Incident Notification
Cayuse IRB

Office of Research and Sponsored Projects
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.
Log-in to Cayuse IRB:

https://fullerton.cayuse424.com/rs/irb
Click to access the study you want to Close.
You’ll be taken to this page. Click on the blue button for "+New Submission".
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
You’re taken to this page. Click on “Edit” to provide a final progress report to close out the study.
Fill out the form.
When you have completed the Unanticipated Problem/Adverse Event Reporting form, click on “Complete Submission”.
Click on “CONFIRM”.
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 CERITY under the Submission Details page, review the PI Certification Statement. After you read the statement click “CONFIRM”.

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 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 may affect the course of this study which may affect the risks and benefits of participation.

I will not begin my research until I have received written 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 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.
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 the IRB Office: irb@fullerton.edu or (657) 278-7719.

• As this is a new IRB system, if you find any issues (typos, unclear questions, etc.) please let us know!