
Reportable New Information

1. IRB Review process

a. Determinations

All reportable events, including unanticipated problems, unresolved subject complaints, and non-compliance must be reviewed by the convened IRB.

Subject complaints are generally managed by the Relying Institution, unless they indicate non-compliance or an unanticipated problem, at which point they will require reporting to the Reviewing Institution.

b. Corrective Action Measures

The study team will propose a corrective and preventative plan at the time of reportable event submission. A standard corrective and preventative action plan template should be implemented for all institutions relying on a single IRB. The Reviewing Institution is responsible for IRB review and recommendations of the plan, however may request additional input and review from the Relying Institution. Standard elements will be provided in the template, which will guide study teams in developing a corrective and preventative plan.

2. Reporting Process

a. Responsible Party

The Principal Investigator (PI) at the Institution where the reportable event is identified is responsible for reporting events to the Reviewing Institution. In cases where an event affects the overall conduct of the study at all institutions, the lead Institution PI is responsible for reporting the event to the Reviewing Institution.

b. Timelines for Reporting

All events must be reported to the Reviewing Institution at most 21 calendar days from the date the study team becoming aware of the event.

An initial report for serious or life-threatening events, or apparent continuing or serious non-compliance, must be provided to the IRB within 7 calendar days.

c. IRB Responsibilities

The Reviewing Institution is responsible for ensuring proper reporting to federal agencies for all federally-funded research. The letter to federal agencies will be drafted by the Reviewing Institution and sent to the Reliance Coordinator or Relying Institution's contact for feedback and additional edits. Relying Institution will have 5 business days to review with the understanding that there may be more or less flexibility depending on the urgency of reporting.

3. Communication of Reportable New Information

- a. The Relying Institution, at the time of site activation, is responsible for reporting any site PI's serious non-compliance that is either relevant to the new study or has not been resolved. This information is captured during the Relying Institution context review.
- b. Final determinations of unanticipated problems are sent to the Relying Institution PI as well as PI's of affected institutions.
- c. All reportable subject complaints and findings of serious or continuing non-compliance require Relying Institution review with final weigh in before final Reviewing Institution determination. The final determination is sent to the Relying Institution PI, Reviewing Institution PI, and Reliance Coordinator or Institutional Contact.
- d. Reviewing Institutions must have a system in place to communicate relevant policies and procedures to Relying Institutions to ensure compliance with requirements for reportable events.