Submitting an Incident Report

1. Open your previously approved study

![Study Details Image]

   - Approval Date: 07-16-2020
   - Admin Check-In Date: 07-16-2021
   - Expiration Date: N/A
   - Closed Date: N/A
   - Organization: Users loaded with unmatched Organization affiliation, Current Policy
   - Active Submissions: N/A
   - Sponsors: N/A

2. Once you have your study open, click New Submission, then Incident (in the right-hand corner)

![New Submission Image]

   - Renewal
   - Modification
   - Incident
   - Closure

3. Click Edit on the left-hand side of Study Dashboard

![Incident Details Image]

   - INCIDENT
   - 20-21-5 - Travel Study 3
   - [Edit], [PDF], [Delete]
4. Or Complete Submission on the right-hand side of Study Dashboard

   Required Tasks:
   Complete Submission

5. Complete all Questions on the Incident Report section

Incident Report

   This form should be used to report any issues that arise during the life of a research study. Information must be reported to the IRB within 5 days of occurrence or discovery.

   Report Type

   Which of the following categories best describes the information you are reporting?

   - New or increased risk to participants
   - Allegation of Noncompliance OR Finding of Noncompliance
   - Unresolved subject complaint
   - Unauthorized disclosure of confidential information
   - Protocol deviation made without prior IRB approval to eliminate an immediate hazard to a subject
   - Protocol deviation due to the action or inaction of the investigator or research staff
   - Protocol deviation that harmed a subject or placed subject at risk of harm
   - Audit, Inspection, or Inquiry by a federal agency
   - Written reports of federal agencies (e.g., FDA Form 483)
   - Written reports of study monitors
   - Suspension or premature termination by the sponsor, investigator, or institution
   - Incarceration of a subject in a research study not approved to involve prisoners
   - Adverse events or IND safety reports that require a change to the protocol or consent
   - State medical board actions
   - Unanticipated adverse device effect
   - Expand Comments

6. Select Complete Submission

   Routing
   Send to PI for certification?

   COMPLETE SUBMISSION

7. Select Certify then Confirm
8. Incident Report will be sent to IRB for review