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 3UL1TR002541-01S1.

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

April: Harmonization Working Group Recommendations on Conflicts of Interest

May: No SMART Talk – AAHRPP virtual conference

June: Reviewing IRBs: Working with 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 Harmonization Working Group: Recommendations for Harmonization of Ancillary Reviews

Other Harmonization Steering Committee Recommendations

- **Single IRB Continuing Review Process** NEW!
- **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 –**
  - **Post-Approval Auditing for Studies Subject to Single IRB Review**

Ancillary Reviews Group Membership

- John Baumann (Indiana U)
- Judy Birk (Michigan)
- Nichelle Cobb (Wisconsin – Madison) – *Co-Leader*
- Valery Gordon (NCATS)
- Kathy Lawry (AAHRPP)
- Mike Linke (U of Cincinnati)
- Helen Panageas (NYU Langone)
- Ada Sue Selwitz (Kentucky)
- Ivana Simic (U of FL) – *Co-Leader*
- Jeanne Velders (Wash U – St Louis)

Best Practice Opportunities

Address variations in the definition of ancillary reviews

Identify reviews that are relevant to sIRB review

Centralization of certain ancillary reviews for multi-site studies

Timing of ancillary review requirements, particularly in relation to IRB review

Assign ancillary review responsibilities to Reviewing IRBs, Relying Institutions, and study teams

What Was Out of Bounds

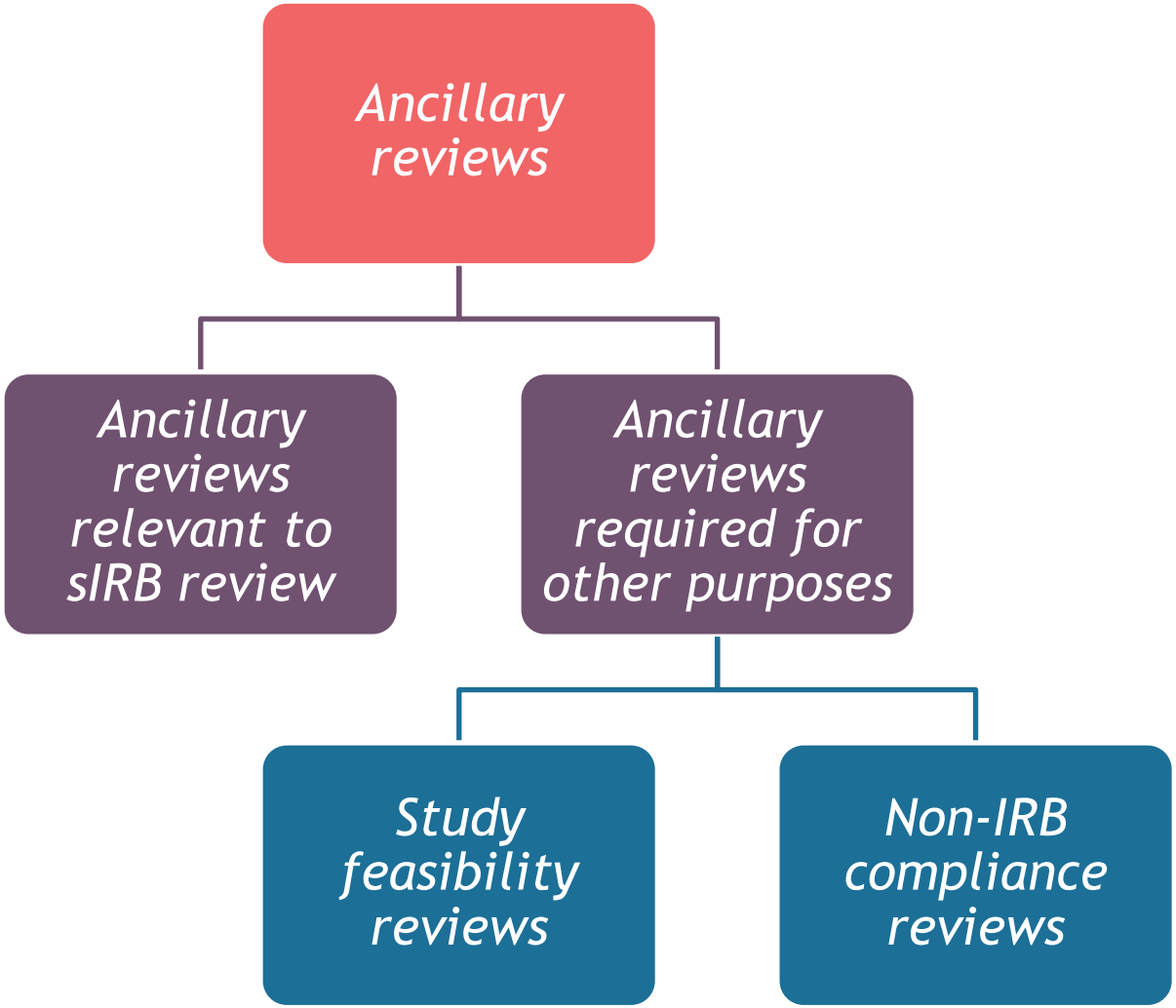
The Working Group did not make recommendations about which ancillary reviews an institution may require for human subjects research.

