# How to File an Incident Report in Cayuse

Please remember that:

- Incidents or adverse events must be reported in writing to the IRB Office at irb@regent.edu within two (2) working days of the occurrence.
- A completed IRB Incident Report Form must be submitted to the IRB within five (5) working days of the occurrence.
- You may refer to the ***Research Handbook and Sponsored Program Handbook*** for full definitions and procedures for adverse events and/or incidents.

1. Login to Cayuse and click on your study.

2. Make sure you are in "Study Details."
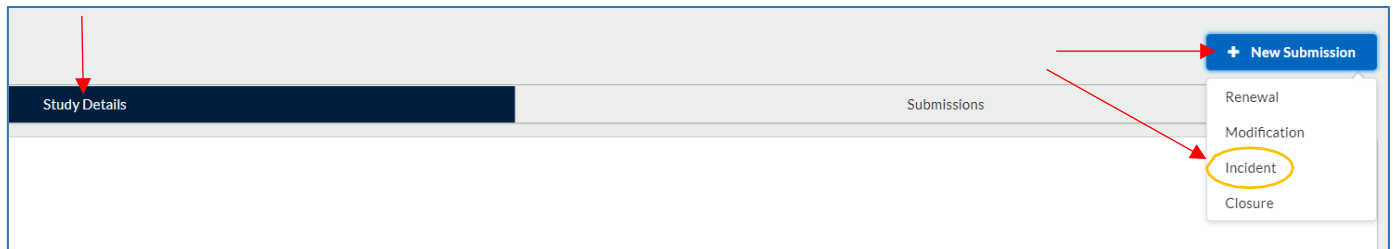
3. At the top right corner, you will see a blue "+New Submission" button. Click on it and select "Incident."

4. Click on the "Edit" button to open the Incident Report Submission.
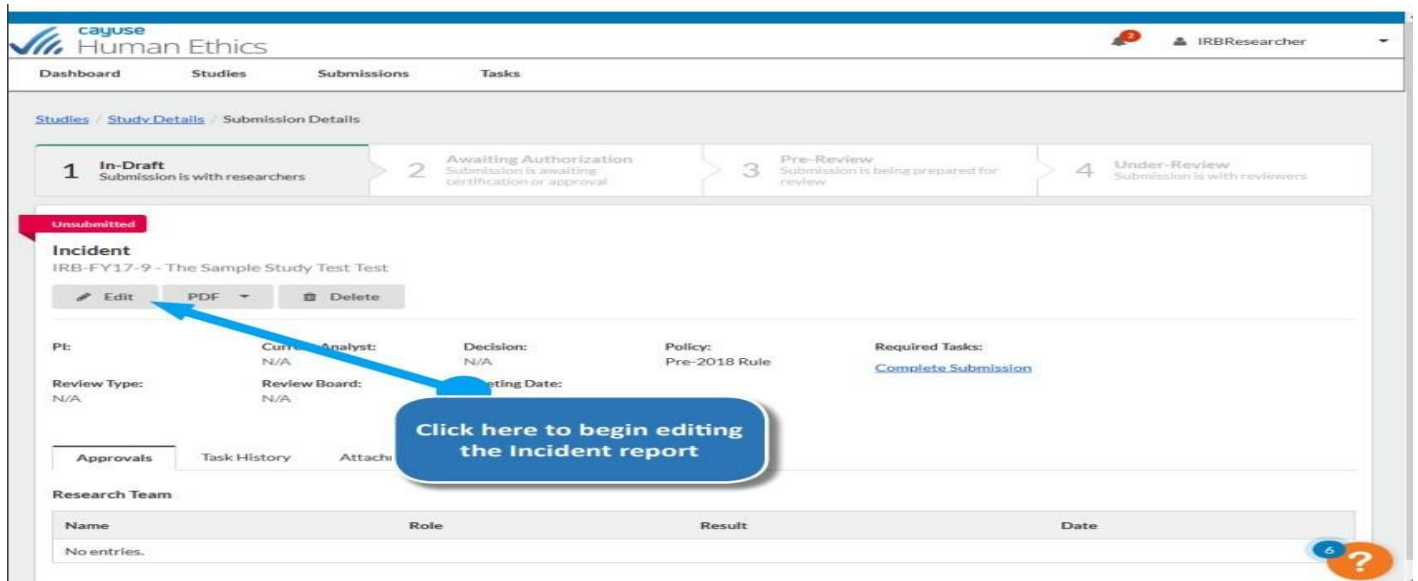
5. Follow the instructions to complete the form, submit, and then certify.

Sections	
Incident Report	

* Type of Report:

○ Unanticipated Problem or Adverse Event
  • Internal or External
  • Internal Subject Death even if anticipated if occurs within 30 days of study procedures
  • Adverse Device Effects

○ Protocol deviation/violation
  • Alteration to approved study procedures
  • Change in research to eliminate an immediate hazard to a subject.

○ Report(s) to or from oversight entity
○ Report of study lapse
○ Accident/incident
  • Data Breach
  • Self Report of Noncompliance

○ Subject Complaint
○ Subject incarceration
○ Subject withdrawal
○ Pertinent publication/public announcement
○ Notification of audit/inspection/inquiry
○ Miscellaneous

Incident Report

➤ Complete all questions
➤ When finished, click COMPLETE SUBMISSION
➤ Recommend submitting all minor study deviations once per year for Exempt/Expedited studies