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: Single IRB for Social, Behavioral, and Education Research

November: break for PRIM&R AER 2021 meeting

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
- 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

Close to being posted!

Using AAHRPP's I-9 Standard to Guide Reliance Arrangements

-Robert Hood, AAHRPP
-Ivy Tillman & Tiffany Coleman, Augusta University
-Hallie Kassan, Northwell Health

Moderator: Nichelle Cobb

SMART Talk
September 15, 2021

Standard I-9: Single IRB Review

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Association for the Accreditation of Human Research Protection Programs, Inc.®

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Overview

- Introduction to AAHRPP Standards
- Q: How did AAHRPP develop Standard I.9 (“Single IRB review”)?
  - First new Standard adopted since the *Evaluation Instrument* was revised in 2009
- Q: What is required by Standard I-9
- Q: Does using the SMART IRB Agreement address most or all the I-9 standard?
  - Yes
  - But AAHRPP does not require SMART IRB

Introduction: AAHRPP accreditation

- Goal is to improve the systems that protect the rights and welfare of individuals who participate in research
- Accredit the entire HRPP
- Evaluate organizations in three areas:
  - Domain I: Organizational responsibilities (for example, control of drugs and devices, review of conflicts of interest)
  - Domain II: IRB or EC review
  - Domain III: Researchers
- Each *Domain* is divided into *Standards* and *Elements*

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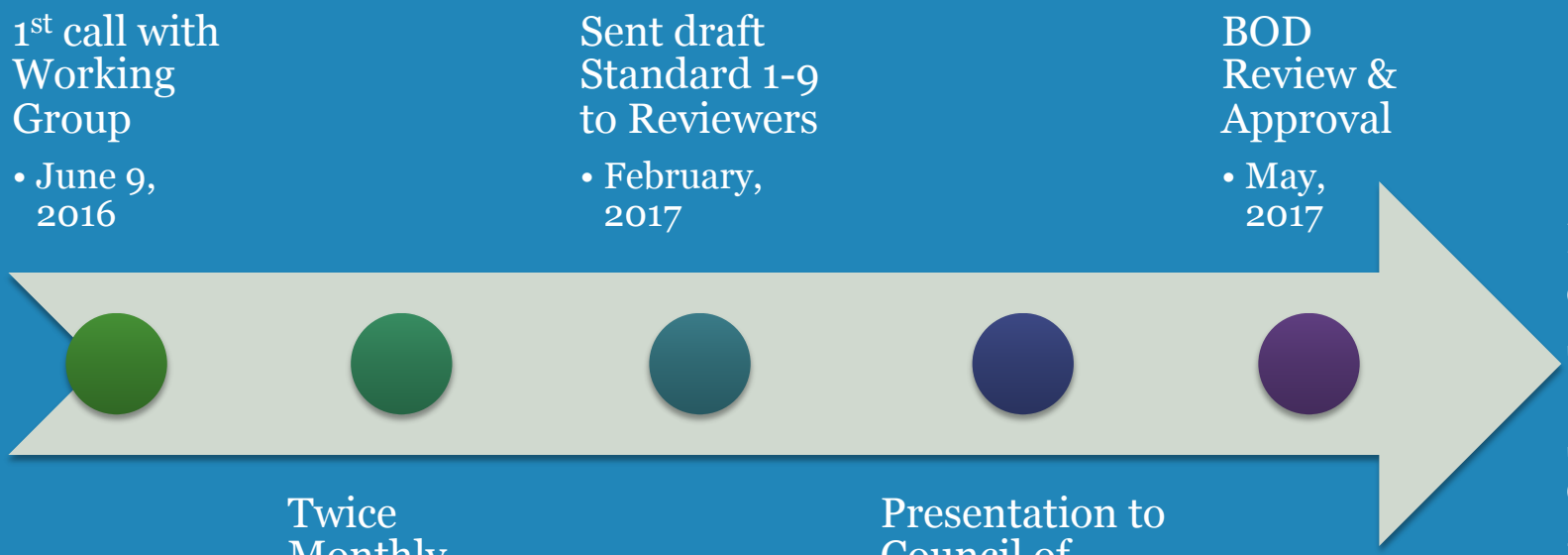
Requests for Information for Working Group

