Create and Submit a Repository Application Incident Report

Incident Reports are the equivalent of the AE/ORIO submission for a HUM application. An Incident Report is submitted when a significant incident occurs that requires acknowledgement by the IRB.

An Incident Report (IR) can be initiated by repository personnel with edit rights listed on the approved application, **but it can only be submitted for review by the repository director.** After submission, the Incident Report is locked and no further changes can be made unless requested by a reviewer.

This procedure contains two parts:
- **Creating a Repository Application Incident Report**
- **Submitting a Repository Application Incident Report**

### Creating a Repository Incident Report

**Home Workspace**

1. Click **Approved** to display approved applications.

   **Note:** An Incident Report can also be submitted for a **Closed** application.

2. Click the **Name** of the repository application to view the application workspace.

**Repository Workspace**

3. Click **Incident Report**.
Incident Report

4. Answer the required questions.

5. Click Continue.

Incident Report (continued)

6. Answer the remaining questions.

Note: Depending on the answer selected, additional questions may display.

7. Click Finish.

Notes:

- The system validates that all required fields are complete. Any errors must be addressed before the IR can be submitted.

- The repository application will have an IR ID number appended to it, where the IR number will increase sequentially for each IR submitted.

- The repository application is in the state of IR Pre Submission.
Incident Report Workspace

8. To notify the Repository Director that the Incident Report is completed, click **Move to Ready to Submit Inbox**.

**Note:** To open an Incident Report that is in-progress, click **Edit Application** from the incident report workspace.

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Submitting a Repository Application Incident Report

Only the Repository Director can submit an application’s Incident Report.

**Home Workspace**

1. On the **My Inbox** tab, under **Require Action by Study Team**, click on the **Name** of the Incident Report. It should be in the state of **IR Pre Submission**.

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Incident Report Workspace

2. Click **Edit Application** to open and review the Incident Report.
3. Review and Save any changes, if needed. Click Exit to return to the incident report workspace.

4. Click Submit.

**Note:** The system validates that all required fields are complete. Any errors must be addressed before the IR can be submitted.

5. Click OK.

**Note:** The state of the repository application changes to IRB Review, and you are returned to the incident report workspace.