Single IRB Review for Multi-Site Research: Resource and Infrastructure Development Workshop
September 12, 2018

RELEVANT INFORMATION AND RESOURCES

Background

The "Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research" establishes the expectation that the domestic sites of all National Institutes of Health (NIH) funded multi-site studies involving non-exempt human subjects research will use a single Institutional Review Board (IRB) (NOT-OD-16-094). NIH has heard a great deal of positive feedback in support of the policy and believes that streamlining IRB review for multi-site studies will reduce unnecessary delays and costs caused by duplicative review.

However, NIH also heard concerns from institutions about the resources that would be required to amend business practices, make system changes, and develop other tools necessary to facilitate single IRB review. In an effort to mitigate some of these concerns, NIH funded seven administrative supplement applications submitted by Clinical and Translational Science Award (CTSA) parent awardees that provided one year of support to develop widely applicable approaches for modifying and enhancing institutional IRB infrastructure and related resources to allow for efficient and effective single IRB review of multi-site studies (NOT-TR-17-018).

This workshop is being held so that the administrative supplement awardees can gather to share successful strategies and lessons learned for modifying and enhancing institutional IRB infrastructure for single IRB review of multi-site studies. After the workshop, best practices and lessons learned will be collated into a report that will be posted on the NIH website to help guide other institutions in achieving success in implementing single IRB review.

Broad Scope Presentation Topics Across Sessions

- What is the potential impact of your work on facilitating single IRB review for multi-site research?
- How are the resources and infrastructure development from your project generalizable to other institutions that might serve as or rely on a single IRB of record?
- If possible, describe any general best practices identified from your project and/or common challenges encountered for facilitating single IRB review for multi-site research.
- How does the work of your study facilitate SMART IRB?

NIH Single IRB Policy for Multi-Site Research Guidelines & Implementation:

For applications with due dates on or after January 25, 2018, and contract solicitations published on or after January 25, 2018, NIH expects that all sites participating in multi-site studies, which involve non-exempt human subjects research funded by the NIH, will use a single IRB to conduct the ethical review required for the protection of human subjects.

This policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research. It does not apply to career development, research training or fellowship awards. Implementation of this policy is expected to reduce unnecessary administrative burdens and systemic inefficiencies while maintaining appropriate human subjects protections.

There are different types of single IRB models, including the following:

- **Central IRB**: The same IRB of record (also known as the *reviewing IRB*) provides the ethical review for all sites participating in more than one multi-site study. The sites are usually in a network, consortium or particular program.

- **Single IRB**: One IRB of record (or *reviewing IRB*), selected on a study-by-study basis, provides the ethical review for all sites participating in that multi-site study.

Applicants are expected to include a plan for the use of a single IRB in the grant applications and contract proposals they submit to the NIH (for due dates on or after January 25, 2018).

For More Information on the NIH Single IRB Policy for Multi-Site Research Visit:

- *General Information*:
  https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm

- *Frequently Asked Questions*:
  https://grants.nih.gov/grants/policy/faq_single_IRB_policy_research.htm

- *Single IRB and Exceptions Process Webinar:*
  https://grants.nih.gov/node/1272

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What is SMART IRB?

Through its Clinical and Translational Science Awards (CTSA) Program, the National Center for Advancing Translational Sciences (NCATS) has developed a single IRB platform for multi-site clinical studies: the NCATS Streamlined, Multi-site, Accelerated Resources for Trials (SMART) IRB Platform. The goal is to provide flexible resources that investigators nationwide can use to harmonize and streamline IRB review for their own multi-site studies. The SMART IRB Platform is flexible and can be used for one investigator-initiated multi-site studies, or for a network conducting many multi-site studies. NCATS intends for SMART IRB Platform to serve as a roadmap to help implement the NIH Single IRB Policy for Multi-Site Research (NOT-OD-16-094).

The SMART IRB Platform was developed with input from experts across the nation, including several CTSA Program representatives who are recognized authorities on IRBs. SMART IRB is based on the successful experiences of NIH central IRB initiatives and on a CTSA program demonstration project using a single IRB reliance model called IRBrely. Building on the IRBrely model, the NCATS SMART IRB Platform is designed to be a flexible option that can be used to set up a central IRB for a network of many studies or a single IRB for one multi-site study.

Joining the NCATS SMART IRB Platform involves two steps:

- The first step is signing on to the NCATS SMART IRB Platform authorization agreement. Institutions sign the joinder, which documents their agreement with the roles established in the authorization agreement. This is done once.
- The second step is designating an IRB to be the single IRB (the *reviewing IRB*) and identifying the participating sites that will rely on the IRB for the review of a multi-site study.

Joining and using the SMART IRB Platform is free; however, some institutions may charge IRB fees in connection with IRB review activities.

CTSA Program hubs and affiliates can visit **SMARTIRB.org** to learn more and join.

Public comments can be submitted to SciencePolicy@od.nih.gov any time before, during, or after the workshop.