SMART TALK

A Community Forum to Explore Issues Surrounding Single IRB Review

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number 3UL1TR002541-04S2.

What Is SMART Talk?

An approximately monthly forum with:

- Presentations on topics relevant for single IRB review
- Q&A on topic presented as well as questions submitted when

Open and free to anyone with interest

Upcoming sessions

July: Single IRB Resources for Reviewing IRBs, Relying Institutions and Study Teams

FYIs

Please provide feedback by completing the survey. A link will be posted in chat and emailed.

A recording of this talk will be posted on the SMART IRB website

A link to the talk will be sent to those who registered for the talk when it is posted

If you have any questions for the panelists, please use the chat function or Q&A function to submit them

SMART IRB Updates

Harmonization Steering Committee Recommendations

- Post-Approval Auditing for Studies Subject to Single IRB Review NEW!
- Single IRB Continuing Review Process
- Single IRB Review: Responsibilities Associated with the Review of Study Personnel
- Reportable Events
- Institutional Profile
- Protocol-specific Document
- Fees and Costing Models under NIH sIRB Policy
- Institution v. IRB Responsibilities Guidance
- Under review –
  - Ancillary Review
  - Conflict of Interest

Meet Our Newest SMART IRB Ambassadors

Lubabah Helwani
UCLA

Carissa Minder
Washington University in St Louis

Meet Our Newest Team Members

Jonathan Green
SMART IRB Program Director,
Strategic Initiatives

Mike Linke
SMART IRB Program Director,
Education

Reviewing IRBs: Working with Relying Institutions and Study Teams

Jenni Beadles, Vanderbilt University
Janelle Maddox-Regis, Johns Hopkins University

Moderator: Nichelle Cobb

SMART Talk
Reviewing IRBs: Working with Relying Institutions & Study Teams

Janelle Maddox-Regis, MS, CIP

Associate Director, IRB Reliance Program

Johns Hopkins Medicine IRB

Jenni Beadles, MEd, CIP

Assistant Director External Partners

Vanderbilt Human Research Protections Program

Moderator: Nichelle Cobb, PhD, Senior Advisor for SMART IRB and Senior Advisor for Strategic Initiatives for AAHRPP

Presenters

Janelle Maddox-Regis, MS, CIP

Associate Director, IRB Reliance Program

Johns Hopkins Medicine IRB

Jenni Beadles, MEd, CIP

Assistant Director External Partners

Vanderbilt Human Research Protections Program

Johns Hopkins sIRB Experience & Key Decisions

- sIRB studies = **103**
  - Participating sites up to **56**
- External IRB studies [including NCI CIRB] = **506**
- Where Johns Hopkins sIRB services are needed, only JHM IRB will serve as the sIRB.
  - JH has three separate IRBs [JHM, Public Health, Homewood Schools]
  - Only JHM IRB is accredited
- Mandatory Use of Online Reliance Request Tool:
  - Investigators may not indicate in a grant application that JH is willing to serve as the sIRB without securing a letter of support + estimated budget for sIRB review.

Johns Hopkins sIRB Experience & Key Decisions

- JHM IRB routinely serves as the sIRB for other academic institutions, hospitals and medical centers and small community practices.

- JHM IRB uses the SMART IRB Master Reliance Agreement as the basis of all reliance relationships, where feasible.

- JHM IRB does **not** offer sIRB services to international sites ***or*** studies where a Johns Hopkins organization is not engaged in human subjects research [*TIN studies are an exception*].

Single IRB at Vanderbilt

- Reviewing IRB for ~120 studies (studies range from 1-72 relying sites)
  - Require a Vanderbilt Reliance Interest Form (REDCap survey) to formally request Vanderbilt serve as the Single IRB
  - Require Single IRB Training for Lead Investigator and Study Coordinator
  - Require SMART IRB agreement whenever possible
  - Require Letter of Indemnification pursuant to SMART IRB agreement
  - Require use of IRB Reliance Exchange (IREx) for documentation of reliance, communication, local considerations, and document sharing
  - Require 2-part ICD format
- Relying Institution for ~400 studies (includes NCI CIRB)
  - Require SMART IRB agreement whenever possible
- One of three Single IRB for the Trial Innovation Network (TIN): Vanderbilt, Johns Hopkins, and Utah
- Do not offer Single IRB services to international sites, VA sites, or studies where Vanderbilt is not engaged in human subjects research [TIN studies are an exception].
- 4 IRBs: 3 biomedical and 1 social behavioral
- Staff: 4 analyst support teams (1 per committee); compliance/PAM team

