
SIRB
ALLIANCE

Introduction

Through consensus, we have built best practice solutions to use in the review process of NIH funded studies that uses sIRB.

Using these best practices eliminates the need for your IRB to read pages of guidance and then invent your own process. The documents are easy to use and can be applied immediately. Implementation of the sIRB Alliance best practices and information technology solutions guarantees a reduction on variations in sIRB review and enables institutions across the country to carry out the NIH's vision for a streamlined and efficient sIRB review model.

We have tested these best practices and had over 100 institutions provide feedback through surveys and working groups. The standardization of IRB review for NIH funded research is here and we encourage you to use this document and the other work we have completed in your interactions with participating sites.

The sIRB Alliance is made up of any institution who has contributed to building these standard practices.

Working groups drafted 3 versions for each solution, each with varying levels of flexibility of modification by participating sites. Working groups chose the two best solutions, which were then voted upon in a survey released to the wider IRB community. The sIRB Consensus survey was available for completion from 08/21/2018 till 09/30/2018. 63 participants from 57 unique Institutions responded to the survey. Out of the 57 Institutions, 25 are CTSA affiliated institutions. The solution with a majority of approving votes was selected as the chosen solution. The solutions in this document won the majority approving votes in the following breakdown:

- Reporting Definitions – **49%**
- Reporting Process – **67%**
- IRB Review Process – **52%**
- Communication of Reportable New Information – **52%**

For more information, refer to our consensus document on the SIRB Alliance website. To provide feedback, please head to www.sirballiance.org.

**Portions of this work were informed by SMART IRB committee members and their draft work on "Reportable Events: Recommendations for Investigator-initiated Multisite Studies" for the SMART IRB Harmonization Steering Committee. Their final version of their work was published to SMART IRB as of February 2019. We thank them for their contributions to this project.*

SIRB ALLIANCE
SIRBALLIANCE.ORG
1 Park Avenue | 6th Floor | New York, NY 10016

Reportable New Information

1. **Standard Definitions**
   a. ***Reportable event*:** New information that meets one or more of the following criteria:
      i. Unanticipated problem
      ii. Non-compliance
      iii. Information that indicates one of the following:
         1. Changes to the protocol taken to eliminate an immediate hazard
         2. Incarceration of a participant (where prisoners were not an approved population to be enrolled)
         3. Breach of confidentiality
         4. Disqualification or suspension of investigator by FDA, NIH, or any other agency; or suspension or restriction of an investigator's clinical professional license
         5. Protocol exception request
         6. Subject complaint (as defined by the institution)

   b. ***Non-compliance:*** Failure to follow the federal regulations, Institutional policies, or state or local laws pertaining to human subject protections, or failure to follow the requirements or determinations of the IRB, which compromises the rights and/or welfare of subjects or others.

   c. ***Serious Non-compliance:*** Non-compliance which significantly affects or has the potential to significantly affect the rights and/or welfare of subjects or others.

      Significantly in the above definition is defined as having:
      i. an impact on subjects or others that is life-threatening or results in serious physical, psychological, or legal harm or risk of harm, such that the risks of the study outweigh the potential benefits to participants or generalizable knowledge; or
      ii. an impact on research data, resulting in data that is compromised to the point of which the data is unusable.

   d. ***Continuing Non-compliance:*** A pattern of non-compliance that suggests that non-compliance will continue without intervention.

   e. ***Unanticipated Problem:*** Any incident, experience, or outcome that meets all of the following criteria:
      i. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
      ii. Related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
      iii. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

      *Note that the definition of unanticipated problem cannot be revised as it is defined by OHRP guidance on Unanticipated Problems Involving Risks & Adverse Events dated January 15, 2007.

   f. **Complaint:** Reviewing Institutions are responsible for defining reportable subject complaints.

2. **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.

3. **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.

4. **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.