

# NIH Single IRB Policy

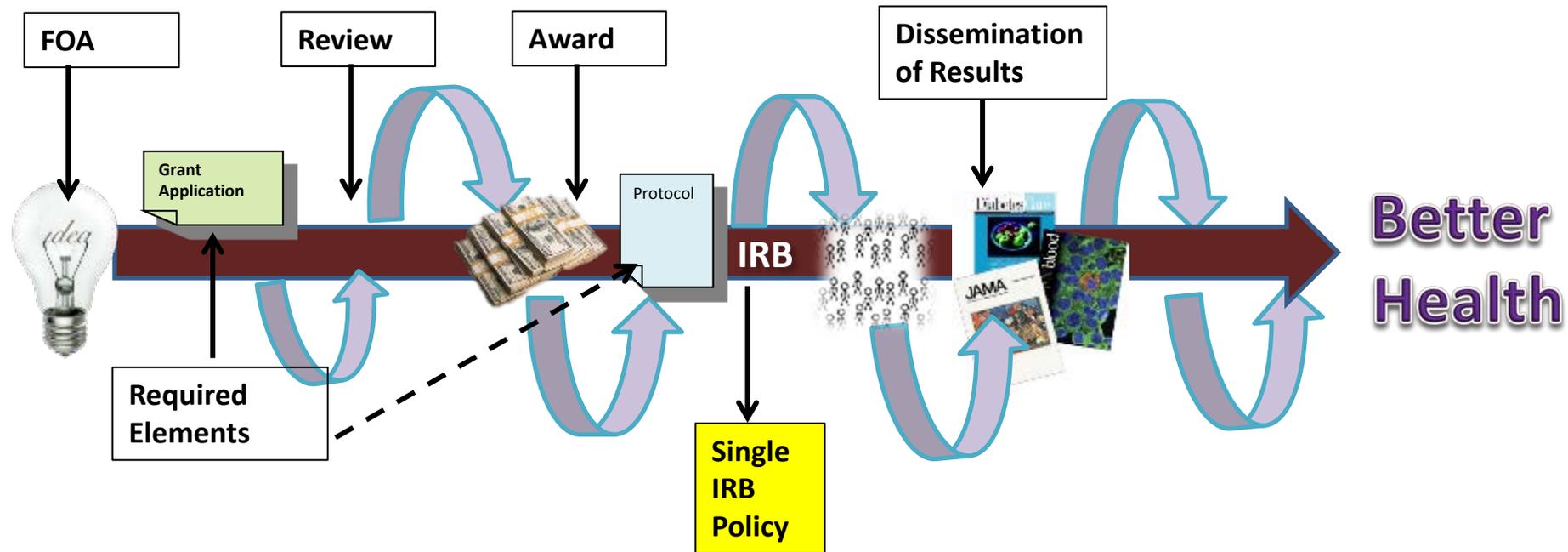
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# Research involving Human Participants

## Quality Critical at Every Point



# NIH Single IRB Policy

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

- <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html>
- <https://www.federalregister.gov/articles/2016/06/21/2016-14513/final-nih-policy-on-the-use-of-a-single-institutional-review-board-for-multi-site-research>

## 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 sIRB Policy

- 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.

# Additional comments on Draft sIRB 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](mailto:SingleIRBPolicy@mail.nih.gov)
- Webpage for links to resources: <http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/models-irb-review>