Examples of how ancillary reviews can affect the efficiency of sIRB review and delay study activation

- Withholding permission for study teams to rely on an sIRB until all institutionally required ancillary reviews are completed, even when they are not relevant to IRB review
- Having inflexible electronic systems that require completion of all ancillary reviews before IRB review
- Ancillary review committees that meet infrequently
- Conducting ancillary reviews that duplicate study-wide assessments

Definitions

Definitions



Ancillary reviews

Reviews that include signs-offs or approvals that are in addition to IRB approval of human subjects research and are required by institutional or funding entity policy(ies) or by regulation, statute, or law.

- Ancillary reviews vary in whether they may occur before, during, or after IRB review, but most must be completed before site activation.

Ancillary reviews relevant to sIRB review

Evaluations to ensure compliance with institutional, state and federal requirements that may have an impact on an sIRB's review and approval of a relying site, including any site-specific changes in study materials, such as informed consent or recruitment documents.

- Ancillary reviews relevant to sIRB review should be provided to the reviewing IRB before IRB review of that site occurs.
- Some ancillary reviews relevant to sIRB review continue to be required after IRB approval of the site.

Ancillary reviews required for other purposes

Evaluations to ensure compliance with institutional or funding entity policies, or by regulation, statute or law that do not have an impact on sIRB review and approval of a relying site nor affect content of study materials (e.g., as informed consent or recruitment documents).

- Some ancillary reviews required for other purposes must be completed before a ceding request is submitted and before the sIRB's review of a site or before study activation (e.g., sign off from a State agency to comply with State law), while others must be monitored throughout the life of the study.

What Ancillary Reviews Are Not…

They are not information

- A reviewing IRB can collect via its submission system; or
- Reliance points of contact (POCs) at relying institutions can confirm based on their authority to interpret institutional policies or apply institutionally agreed upon language (e.g., permitted injury compensation language wording)

Centralization of Ancillary Reviews

Can Some Ancillary Reviews Be Centralized?

Considerations

If it's good enough for IRBs, could be good for other review processes

Can be documented through written agreements

Distribute review components between central and local assessments

Examples

Institutional Biosafety Committee (IBC)

- Central review: assess for compliance with NIH guidelines
- Local review: assess environmental health & safety issues

Radiation Safety

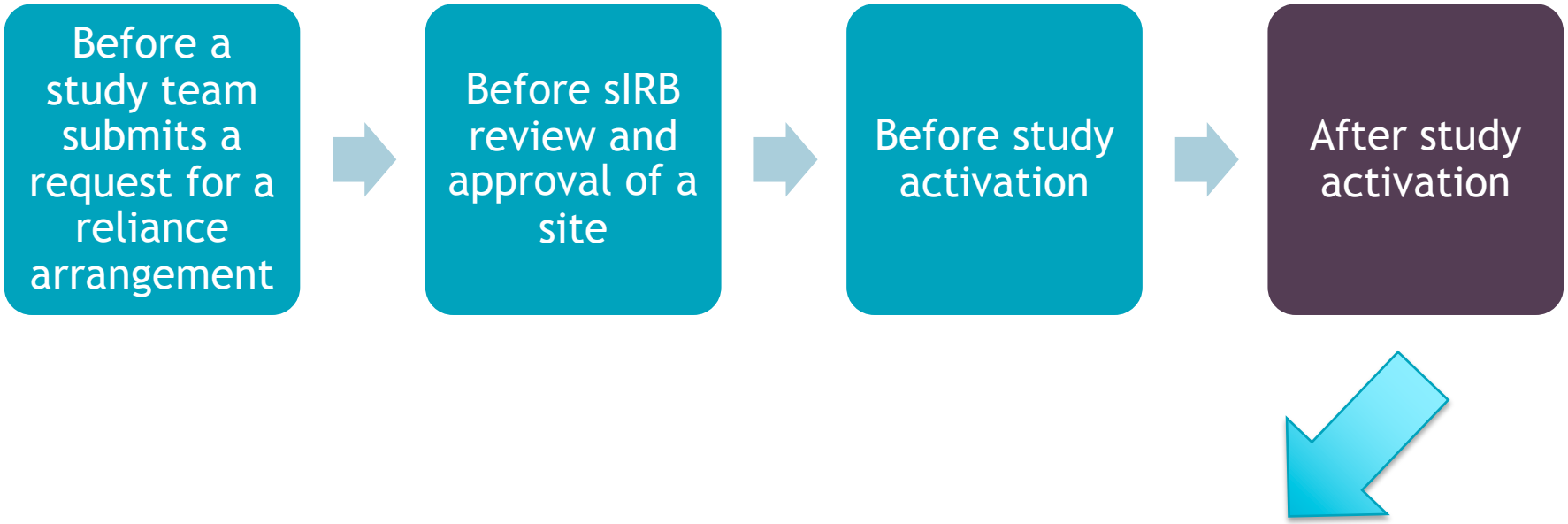
- Central review: radiation risks, consent form language (taking into account potential variations across sites)
- Local review: implementation at the institution, personnel training, facilities and equipment, State laws

