or amendment to the protocol

Incident = reporting an adverse event

Closure = you are finished collecting data for the study

cayuse Human Ethics

Dashboard Studies Submissions Tasks

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

Incident

HSR-22-23-68 - Test Study

Edit PDF Delete

You're taken to this page. Click on "**Edit**" to provide a final progress report to close out the study.

PI:

Review Type:
N/A

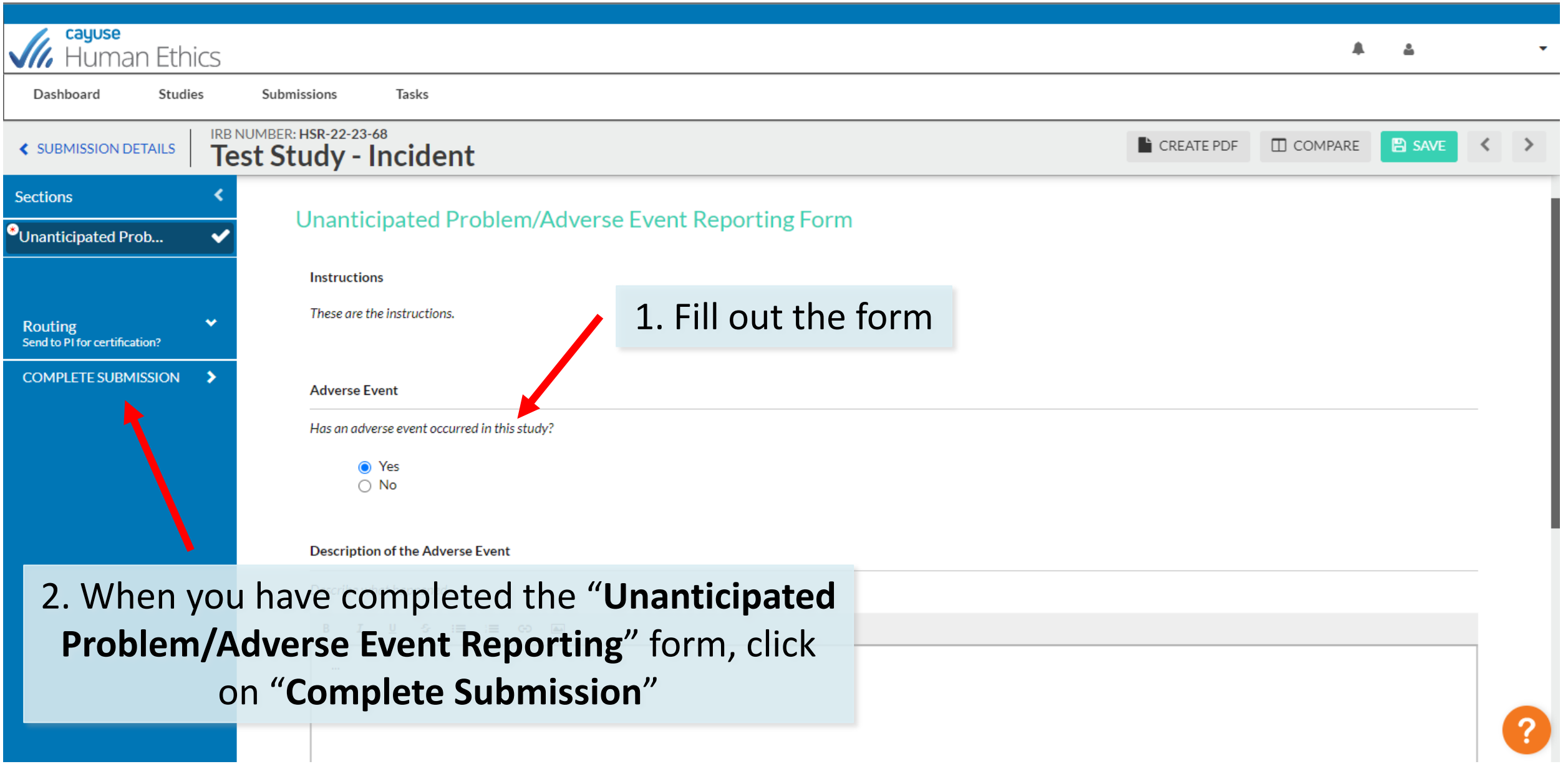
Rule

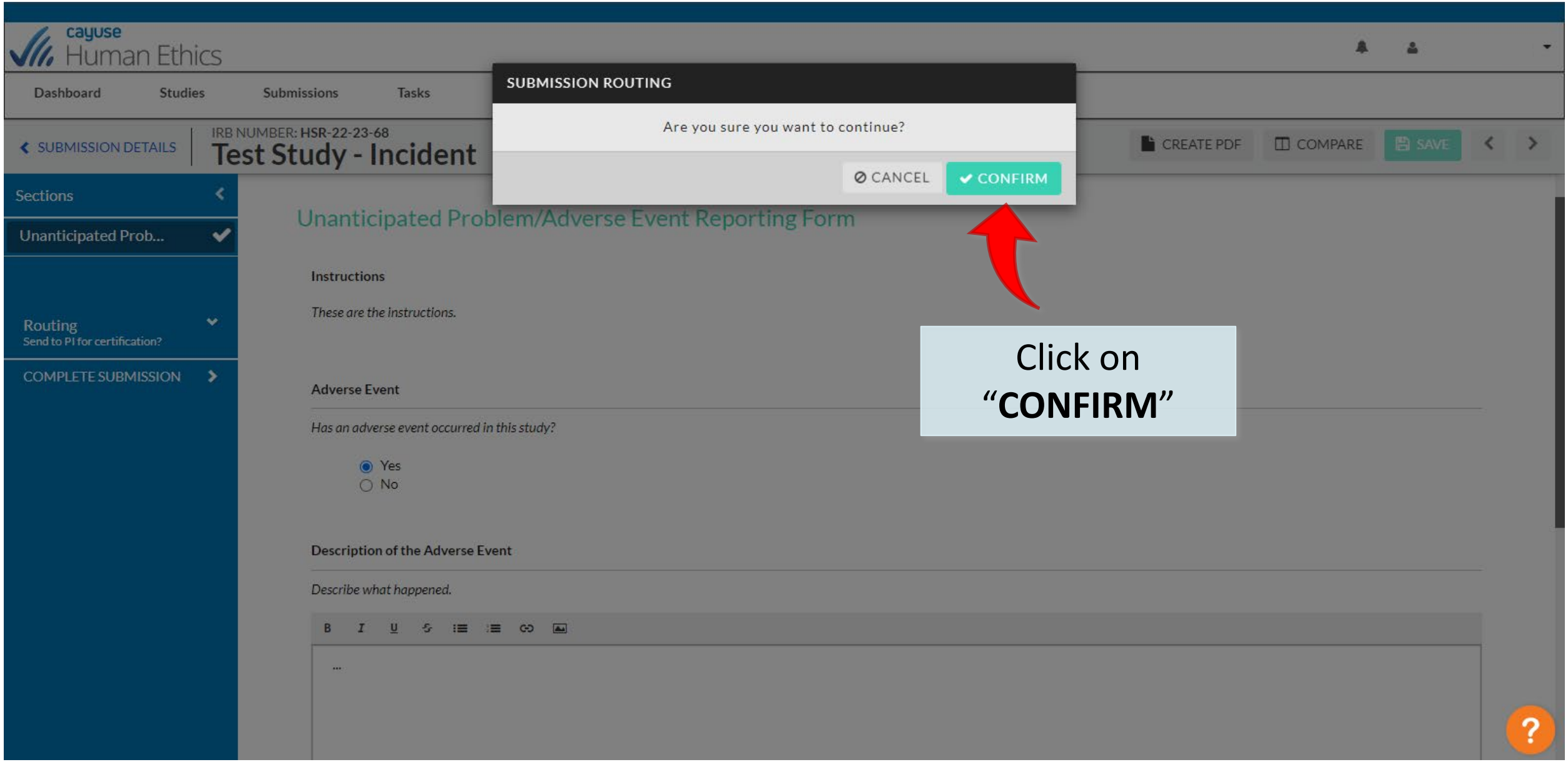
Required Tasks:
Complete Submission

Approvals Task History Attachments

Research Team

Name	Role	Result	Date


cayuse
Human Ethics
Dashboard
Studies
Submissions
Tasks
SUBMISSION DETAILS
IRB NUMBER: HSR-22-23-68
Test Study - Incident
CREATE PDF
COMPARE
SAVE
Sections
Unanticipated Prob...
Routing
Send to PI for certification?
COMPLETE SUBMISSION
Unanticipated Problem/Adverse Event Reporting Form
Instructions
These are the instructions.
1. Fill out the form
Adverse Event
Has an adverse event occurred in this study?
Yes
No
Description of the Adverse Event
2. When you have completed the "Unanticipated Problem/Adverse Event Reporting" form, click on "Complete Submission"


cayuse
Human Ethics
Dashboard
Studies
Submissions
Tasks
SUBMISSION ROUTING
Are you sure you want to continue?
CANCEL
CONFIRM
SUBMISSION DETAILS
IRB NUMBER: HSR-22-23-68
Test Study - Incident
CREATE PDF
COMPARE
SAVE
Sections
Unanticipated Prob...
Routing
Send to PI for certification?
COMPLETE SUBMISSION
Unanticipated Problem/Adverse Event Reporting Form
Instructions
These are the instructions.
Adverse Event
Has an adverse event occurred in this study?
Yes
No
Description of the Adverse Event
Describe what happened.
Click on
“CONFIRM”

cayuse Human Ethics

Dashboard | Studies | Submissions | Tasks

Studies / Study Details / Submission Details

In-Draft	2 Awaiting Authorization	3 Pre-Review	4 Under-Review
Submission is with researchers	Submission is awaiting certification or approval	Submission is being prepared for review	Submission is with reviewers

