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 participants register

Open and free to anyone with interest

Upcoming sessions

October: No SMART Talk

November: A Conversation with the FDA and OHRP about Single IRB

December: No SMART Talk → PRIM&R Annual Conference

January 2023: Everything You Wanted to Know About Single IRB but Were Afraid to Ask, Part Deux

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

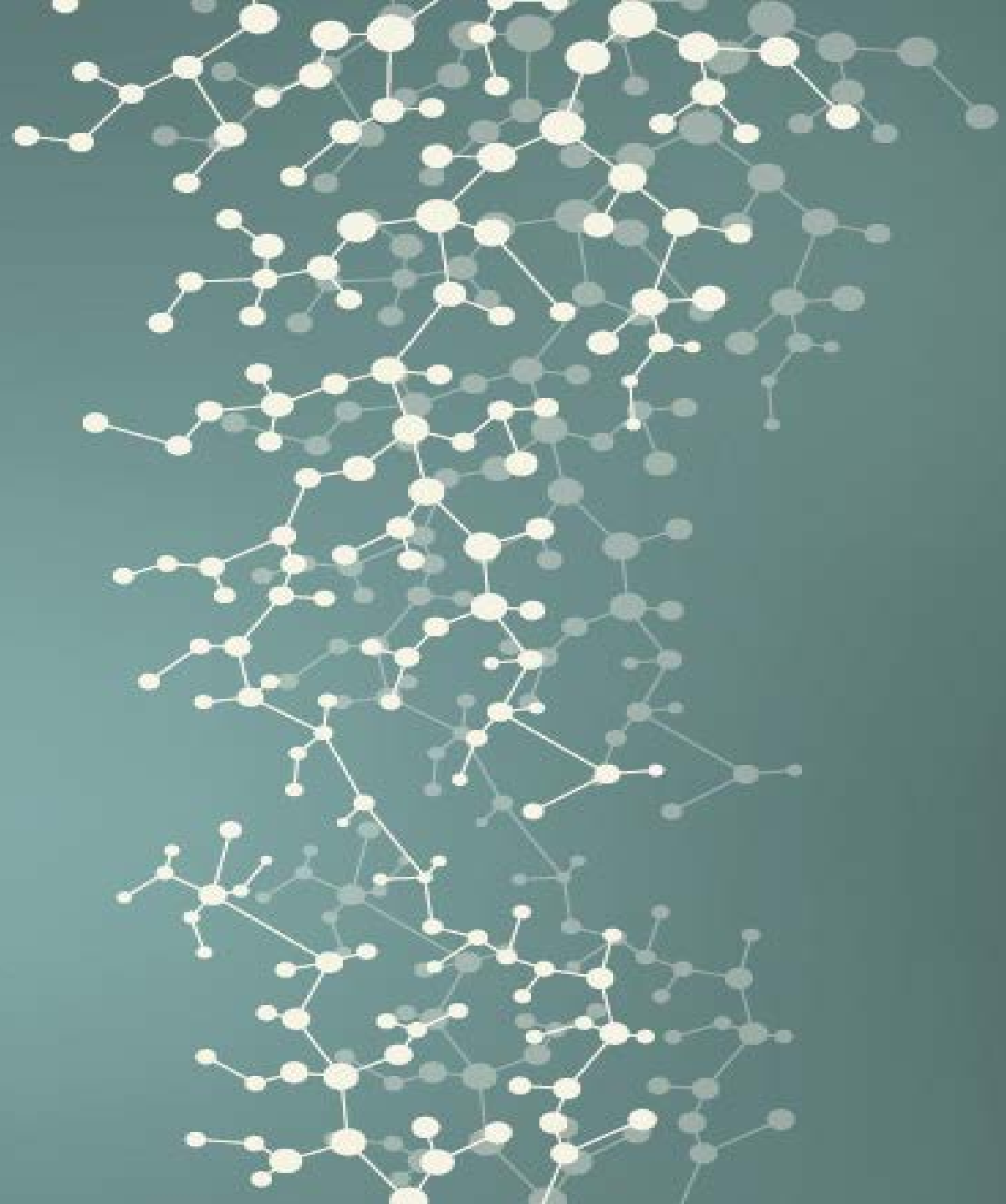
Harmonization Steering Committee Recommendations
https://smartirb.org/harmonization/

- Ancillary Review
- Conflict of Interest
- Post-Approval Auditing for Studies Subject to Single IRB Review
- 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

In progress:
Local considerations recommendations

What the SMART IRB Agreement Says About Noncompliance:

Responsibilities of the Reviewing IRB(s) and Reviewing IRB Institution(s)