Ancillary Review Timing

Ancillary Reviews Mapped to Study Life Cycle

Before a study team submits a request for a reliance arrangement	• Reviews assessing if a study be performed at the institution (e.g., feasibility)
Before sIRB review and approval of a site	• Reviews that could affect IRB assessment of study team, site, site documents (e.g., COI)
Before study activation	• Reviews that do not affect IRB review but must be completed before a study can start (e.g., contract reviews)
After study activation	• Reviews that can only be completed after a study starts (e.g., clinical trial registration) OR triggered by a change or event

Ancillary Reviews Triggered After Initial Approval



Determine if local ancillary review is needed and if that outcome must be reported back to the sIRB

Examples

HIPAA-Related Events

Local ancillary review: HIPAA assessment

Inform sIRB: new information that affects informed consent document or breach requires communication to participants

Personnel Changes

Local ancillary review: Confirm licensing and qualifications; assess COI

Inform sIRB: if COI related to the ceded research study

Responsibilities Related to Ancillary Reviews

Reviewing IRB

Communicate what ancillary review information should be provided to them, how this information is communicated, and when the information should be provided

Identify any specific ancillary reviews they expect to be conducted before they review a site

Only require the completion of ancillary reviews relevant to their assessment of that site

Obtain an attestation from relying institutions that any ancillary reviews that could affect their review of a site or their site's materials have been completed (as opposed to asking relying institutions to identify the specific ancillary reviews they require)

Relying Institution

Identify the ancillary reviews they require, when these reviews must be completed in regard to the key study life cycle timepoints identified above, when types or studies or study procedures the reviews apply to, the appropriate contacts for those reviews, and the review process (e.g., whether specific forms are required and how the review is initiated).

Identify the entities responsible for ensuring which ancillary reviews are completed, especially when they may be responsible for ancillary review compliance at different timepoints

Relying institution reliance POCs, as opposed site study teams, should communicate the outcomes of relevant ancillary reviews to the sIRB as part of the local context considerations

Create guidance for and educate study teams about ancillary reviews that are required for research studies in addition to IRB review

Relying Institution (continued)

If ancillary reviews are identified by or routed through an electronic system, build flexibility into those processes so that reviews relevant to sIRB processes can be separated from those that must be completed before study activation or later that are not relevant to IRB considerations

Ensure processes are in place to identify when changes in research or updates in study personnel that occur after IRB approval should initiate ancillary reviews and to provide ancillary review determinations relevant to IRB review to the reviewing IRB

Ensure ancillary reviews occur in a timely manner and use flexible review processes when permitted

When an ancillary review has been performed in support of the study as a whole, as opposed to for a specific site, rely on those reviews when possible to eliminate duplicative effort or only conduct the component(s) of the review relevant to that site

Lead Study Team Responsibilities

Assisting Relying Site Study Teams in understanding the potential need for the completion of institution-specific ancillary reviews before their site is reviewed by the sIRB

If responsible for preparing the IRB application for the site, ensuring all relevant ancillary reviews have been completed that would affect the sIRB review of the site application

Ensuring the correct person has provided confirmation to the sIRB that relevant ancillary reviews have been completed

Relying Site Study Team

Identifying the ancillary reviews relevant to their research at their institution

Modifying study template documents and other research materials (e.g., informed consent or other study materials) to reflect the outcomes reflected of ancillary reviews

Providing the outcomes of the ancillary reviews to their institutional reliance POC if the outcome of the review is not available to them otherwise (e.g., via an electronic system)

Ensuring ancillary reviews are completed by the appropriate timepoint of the study life cycle (e.g., before IRB review or before study activation)

Identifying events that occur during a study or amendments that could trigger local ancillary reviews and consulting with personnel responsible for those reviews, as appropriate

Discussion & questions

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

Harmonization Working Group Recommendations on Conflicts of Interest

Questions?
Contact
help@smartirb.org

Register at smartirb.org

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