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Investigator Checklist: Protocol Deviation

For reporting a Protocol Deviation or Exception request 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 Protocol Deviation/Exception Report
- ☐ Copy of sponsor notifications
- ☐ Copy of sponsor correspondence
- ☐ Copy of FDA notification
- ☐ Copy of FDA correspondence
- ☐ Corrective Action Plan

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: Protocol Deviation/Exception Report Form

☐ Protocol Deviation/Exception Report* (Document Type, Protocol Deviation/Violation 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

☐ Corrective Action Plan

☐ Any other information that would be relevant to the IRB

4. SIGN THIS PACKAGE

☐ Protocol Deviation/Violation package must be **signed** by the PI*

5. SUBMIT THIS PACKAGE

☐ Submission Type: Protocol Deviation/Violation 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.