- Working Group created in 2016
  - Independent IRBs, academic health centers, hospitals, research networks
- Should AAHRPP describe responsibilities throughout the *Evaluation Instrument*, or consolidate requirements?
- What responsibilities are new, what responsibilities extend existing AAHRPP requirements?
- What goes in the Standard
  - Outcomes and essential requirements
- What goes in the Tip Sheet
  - Recommendations about best practice, operational issues

Single IRB Review Working Group Timeline



AAHRPP IRB Working Group Members

Co-Chairs:	Michelle Feige, MSW, LCSW-C AAHRPP Executive Vice President	Megan Kasimatis Singleton, J.D., M.B.E., C.I.P Assistant Dean for Human Research Protection and Director of HRPP Johns Hopkins University School of Medicine
Rebecca Ballard, J.D., M.A., C.I.P. Director for the Office of Research Integrity MedStar Health Research Institute	**Michele Russell-Einhorn, J.D.** SACHRP Working Group on Single IRBs; Vice President of Human Research Protection Services Schulman IRB	**Kathy Lawry, M.S.S.A., C.I.P.** SMART IRB Ambassador for CTSA/NCATS SMART IRB Senior AAHRPP Consultant
Lauri Carlile, M.S., C.I.P. Executive Director Chesapeake IRB	**Martha Jones, M.A., C.I.P.** AAHRPP Council Member; CTSA Clinical Trials Task Force Executive Director, Human Research Protection Office Washington University in St. Louis	**Michael Linke, Ph.D., C.I.P.** Chair, NIH StrokeNet CIRB Health Science Officer Department of Veterans Affairs Medical Center-Cincinnati
Nichelle Cobb, Ph.D. Chief Regulatory Operations Officer for Implementation, SMART IRB Director, Health Sciences Institutional Review Boards Office University of Wisconsin-Madison	**Nancy Klunder, B.S., C.H.C., C.P.C., NREMT-I** Director of Compliance & HIPAA Regional Health	**Ada Sue Selwitz, M.A.** Member of SACHRP Subcommittee on Subpart A; Smart IRB Ambassador for CTSA funded institutions Executive Integrity/Compliance Advisor University of Kentucky

AAHRPP IRB Working Group Outside Peer Reviewers/Readers: Suggested by Working Group

Barbara Bierer Faculty Co-Director & Co-Chair, MRCT Executive Committee Professor of Medicine, Harvard Medical School	**Susan Z. Kornetsky, MPH** Senior Director of Clinical Research Compliance Boston Children's Hospital
Jeremy Corsmo, MPH, CIP Co-Director, Regulatory Knowledge and Support Director, Office of Research Compliance and Regulatory Affairs (ORCRA) CCHMC	**Todd W. Rice, MD, MSc** Associate Professor of Medicine Division of Allergy, Pulmonary, and Critical Care Medicine Vanderbilt University School of Medicine
Tammi Gausepohl, MHA, CIP Office of Research Integrity University of Kentucky	**Rachael Sak, BSN, MPH** Director UC BRAID
Cami Gearhart, JD CEO of Quorum Review	

STANDARD I-9

The organization has written policies and procedures to ensure that, when sharing oversight of research with another organization, the rights and welfare of research participants are protected.

STANDARD I-9

STANDARD I-9 **The organization has written policies and procedures to ensure that, when sharing oversight of research with another organization, the rights and welfare of research participants are protected.**

COMMENTARY

An organization may rely on IRB or EC review, or other services, such as those of the contracting office or conflict of interest committee, of another organization to supplement its resources. Relying upon the services of one or more other organizations can facilitate research and increase the efficiency and cost-effectiveness of review.

