NIH Single IRB of Record (sIRB)

IRB MEMBER TRAINING SEPTEMBER 2016

Historical Perspective of Reliance Agreements

- In past: reluctance to rely
  - Reliance generally limited to affiliated institutions, programmatic relationships, specific one-offs
- Last 5-10 years: expansion of reliance arrangements, including broader scope of protocols and greater number and geographical diversity of sites
  - Prompted by CTSAs, NIH/other funding environment
- Now: NIH Policy and proposed Common Rule mandate for single IRBs further expand reliance and bring new requirements and challenges

Current and Future Landscape

- Many new relationships, including large-scale, multi-protocol, “master” agreements
- Participants may:
  - be very geographically diverse
  - include sites of different types (public/private, institutions/MD groups/health centers, large/small), as well as independent IRBs
  - shift roles and alternately rely on another IRB or provide IRB review
- Participants may need to enter multiple such arrangements -- “single IRB” is from the perspective of a study, not a site

New NIH Single IRB Policy

- In December 2014, NIH released a draft of the new single IRB policy for feedback
  - Collected feedback for two months
  - Evaluated common themes and concerns
  - Results: about 70% in favor, with still numerable comments on how to approve or adjust the policy
- NIH published the final version of this policy on June 21st of this year
- Policy goes into effect on May 25, 2017

Scope of the Policy

- *Who does the policy apply to?*
  - U.S. NIH-funded studies that involve non-exempt research on human subjects at multiple sites
  - Note: career/training/fellowship grants don't apply, but other grants and NIH contracts do
- *What will it look like?*
  - Study teams must include their plan for single IRB review at the time of application (including communication plans, identification of the IRB of record, and confirmation from all sites that they will comply with the IRB of record's policies)
  - If awarded, NIH approval of the proposal for single IRB use will appear as a term and condition in the Notice of Award or Contract Award letter
- *Can I get an exception?*
  - Only if either (1) IRB of record policy prohibited by local law; or (2) there's a particularly compelling reason
  - Exceptions need to be submitted for NIH review

Outline of the NIH Single IRB Policy

At Time of Application

Study team has to list who will be IRB of record (in other words, have to use single-IRB to get funding)

Clear plan needs to be proposed about how IRB of record and local sites will communicate

Application must include documentation affirming that local sites will follow the IRB of Record's policies

Study team may request additional funding support to cover selected IRB's review

After Awarded

Study Team: Responsible for making sure all IAAs organized and communication means established; if necessary, study team may delegate to others the required actions involved in both of these responsibilities

Sponsor: Responsible for oversight of funds and resolving issues in original plan for collaboration; also must assist study team with complying with the IRB of record's policy

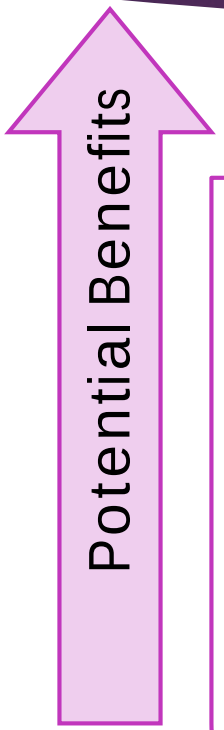
During Study

IRB of Record: Conduct review, fulfill all regulatory requirements, and help study team with communication plan

Relying Sites: Meet other regulatory requirements (e.g. getting consent, report unanticipated problems) but NIH will not pay for local review

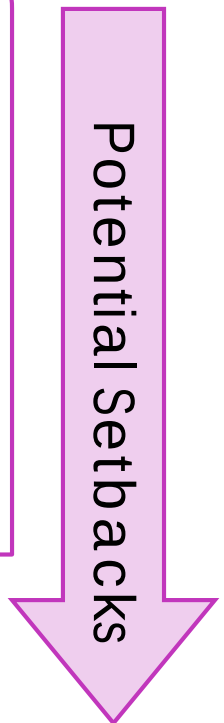
Study Team: Continue to facilitate communication plans and uphold all policy as outlined by IRB of record; coordinate information and reports from all sites

Topics to Consider Moving Forward



- Reduced administrative burden and increased efficiency overall
- Possible boost in recruitment
- Conduct reviews where information regarding all sites is readily available
- Clearer definition of responsibilities for both IRB of Record and local IRBs

- No financial infrastructure included in policy
- How to obtain knowledge of unique local site vulnerabilities
- Potentially vast differences across IAA negotiations (especially given broad nature of policy)
- Alignment with Common Rule



Debates to Watch: Are local IRBs in a unique position to protect local subjects?

NO:
Central IRBs have the knowledge they need

Institutions and recruited subjects, especially in a globalized world, are not immensely different from each other

Any differences that do arise can simply be communicated and outlined in the communication plan

YES:
Local IRBs play a crucial role that needs to be factored in

Local IRBs know the potential vulnerabilities of their communities best

Local IRBs are aware of potential conflicts and investigator issues in a way that an external IRB cannot be

Debates to Watch: How does splitting the IRB doing review from the IRB potentially penalizing investigators work for compliance?

WELL:
IRBs can focus on their core purpose

IRBs' functions have expanded over the years, and focusing on just human protections centers the IRB on its true role

IRBs of record have a better view of how study teams' compliance factors in with the rest of the arms of the study

Compliance and review are inextricably linked and shouldn't be separated from each other

Local IRBs know the histories of site investigators better than external IRBs

NOT WELL:
Compliance and review need to stay together

Potential Issue to Consider

- Conflicts of Interest Reporting and what is shared among institutions
- HIPAA (Serving as the Privacy Board)
- Requirement for competing renewals
  - Studies that are up and running are expected to shift to the sIRB model with their competing renewal requests
- Appropriate charges for sIRB costs (direct vs. indirect costs)

Required Prior to Effective Date of Policy (May 25, 2017)

- Standardized template letter from IRB willing to serve as sIRB to report that the IRB meets the criteria and any special circumstances that need to be considered
- Standardized budget form for additional sIRB resources
- Develop SOPs for execution of reliance agreements for reference
- Develop “best practices” guidance for researchers
- Consider additional personnel needed to function in the “facilitator” role to align communications between sIRB and relying IRBs