Salus IRB

Investigator 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 investigator reporting responsibilities and how to report information that must be submitted to Salus IRB. Salus IRB aims to foster a consultative relationship with investigators and their research 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
    - For Federally supported or conducted research, if the grant is updated ensure the protocol is revised and submitted to the IRB for approval prior to implementation of the change.
  - Planned Protocol Deviations
  - Revisions to the Investigator Brochure/Product Information
  - New or Revised Informed Consent Document **OR** Recruitment/Study Material **AND/OR** their translations
- ***Submission Form 140 "Additional Site/Site Change"*** (to report site additions, removals, or an address change)
- ***Submission Form 150 "Principal Investigator Change"*** [to report a change of the Principal Investigator (PI)]
- ***Submission Form 120.SS "Continuing Review Report for Single Site Research"***
  - For Single-Site Studies [submit at least two (2) weeks prior to the IRB approval expiration date]
- ***Submission Form 120.I "Interim Report for Investigators"***
  - For PIs participating in Multi-Site Studies [submit at least two (2) weeks prior to the IRB approval expiration date]
- ***Submission Form 130 "Final-Close Out Report"***
- ***Submission Form 300 "Event Determined to be an Unanticipated Problem"***
  - See "Reporting Guidelines for Unanticipated Problems, Deviations, and Other Safety Information"
- ***Submission Form 320 "Non-Reportable Events"***
  - For events that do not meet the criteria of an Unanticipated Problem, but must be reported to satisfy sponsor or site reporting requirements
- ***Submission Form 515 "Reporting Changes in Financial Disclosure and Conflicts of Interest"*** [includes PI's *and* research staff's potential, actual, or perceived conflicts of interest (COIs) *and* COIs of the PI's *or* research staff's immediate family members]

  Definitions: "Immediate family member" means (at a minimum) an individual's dependent children *or* a person with whom an individual resides, in the same residence, where both individuals share responsibility for each other's welfare and financial obligations (e.g., spouse, domestic partner). "Research staff" means **anyone** responsible for the design, conduct, or reporting of research (e.g., sub-investigators, research coordinators).
- ***Submission Form "Request to Enroll Vulnerable Populations"***
- ***Submit the following items in writing, email is sufficient:***
  - Change in site contact or billing information
  - Removal of/change in GlobeSync access