There are multiple models of how organizations work together to share resources: reliance agreements, such as with an independent IRB or EC; reliance upon a central IRB or EC; reliance upon a lead IRB or EC; participating in a group of organizations that form a joint IRB or EC; assuming the role of a reviewing IRB or EC; or some combination of options. The options may be used for review of a single study or for review of all research, and organizations may decide to implement multiple options rather than having to select only one model. Regardless of the approach, the roles and responsibilities of each organization must be described in a written agreement.

If an organization relies on the services of another organization, policies and procedures must describe the steps followed to ensure that the review service, protects the rights and welfare of participants. Unless explicitly ceded to the reviewing IRB or EC, the organization retains the organization's responsibilities defined in Domain I, such as control of investigational drugs.

Relying upon an AAHRPP-accredited IRB or EC ensures the reviewing IRB or EC meets accreditation standards. If the organization relies upon a non-accredited IRB or EC, it should ensure the IRB or EC provides appropriate human participant protections, given the risks of the research.

Some services may be provided by either the relying organization or the reviewing IRB or EC; policies and procedures or a written agreement must define shared responsibilities. AAHRPP strongly supports the notion that resources devoted to the evaluation and management of research – whether internally or externally reviewed – should be calibrated appropriately according to the risks posed by the research. This extends to the content, assessment, and implementation of reliance agreements that the written policies and procedures required under this standard are designed to address. Standards and Elements cited below highlight areas where existing policies may need to be revised to address single IRB or EC review. Requirements listed below describe requirements for IRB or EC review; however, similar considerations exist concerning other shared services.

See AAHRPP Tip Sheet 24

REGULATORY AND GUIDANCE REFERENCES

- **DHHS**: 45 CFR 46.103(b)(2), 45 CFR 46.103(d), 45 CFR 46.109(d), 45 CFR 46.114
- **FDA**: 21 CFR 56.109(e), 21 CFR 56.114, FDA Information Sheet: Non-Local IRB Review, and Information Sheet: Cooperative Research
- **NIH**: Policy on the Use of a Single Institutional Review Board for Multi-Site Research (June 20, 2016)
- **ICH-GCP**: 4.2.3

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REQUIRED WRITTEN MATERIALS

(1) Essential requirements for IRB or EC review:

(a) For AAHRPP-accredited HRPPs that provide IRB or EC review services to other entities, the relied upon organization must have policies and procedures that describe the roles of the reviewing IRB or EC, including:

(i) Ensuring the structure and composition of the IRB or EC is appropriate to the research reviewed and complies with applicable laws. This includes ensuring the IRB or EC is properly constituted; members are appropriately qualified; that members do not participate in the review of [illegible] have a conflict of interest [illegible] policy to separate business [illegible] review services. (Standard II.1)

(ii) Conducting review of research to determine that research is ethically justifiable, according to all applicable regulations and laws, including initial review, continuing review, and review of modifications to previously approved research. (Standards II.2, II.3, and II.4)

(iii) Conducting review of the addition of investigative sites to previously approved protocols. The IRB or EC may decide to review these additions as separate protocols or as modifications to previously approved research, and they may decide to handle such modifications using the expedited procedure rather than the convened IRB or EC for review. When the expedited procedure is used, the IRB or EC must specify the criteria for when the addition of an investigative site is considered to be a minor modification. (Element II.2.F.)

(iv) Ensuring the IRB or EC has the final authority to decide whether researcher or research staff conflict of interest and its management, if any, allows the research to be approved. (Element I.6.B.)

(v) Reviewing unanticipated problems involving risks to participants or others. (Element II.2.G.)

(vi) Suspending or terminating IRB or EC approval. (Element II.2.H.)

(vii) Notifying the researcher, and if applicable the organization, of its decisions, consistent with any reliance agreement. (Element II.2.E.)

(viii) Making available relevant IRB or EC records, including but not limited to minutes, approved protocols, consent documents, and other records that document the IRB's or EC's determinations to the relying organization upon request. (Element II.5.A.)

(ix) Having authority to request an audit of research being reviewed. (Element I.5.A.)

