Salus IRB

Sponsor Reporting Responsibilities

In accordance with federal regulations and federal and international guidance, Salus IRB requires that certain information be reported during the course of a study. This document outlines sponsor reporting responsibilities and how to report information that must be submitted to Salus IRB. Salus IRB aims to foster a consultative relationship with study managers and their support staff. Please contact us with any questions or concerns regarding submission documents or reporting requirements.

Changes in research require IRB approval **prior to implementation** *except* when necessary to eliminate an apparent immediate hazard to research participants. However, the IRB **must be notified** of the occurrence within 10 business days of discovery (or 5 days for device research). Report the occurrence on *Form 300*.

If research is being conducted under ICH-GCP E6(R2), refer to the *Guideline for Good Clinical Practice E6(R2)* for additional reporting responsibilities to the institution, sponsor, and regulatory agencies that may be applicable to the research. [Click hyperlink above].

Process for Reporting to Salus IRB

Note: Forms and guidelines listed below can be found at https://www.salusirb.com/getting-started/submission-forms/.

- ***Submission Form 220 "Modifications to Approved Research"***
  - Revisions/Amendments or Administrative/Clarification Letters to the protocol
  - Planned Protocol Deviations
  - Revisions to the Investigator Brochure/Product Information
  - New or Revised Template Informed Consent Document(s)
  - New or Revised Template Recruitment/Study Material
  - Request for Translation or Approval of a Translated Document
- ***Submission Form 120.PM "Project Manager Continuing Review Report"***
  - Submit at least two (2) weeks prior to the IRB approval expiration date
- ***Submission Form 300 "Event Determined to be an Unanticipated Problem"***
  - See "Reporting Guidelines for Unanticipated Problems, Deviations, and Other Safety Information"
- ***Submission Form "Change in Project Manager"***
  - Submit for changes in significant study management personnel such as the Project Manager and staff responsible for receiving documents or corresponding with Salus IRB
- **Study Close-out**
  - Salus IRB will automatically close the research after review of the last Investigator's Final-Closeout report. The Project Manager will be notified, in writing, after the acceptance of the final site closure. Separate notification by the Project Manager of research completion is not required
- ***Submit the following in writing, email is sufficient***
  - Change in billing information
  - Removal of/change in GlobeSync access