Vanderbilt is an AAHRPP-accredited HRPP

Single IRB at Vanderbilt

- **Question 1:** Is the study currently supported or will it be supported by a federal agency that is a signatory to the Common Rule?
- **Question 2**: Is the study a multisite study? *["multisite" is defined as two or more sites].*
- **Question 3:** Did the study receive funding after **January 25, 2018** *[the effective date of the NIH Single IRB mandate]* or final IRB approval on or after **January 20, 2020?** *[the effective date of the Common Rule's Single IRB requirement]*

Note: *If yes to all of these questions, the study likely requires Single IRB review. Vanderbilt will only cede review or serve as the single IRB for federally funded, non-exempt, multi-site research studies.*

Panelist questions: Serving as a Reviewing IRB

Reliance Agreements and FWAs

- Why do you generally require the SMART IRB agreement?
- What kind of push back have you received related to requiring the SMART IRB and how have you addressed it?
- What do you do when institutions are not signed on to SMART IRB and/or do not have a Federalwide Assurance (FWA)?
- What assistance and guidance do you provide for these institutions?

Engaged vs Not Engaged in research

- As you know, if an institution is not engaged in human subjects research, an IRB is not required to oversee that organization's activities. Can you give some examples of times when your institutions did not view another institution as engaged in human subjects research, but the other site insisted on a reliance agreement, and how you worked through these situations?

Local Context and HIPAA

- What are some of the most challenging local context issues you have encountered? Which areas has your institution offered flexibility and which areas are you unable to be flexible?
- One of the biggest challenges we've seen is around HIPAA authorizations and language. Who reviews? Whose language to use?

Expedited Review

- Have you served as the Reviewing IRB for social behavioral studies that aren't clinical trials?
- Research that could qualify for expedited review?
- If so, what are the differences you see as serving as a Reviewing IRB for those studies vs. biomedical clinical trials?

Communication and Training

- How does your institution handle requests to serve as the Reviewing IRB for multi-site studies?
- Does the institution consider whether sIRB is required?
- What are the best details for a reviewing IRB to ensure are clear with a relying site during a study start up discussion?

Communication and Training (cont.)

- What communication model do your IRBs use when working with study teams. For example, some IRBs work with each relying site study team directly, whereas others go through a lead study team that acts like a coordinating center.
  - How has this communication model influenced how you work with study teams?
  - What do you see as your role as the Reviewing IRB in working with study teams from relying institutions?
  - Is it best practice to directly communicate approvals/etc. to the site PIs and IRB office, or rely on your PI to do this?
  - What are institutions requiring from lead study teams in the IRB submission - study management plans, communication plans, etc.
  - Who should reach out first - the relying IRB staff or the reviewing IRB staff?

Communication and Training (cont.)

- Has the expansion of single IRB requirement from the NIH policy to the revised Common Rule had an impact on your training and education approaches for study teams?
- What are common points of confusion for either lead study teams or relying site study teams?
- How do you provide Reviewing IRB policies to relying site study teams and what policies do you provide?
- How can we set up study teams for single IRB success?
- What is the most important information for study teams to know that are new to single IRB?

General

- How has serving as a reviewing IRB affected your IRB review processes?
- How many staff do you have dedicated to Single IRB responsibilities and what are they?
- If someone approached you for advice on whether their organization should serve as a reviewing IRB, what would you encourage them to consider in making this decision?
- What are the expected approval timeframes under a reliance agreement?
- If an institution does not have an IRB, where would you recommend they establish an IRB of Record and search for External IRB?
- Have you transitioned existing non-sIRB protocols to sIRB?

Thank you!

Discussion & questions

Save the date for the next SMART Talk
July 21, 2021
2:00-3:30 pm ET

Single IRB Resources for Reviewing IRBs, Relying Institutions and Study Teams

Questions?
Contact
help@smartirb.org

Register at smartirb.org

Sign up for our mailing list to be notified of future offerings