(x) Making relevant IRB or EC policies readily available to the relying organization, including HRPP staff, and researchers and research staff, and having a mechanism for communicating to the organization when policies are updated, as appropriate. (Element I.1.D.)

(xi) Specifying the contact person and providing contact information for the reviewing IRB or EC for researchers and research staff to obtain answers to questions, express concerns, and convey suggestions regarding the IRB or EC. (Element I.5.C.)

(b) For AAHRPP-accredited HRPPs that rely on another organization's IRB or EC, the relying organization's policies and procedures must describe the roles of the organization and researchers when relying upon another organization's IRB or EC, including:

(i) Specifying which studies are eligible for review by another organization's IRB or EC, and describing the mechanism for making the determination. (Element I.1.A.)

(ii) Ensuring, through education or other support, that researchers understand which activities are eligible for review by another IRB or EC. (Element III.1.A.)

(iii) Ensuring that researchers are knowledgeable about the need to obtain any approvals from their own organization prior to seeking review by another IRB or EC, and that researchers know when to seek guidance. (Element III.1.A.)

(iv) Complying with the determinations and requirements of the reviewing IRB or EC. (Element III.2.C.)

(v) Providing the reviewing IRB or EC with requested information about local requirements or local research context issues relevant to the IRB's or EC's determination, prior to IRB or EC review.

(vi) Notifying the reviewing IRB or EC when local policies that impact IRB or EC review are updated. (Element I.1.D.)

(vii) Ensuring that officials of the relying organization may not approve the research subject to the reliance agreement if it has not been approved by the reviewing IRB or EC. (Element I.1.C.)

(viii) Acknowledging that researchers must cooperate in the reviewing IRB's or EC's responsibility for initial and continuing review, record keeping, and reporting, and that all information requested by the reviewing IRB or EC must be provided in a timely manner. (Element II.2.D.)

(ix) Requiring researchers and research staff disclose conflicts of interest according to the process

REQUIRED WRITTEN MATERIALS

agreed upon betwe[illegible] reviewing IRB or EC[illegible] of interest management plans that may res[illegible] (Element III.1.B.)

(x) Reporting promptly to the reviewing IRB or EC any proposed changes to the research. The investigator cannot implement changes to the research (including changes in the consent document) without prior IRB or EC review and approval, except where necessary to eliminate apparent immediate hazards to the participants. (Element III.2.C.)

(xi) Ensuring researchers will not enroll participants in research prior to review and approval by the reviewing IRB or EC, and meeting all other applicable requirements and approvals for the study. (Element III.1.E.)

(xii) Ensuring that researchers, when responsible for enrolling participants, will obtain, document, and maintain records of consent for each participant or each participant's legally authorized representative. (Element III.1.F.)

(xiii) Reporting promptly to the reviewing IRB or EC any unanticipated problems involving risks to participants or others according to the requirements specified in the reliance agreement. (Element III.2.D.)

(xiv) Ensuring researchers provide to the reviewing IRB or EC data safety monitoring reports they receive, according to the IRB's or EC's reporting policy. (Element III.2.D.)

(xv) Ensuring reporting of non-compliance, pa[illegible]pant complaints, protoc[illegible] according to the re[illegible] liance agreement. [illegible] and III.2.D.)

(xvi) Conducting monitoring in addition to, or in cooperation with, the reviewing IRB or EC, when appropriate. (Element I.5.D.)

(xvii) Specifying the contact person and providing contact information for researchers and research staff to obtain answers to questions, express concerns, and convey suggestions regarding the use of the reviewing IRB or EC. (Element I.5.C.)

(xviii) Ensuring researchers and research staff have appropriate qualifications and expertise to conduct the research, are knowledgeable about laws, regulations, codes and guidance governing their research, and are knowledgeable about the organization's policies and procedures. (Element III.2.A.)

(c) When there is a reliance relationship for IRB or EC review, a written agreement or policies and procedures must describe whether the organization conducting the IRB or EC review, or the relying organization, is responsible for the following:

(i) Providing education to researchers and research staff. (Element I.1.E.)

