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Investigator Checklist: UP/AE

For reporting an Unanticipated Problem(s) and/or Adverse Event(s) to the IRB

This checklist is a guide to complete the submission process, not a required submission document. Incomplete submissions will be unlocked and increase processing time.

QUICK LIST OF DOCUMENTS

- ☐ Completed Unanticipated Problem Report
- ☐ Copy of sponsor notifications
- ☐ Copy of sponsor correspondence
- ☐ Copy of FDA notification
- ☐ Copy of FDA correspondence
- ☐ Relevant Data Safety Monitoring Report(s)
- ☐ Follow-up Report

See detailed list of required actions and documents below.

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REQUIRED DOCUMENTS AND ACTIONS

1. CREATE A NEW PACKAGE

☐ Click to add package description or notes (optional but recommended)

2. DESIGNER – Download Required Form

Select a Library: Lifespan – Rhode Island Hospital IRB or Lifespan – The Miriam Hospital IRB
Select a Document: Unanticipated Problem Report Form (report form will vary by event)

☐ Unanticipated Problem "Type" Report (Document Type, Unanticipated Problem Report)

3. DESIGNER – Attach New Document

Use the "Attach New Document" option when the document you are adding is not a revised or updated version of an existing project document.

☐ Copy of notification to Sponsor and any correspondence

☐ Copy of notification to FDA and any correspondence

☐ Data Safety Monitoring Report(s)

☐ Corrective Action Plan

☐ Follow-Up Report

☐ Any other information that would be relevant to the IRB

4. SIGN THIS PACKAGE

☐ Unanticipated Problem (UP) package must be **signed** by the PI*

5. SUBMIT THIS PACKAGE

☐ Submission Type: Unanticipated Problem (UP) Report

What happens next?

1. IRB Coordinator conducts a pre-review of the submission
2. Incomplete submissions will be unlocked to allow for revisions.
3. Complete submissions will be assigned for review. Click on "Reviews" to check the status of your submission.