





## 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 **60%**. For more information, refer to our [consensus document](#) on the SIRB Alliance website.

To provide feedback, please head to [www.sirballiance.org](http://www.sirballiance.org).



### Review of Financial Conflicts of Interest

1. Relying Institutions make determinations on financial conflict for their site's study team members. Management plans set by the Relying Institution are submitted to the Reviewing IRB - the Reviewing IRB evaluates the plan prior to approval. Any additional changes have to be cleared by the Relying Institution's COIC.
2. No IRB should review the management plan on a study that has institutional conflict with the Relying Institution.
3. If the lead PI of the study has a financial conflict that requires subject notification, subjects at all sites are to be notified.
4. Target return time for review of other IRB documents
  - 8-15 days
5. Significant modifications:
  - a. **Pre-approval** – N/A
  - b. **Post-approval**

Any changes to the financial conflict of interest management plan are reviewed at the Relying Institution level. The change is then submitted to the Reviewing IRB for approval.