



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.

+ New Study

 **0**
In-Draft


 **0**
Awaiting
Authorization

 **0**
Pre-Review

 **0**
Under Review


My Studies

HSR-22-23-68	Test Study
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View All

My Tasks


All Tasks Complete

Submissions by Type

Renewal	0
Initial	1
Modification	0
Incident	0
Withdrawal	0
Closure	0
Legacy	0

Approved Studies

HSR-22-23-68	Test Study
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Studies Expiring in 30 days ▾

Expired Studies



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

+ New Submission

Study Details

Submissions

Approved

HSR-22-23-68 Test Study

PDF Delete

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

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



Key Contacts ⓘ

Attachments

Team Member	Role	Number	Email
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+ New Submission

Study Details

Submissions

Approved

HSR-22-23-68 Test Study

PDF

Delete

Approval Date:
08-17-2022

Expiration Date:
N/A

Admin Check-In Date:
N/A

Closed Date:
N/A

Organization:
Child & Adolescent
Studies
Current Policy
Post-2018 Rule

Active
Submissions:
Sponsors:

Key Contacts ⓘ

Attachments

Team Member

Role

- Renewal
- Modification
- Incident
- Closure

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

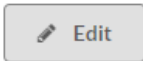
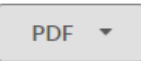
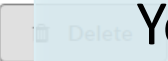
Closure = you are finished collecting data for the study



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

Current Analyst:
Decision:
Policy:
Meeting Date:
2018 Rule

Required Tasks:
[Complete Submission](#)

Approvals Task History Attachments

Research Team

Name	Role	Result	Date



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”



IRB NUMBER: HSR-22-23-68

Test Study - Incident

< SUBMISSION DETAILS

Sections <

Unanticipated Prob... ✓

Routing

Send to PI for certification? ▾

COMPLETE SUBMISSION >

SUBMISSION ROUTING

Are you sure you want to continue?

⊘ CANCEL

✓ CONFIRM

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.

B I U ↺ ☰ ☷ ↻ 🖼

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📄 CREATE PDF

📄 COMPARE

📄 SAVE

< >

Click on
“CONFIRM”



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
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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).



Certify



As Principal Investigator of this study, I assure the IRB that the following statements are true:

The information provided in this form is correct.

I have evaluated this protocol and determined that I have the resources necessary to protect participants, such as adequate funding, appropriately trained staff, and necessary facilities and equipment.

I will seek and obtain prior written approval from the IRB for any substantive modifications in the proposal, including changes in procedures, co-investigators, funding agencies, etc.

I will promptly report any unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur during the course of this study.

I will report in writing any significant new findings which develop during the course of this study which may affect the risks and benefits to participants.

I will not begin my research until I have received written notification of final IRB approval.

I will comply with all IRB requests to report on the status of the study.

I will maintain records of this research according to IRB guidelines.

The grant that I have submitted to my funding agency which is submitted with this IRB submission accurately and completely reflects what is contained in this application.

In the case of student protocols, the faculty adviser and the student share responsibility for adherence to policies.

If these conditions are not met, I understand that approval of this research could be suspended or terminated.

Cancel

Confirm

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



Under Pre-Review

Incident

HSR-22-23-68 - Test Study

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

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**