Review potential noncompliance

- Reviews of potential noncompliance with applicable human subjects protection regulations or with the requirements or determinations of the Reviewing IRB

Notifications of any findings of serious and/or continuing noncompliance

- **Who gets notified:** Overall PI, Site Investigator(s), and Relying Institution(s)
- **What prompts notification:** Any findings of serious and/or continuing noncompliance with applicable human subjects protection regulations or with the requirements or determinations of the Reviewing IRB, or of apparent serious and/or continuing noncompliance with such regulations or requirements, pertaining to the Relying Institution or its Research Personnel
- **What is included in the notification:** Any actions taken (including any suspension or termination of IRB approval of the Research) and the steps the Reviewing IRB deems necessary for remediation of the noncompliance at the Relying Institution.
- **Which sites are notified:** The Reviewing IRB will also notify the Overall PI, Site Investigator(s), and Relying Institution(s) of any suspension or termination of IRB approval and any remediation actions pertaining to findings of serious and/or continuing noncompliance at any other institution if such finding or actions relate to or may affect the conduct of the Research or the safety, rights, or welfare of human subjects participating in the Research at the Relying Institution(s).

Other Implications of Noncompliance

- If the Reviewing IRB determines that the facts of a noncompliance matter…raise issues apart from or in addition to noncompliance with human subjects protection requirements (such as a potential allegation of research misconduct), the Reviewing IRB shall notify and refer those issues to the Relying Institution for review. Any of the notifications required in this section may be made through the Reviewing IRB's designee, as determined by the Participating Institutions in connection with the specific Research.

Reporting to Federal Agencies or Departments

- Notify a Relying Institution in advance if it determines that under applicable regulations or under the terms of the Relying Institution's FWA a report is required to a regulatory agency (e.g., OHRP, FDA), sponsor, funding agency, and/or other oversight authority of any unanticipated problems involving risks to human subjects or others, serious and/or continuing noncompliance with applicable human subjects protection regulations or with the requirements or determinations of the Reviewing IRB, and/or any suspensions or terminations of IRB approval.

Follow Up

- Promptly notify the Relying Institution(s) of any communications regarding unanticipated problems, suspension or termination of IRB approval, serious and/or continuing noncompliance, or other regulatory compliance concerns regarding the Research received from the FDA, OHRP, and/or other regulatory agencies.

What the SMART IRB Agreement Says About Noncompliance:

Responsibilities of the Relying Institution(s)

Notification

- Promptly notify the Reviewing IRB of any potential noncompliance with applicable human subjects protection regulations or with the requirements or determinations of the Reviewing IRB in connection with the Research at the Relying Institution, and of any suspension or restriction by the Relying Institution or any third parties of any of its Research Personnel's authority to conduct the Research.

Comments on Reports to External Parties

- Promptly provide any comments on any draft report to external parties that will be made by the Reviewing IRB/Reviewing IRB Institution
- If the Reviewing IRB/Reviewing IRB Institution requests that the Relying Institution make the report, the Relying Institution will promptly prepare the draft report and provide the Reviewing IRB/Reviewing IRB Institution with the opportunity (no fewer than five (5) business days, whenever possible) to review and comment on the draft report, after which time the Relying Institution may finalize and send the report to external recipients.
- If the Relying Institution elects to make its own additional report, it will provide a copy of such report to the Reviewing IRB/Reviewing IRB Institution.

Follow Up

- The Relying Institution will also promptly notify the Reviewing IRB/Reviewing IRB Institution of communications received by the Relying Institution or between the Relying Institution and FDA, OHRP, and/or other regulatory agencies, regarding unanticipated problems, noncompliance, or other compliance concerns regarding the Research, and will require the Overall PI and Site Investigator(s) to do the same with respect to such communications between the Overall PI or Site Investigator(s) and such agencies.

Single IRB and Noncompliance - A Case Study

Panelists:

- **Carissa Minder, Associate Director, Human Research Protection Office, Washington University in St. Louis**
- **Andrea Morris, Assistant Director, Education, Human Research Affairs, Compliance & Education Office, Mass General Brigham**
- **Kim Summers, Assistant Vice President for Research, University of Texas Health San Antonio**

Moderator: Nichelle Cobb, Senior Advisor for SMART IRB and Senior Advisor for Strategic Initiatives for the Association for the Accreditation of Human Research Protection Programs (AAHRPP)

Save the date for the next
SMART Talk
November 16, 2022
2:00-3:30 pm ET

A Conversation with the FDA and OHRP about Single IRB

Questions?
Contact
help@smartirb.org

Register at
smartirb.org

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