
SIRB
ALLIANCE

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SIRBALLIANCE.ORG
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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. This solution won majority of votes at **54%**. For more information, refer to our consensus document on the SIRB Alliance website.

To provide feedback, please head to www.sirballiance.org.

Recruitment Materials

1. The Reviewing IRB is solely responsible for reviewing and approving the recruitment plan and materials for the study. Recruitment plans and materials cannot be modified for each site with the exception of local contact information.

2. The Reviewing IRB evaluates recruitment plan based on its effect on equitable subject selection and study inclusion/exclusion criteria, and should not include payment arrangements that target economically disadvantaged participants or can lead to unfair selection of participants.

3. The Reviewing IRB reviews proposed recruitment plan and advertising materials to judge whether they fulfill the requirements for consent.

4. Suggested Key Elements:
    a. Purpose of the study
    b. Risks of the study
    c. Benefits of the study
    d. Description of study procedures
    e. Basic eligibility criteria

5. Target return time for review of IRB documents:
    - 5-7 days

6. Significant Modifications:
    a. **Pre-approval:** N/A
    b. **Post-approval:**
    Any changes to the recruitment materials first vetted through Relying Institutions for any local institutional policies related to recruitment including local contact assessments. Once its verified, the recruitment is sent to the Reviewing IRB