Awaiting Certification

Incident

HSR-22-23-68 - Test Study

View | PDF | Delete

Routing: Return | Certify

PI:

Current Analyst: N/A

Decision: N/A

Review Type: N/A

Review Board: N/A

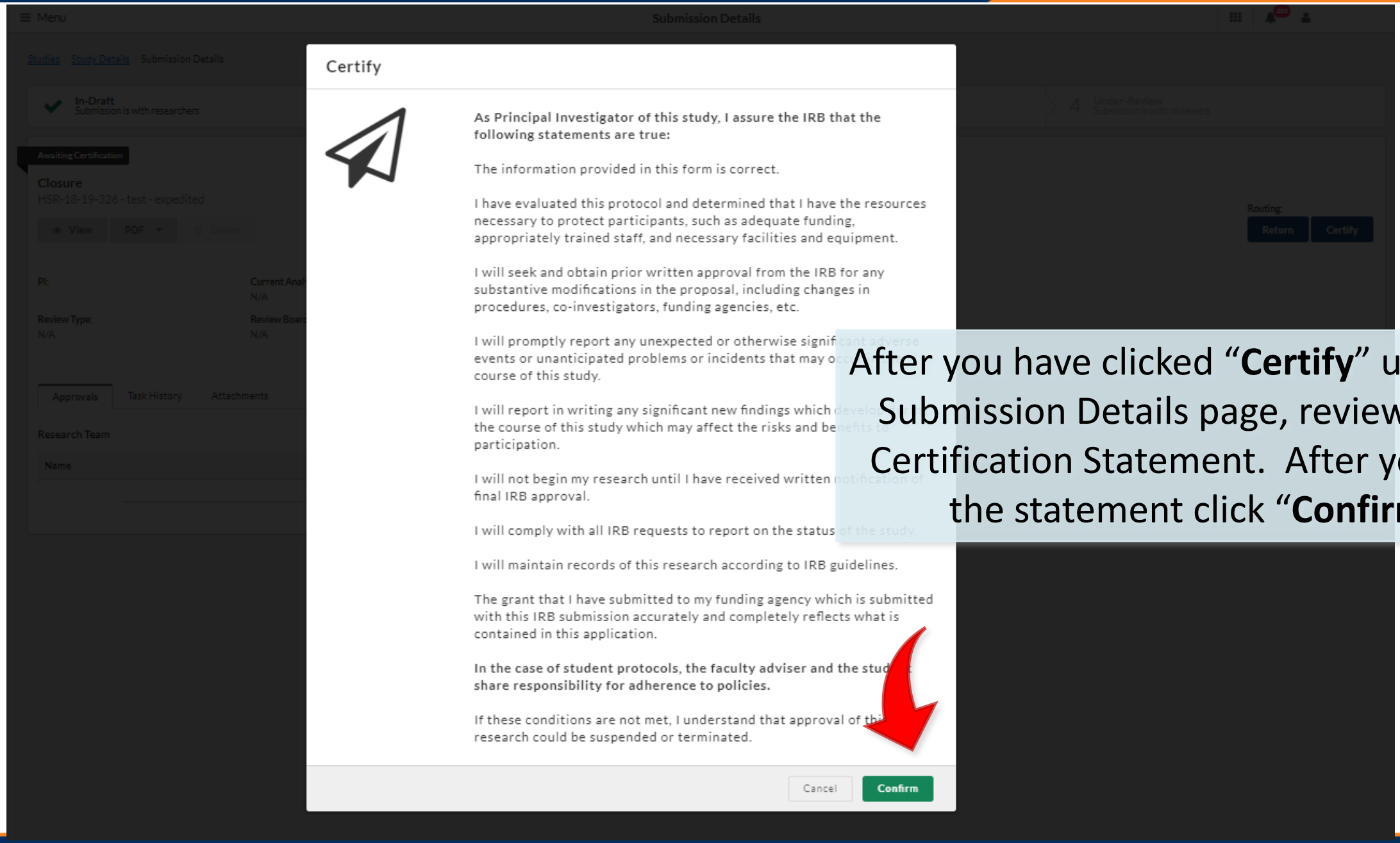
Meeting Date: N/A

Approvals | Task History | Attachments

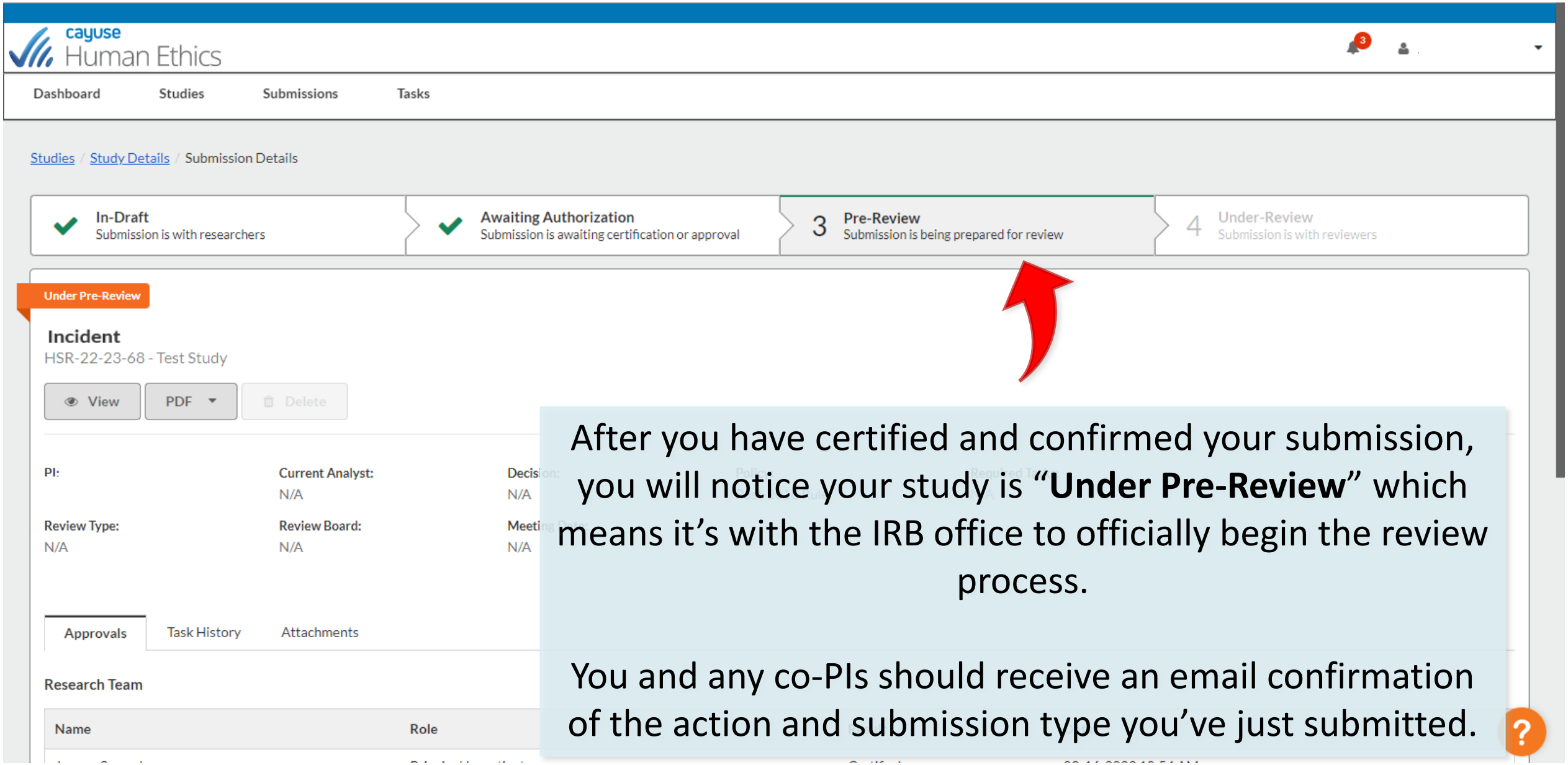
Research Team

Name	Role	Result	Date

You will then be redirected to the Submission Details page. You will need to "**CERTIFY**" in order to finalize the submission. Certification says you knowingly mean to take this action (to renew, amend/modify, or close).



After you have clicked "**Certify**" under the Submission Details page, review the PI Certification Statement. After you read the statement click "**Confirm**"



After you have certified and confirmed your submission, you will notice your study is "**Under Pre-Review**" which means it's with the IRB office to officially begin the review process.

You and any co-PIs should receive an email confirmation of the action and submission type you've just submitted.

If you have any issues or questions, please contact

IRB Office: **irb@fullerton.edu**
or **(657) 278-7719**