NIH Single IRB POLICY: Update

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NIH POLICY on the USE of a SINGLE INSTITUTIONAL REVIEW BOARD for MULTI-SITE RESEARCH

Published in NIH Guide and Federal Register: June 21, 2016; revised effective date

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html

Purpose: reduce start-up time without increasing potential subject harm

Effective Dates:

- Competing grant applications

  Application due dates on/after **January 25, 2018**

- R&D Contract proposals

  Solicitations issued on/after **January 25, 2018**

sIRB POLICY PROVISIONS

APPLIES TO

- ✓Domestic sites of multi-site studies
- ✓Same/shared protocol
- ✓All non-exempt human subjects; not just clinical trials
- ✓All new and re-competing applications/proposals
- ✓Grants and R&D Contracts

DOES NOT APPLY TO

- **Exclusions:**
  - ✖Foreign sites
  - ✖Career development (K), institutional training (T), and fellowship awards (F)
- **Exceptions**
  - ✖When Federal, State, Tribal, local requirements require local review
    - ✖ Tribal regulations/policies given specific consideration in order to ensure that the importance of their role is recognized
  - ✖Time-limited Exception – ancillary studies to ongoing parent studies without single IRB
  - ✖*Other Exceptions* may be considered:
    - ✖ When there is a compelling justification

Do not require NIH approval

Require NIH approval

CHOOSING the BEST sIRB

IRB models that would meet the policy:

1. Existing IRB can agree to serve as sIRB
   - Awardee or participating site
2. Independent/Unaffiliated IRB
3. Central IRB organized to review specific projects

Single IRB of record does not have to be the IRB of the parent award.

It is the best IRB for the study.

NOTE: sIRB must be registered with OHRP and must have membership to adequately review the proposed study

- Participating sites should work together ahead of time to determine the best IRB for the study
- Make sure that reliance agreements are in place and up to date
- May include working with local IRBs to determine the best IRB, gather relevant local context and policies

SINGLE IRB PLAN

Budget as if no *Compelling justification exception*

- Name of the sIRB of record
- Indicate that:
  - All sites, including any added after award, agree to rely on sIRB
  - Sites will sign reliance agreement that will include a communication plan
  - Indicate who will maintain records of this agreement
- Exceptions
  - **Policy-based exceptions** - legal or regulatory: provide specific citation and indicate which sites are impacted
  - **Time-limited exceptions**, provide parent study information
  - **Compelling Justification exceptions,** identify sites and provide justification

If delayed onset, in justification include statement that awardee will follow the policy and will provide sIRB info prior to start

sIRB COSTS

- Policy allows, but does not require, sIRB costs to be direct charged.
- sIRB costs may be charged direct if:
  - Institution can differentiate the costs that are charged direct vs. indirect.
  - Cost incurred for the same purpose in like circumstances are treated consistently as either direct or indirect
- It is an institutional responsibility to determine if sIRB costs are appropriately classified as direct or indirect.
- Since cost principles remain unchanged, if using sIRB prior to the January 25, 2018 implementation date, applicants may choose to include sIRB costs in their direct cost budget.

CHALLENGES

- **Infrastructure/Technologies**
  - Capacity to facilitate tracking and sharing of sIRB related documents across multiple sites
- **Negotiation of Reliance/Authorization Agreements**
  - Willingness to use a Master Agreement
  - Ability to clearly define roles and responsibilities of sIRB and local IRBs
- **Budget Development Challenges**
  - Cost considerations vary across studies

SOLUTIONS

Reliance Agreements

- **Clinical Trials Transformation Initiative (CTTI)**
- **SMART IRB**

sIRB IMPLEMENTATION RESOURCES

- Policy Web Page: https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm
- Guide Notices: OD-16-094, OD-17-076, OD-16-109 (costs), OD-18-003, OD-18-004
- OSP Webpage: https://osp.od.nih.gov/clinical-research/irb-review/
  - Implementation FAQs: https://osp.od.nih.gov/clinical-research/implementation-of-the-sirb-policy/
  - Cost FAQs: https://osp.od.nih.gov/clinical-research/nih-policy-on-the-use-of-a-single-irb-for-multi-site-research-faqs-on-costs/
- OER Webinars: https://grants.nih.gov/news/virtual-learning/upcoming_webinars.htm
- Mailboxes
  - SingleIRBpolicy@mail.nih.gov
  - GrantsCompliance@nih.gov
- SMART IRB: https://smartirb.org/
- SMART IRB Exchange: https://trialinnovationnetwork.org/home-page/smart-irb-exchange/
- Clinical Trials Transformation Initiative (CTTI): https://www.ctti-clinicaltrials.org/projects/central-irb