Process of Registering Amendments and Adverse or Un-Anticipated Events to a Multi-Site Study into the Reliance Registry – Overview of Steps by User Category

1a. Identify changes/events requiring review by RevIRB

2a. Submit all proposed changes or necessary documents to the Reviewing Campus IRB for review/approval.

1b. Identify changes/events requiring review by RevIRB and ASAP inform the RevPI

2b. Review Documentation/Information provided by the RelPI and discuss with RevIRB

3. Review the documentation uploaded by the RevPI and discuss with RelIRB

4. Find the study in the Registry and:
   - Enter the Amendment Approval and Upload the relevant documents or supply notes/comments

5a. Notify Rev and Rel PIs and Rel IRBs

5b. Closed/Archived

Amendments approved?

No

Yes

Requires Full Committee?

No

Yes

4. Find the study in the Registry and:
   - Enter the Amendment Approval and Upload the relevant documents or supply notes/comments

6. Review the documentation uploaded by the RevIRB

5a. Notify Rev and Rel PIs and Rel IRBs

5b. Closed/Archived

Amendments approved?

Yes

No

LEGEND

Action performed in the IRB Reliance Registry

Action performed outside the Reliance Registry

Decision Point

Action that triggers automatic notification or changes in the Registry

Automatic e-mail notification sent to users by the Registry