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 and 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.
4. Answer the required questions.

5. Click **Continue**.

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.