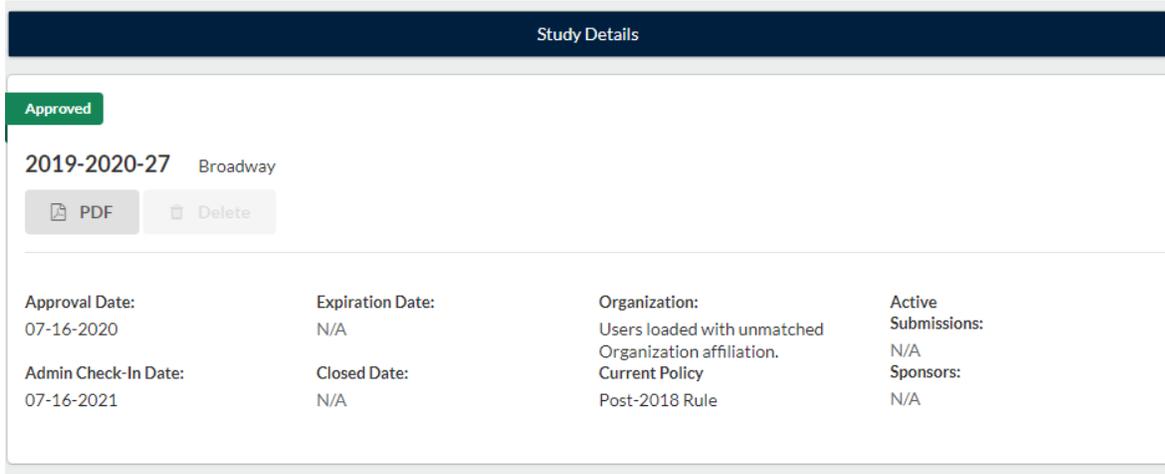


## Submitting an Incident Report

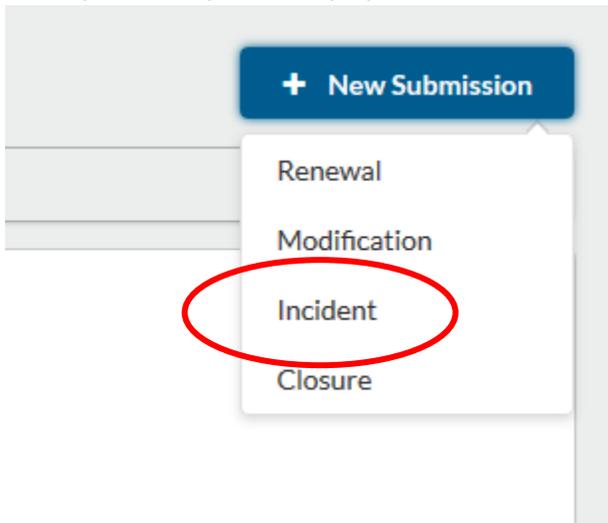
1. Open your previously approved study



The screenshot shows the 'Study Details' page for an approved study. At the top, there is a dark blue header with the text 'Study Details'. Below this, a green tab labeled 'Approved' is visible. The study ID '2019-2020-27' and the name 'Broadway' are displayed. There are two buttons: 'PDF' and 'Delete'. Below this, a table of metadata is shown:

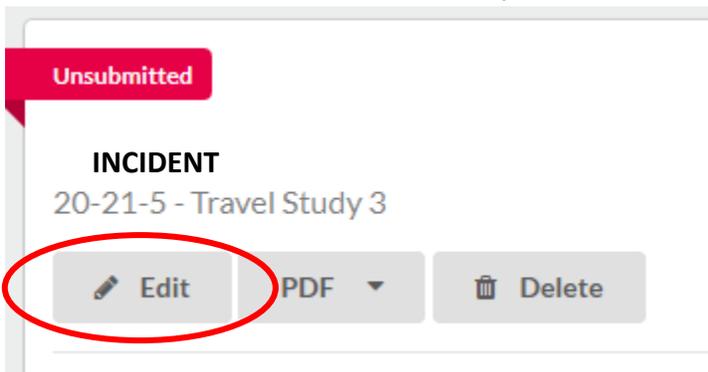
|                                    |                         |                                                                                             |                                                   |
|------------------------------------|-------------------------|---------------------------------------------------------------------------------------------|---------------------------------------------------|
| Approval Date:<br>07-16-2020       | Expiration Date:<br>N/A | Organization:<br>Users loaded with unmatched<br>Organization affiliation.<br>Current Policy | Active<br>Submissions:<br>N/A<br>Sponsors:<br>N/A |
| Admin Check-In Date:<br>07-16-2021 | Closed Date:<br>N/A     | Post-2018 Rule                                                                              |                                                   |

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



The screenshot shows a dropdown menu for 'New Submission'. The menu is open, showing four options: 'Renewal', 'Modification', 'Incident', and 'Closure'. The 'Incident' option is circled in red.

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



The screenshot shows the 'Unsubmitted' study dashboard. A red tab labeled 'Unsubmitted' is visible. Below it, the study ID '20-21-5 - Travel Study 3' is displayed. There are three buttons: 'Edit', 'PDF', and 'Delete'. The 'Edit' button is circled in red.

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.*

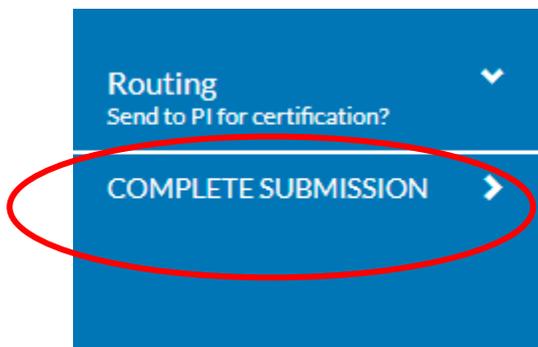
\*Report Type

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



7. Select Certify then Confirm

Awaiting Certification

**Renewal**  
IRB-FY2021-14 - The Pandemic Study

View PDF Delete

Return Certify

PI: Frances Faculty      Current Analyst: N/A      Decision: N/A      Policy: Post-2018 Rule      Required Tasks: N/A

8. Incident Report will be sent to IRB for review

 **In-Draft**  
Submission is with researchers

**Under Pre-Review**

**INCIDENT**  
IRB-FY2021-14 - The Pandemic Study

View PDF Delete

PI: Frances Faculty      Current Analyst: N/A  
Review Type: N/A      Review Board: N/A