Research involving Human Participants
Quality Critical at Every Point

FOA

Review

Award

Dissemination of Results

IRB

Grant Application

Protocol

Required Elements

Single IRB Policy

Better Health
Published in NIH Guide and Federal Register: June 21, 2016


Effective Dates

- Competing grant applications
  Receipt dates on/after May 25, 2017

- Contract proposals
  Solicitations issued on/after May 25, 2017

- NIH Intramural research
  Multi-site studies submitted for initial review on/after May 25, 2017
Draft Policy proposed exceptions:

- when designated single IRB is unable to meet the needs of specific populations, or
- where local IRB review is required by federal, tribal, or state laws or regulations
Comments on Draft sIRB Policy

- Most commenters agreed that there was a need to allow for exceptions to the uses of a single IRB. There were a number of comments calling for additional exceptions to those proposed in the policy.

- Tribal Nation commenters pointed to the importance of firsthand knowledge of local tribal customs, cultural values, and tribal sensitivities and supported exceptions to address those needs and also as a way of respecting tribal sovereignty.
Comments from Tribal Communities

- **Indian Health Service (IHS) National Institutional Review Board**
  - All research with human participants conducted in IHS facilities or with IHS staff or resources must be approved by an IHS IRB.
  - IHS IRB review ensures consideration of local political, social, cultural, and spiritual issues.
  - Prevents misunderstandings and avoids “helicopter research.”
  - Request for an exemption from the NIH policy for studies conducted with the jurisdiction of American Indian/Alaska Native tribes.

- **Cherokee Nation**
  - A single IRB cannot adequately represent the unique needs and interests of the Cherokee Nation and other Native peoples.
  - Tribal IRB reviews
    - “preserve tribal sovereignty and the rights of its citizens.”
    - prevent irresponsible interpretation or publication of research data.
  - Supports the exemption in the draft policy.
Other commenters said that the policy should allow for situational exceptions related to:

- Types and complexity of studies and study teams,
- Types and numbers of involved institutions,
- IRBs’ experience reviewing a particular type of research, or
- if relying on the single IRB would affect an institutional IRB’s accreditation status.
Final Provisions of NIH sIRB Policy

- Consistent with provisions in Common Rule NPRM
- Applies to domestic sites of multi-site non-exempt studies
  - All sites conducting the same protocol
- Exclusions:
  - Foreign sites
  - Career development (K), institutional training (T), and fellowship awards (F)
  - When there are Federal, State, Tribal, requirements for local review
    - Tribal regulations/policies mentioned specifically in order to ensure that the importance of their role is recognized
- Exceptions may be considered:
  - May be requested when there is a compelling justification
NIH sIRB Policy – Implementation

- Implementation Efforts
  - Implementation guidance (e.g., FAQs, Roles & Responsibilities)
  - Language for Funding Opportunity Announcements
  - Language for Notices of Award
  - Training for the Extramural Research Community
  - Exceptions process
  - Policy evaluation criteria and metrics

- NIH Guidance on Use of Direct and Indirect Costs
  NOT-OD-16-109

- Model Reliance Agreement
  - NCATS SMART IRB Reliance Platform
Resources

- Mailbox for questions: SingleIRBPolicy@mail.nih.gov