(ii) Conducting scientific review. (Element I.1.F.)

(iii) Reviewing potential non-compliance, including complaints, protocol deviations, and results of audits:

(iv) Identifying which organization is responsible for deciding whether each allegation of non-compliance has a basis in fact.

(v) Identifying which organization's process is used to decide whether each incident of non-compliance is serious or continuing. (Element I.5.D.)

(vi) Obtaining management plans for researcher and research staff conflicts of interest. If the relying organization maintains responsibility for this issue, the management plan must be provided to the IRB or EC in a timely manner prior to the decision by the IRB or EC. (Element I.6.B.)

(vii) Managing organizational conflict of interest related to the research. (Element I.6.A.)

(viii) Ensuring that, should termination of a reliance agreement occur, one of the parties clearly is responsible for continued oversight of active studies until closure or a mutually agreed upon transfer of the studies.

(2) When following DHHS and FDA regulations, policies and procedures or a written agreement must define the responsibilities of the relying organization and reviewing IRB or EC, including but not limited to:

(a) Determining whether the relying organization applies its FWA to some or all research, and ensuring the IRB or EC review is consistent with requirements in the relying organization's FWA.

(b) Determining which organization is responsible for obtaining any additional approvals from DHHS when the research involves pregnant women, fetuses, and neonates; or children; or prisoners.

(c) Determining which organization is responsible for reporting serious or continuing non-compliance; unanticipated problems involving risks to participants or others; and suspensions or terminations of IRB or EC approval. Reporting may be done by the reviewing IRB or EC, the relying organization, or jointly, but must be clearly defined in policies or a written agreement.

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Topics addressed in Standard I.9

- Essential requirements:
  - IRB review services for other organizations - Section I(a)
  - Relying on another organization's IRB - Section I(b)
  - Flexibility – tasks that can be done by either organization (per study or in general) - Section I(c)
  - Research is covered by DHHS regulations or NIH policy on single IRB review - Section (2)
  - Working with non-accredited organizations - Section (3)
  - Ancillary reviews - Section (4)

Responsibilities when reviewing for another organization

Written materials should address - Section I(a):

- Process for leadership of reviewing organization to decide scope of service
- Reviewing IRB or EC - responsible for all requirements in Domain II; and parts of Domain I: I.1.D. (audits); I.5.D. (non-compliance); I.5.C. (contact person); I.6.B. (conflict of interest)
- Process for adding research sites
- Review of non-compliance, unanticipated problems, suspensions, terminations
- Reporting to regulatory agencies

Responsibilities when relying on another organization

Written materials should address – Section I(b):

- Process for leadership of relying organization to decide what research is eligible, which external organizations can be relied upon for IRB review, who conducts ancillary reviews
- Relying organization - retains responsibilities for all Domain I requirements, unless explicitly ceded in written agreement
- Relying organization - retains responsibilities for Domain III requirements for researchers
  - Education about use of external IRB or EC
  - Other Domain III responsibilities

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Responsibilities that can be assigned to either organization

- Written materials (memorandum of understanding) - should define who is responsible for – Section (1)(c)
  - I.1.E. (education)
  - I.5.D. (non-compliance)
  - I.6.A. and I.6.B. (conflict of interest)
  - Ancillary reviews (biosafety, radiation safety, scientific review) – relevance to IRB review
- Key concept: communication

Additional federal requirements – Section

- DHHS and FDA – Section (2)
  - Why does AAHRPP include FWA:
    - Applying FWA to covered research vs applying FWA to all research
    - Additional approvals for vulnerable populations
    - Reporting to regulatory agencies
- NIH policy
  - Describes requirements

Responsibilities when relying on non-accredited IRB (Section (3)

- Calibrate oversight of non-accredited IRBs or ECs in proportion to the risks in the research - Section (3)
- Different degrees of oversight based on different types of research
  - Examples: Minimal risk unfunded research vs federally-funded research vs clinical research vs investigator-initiated phase I clinical trials
- Expectation that organizations should be flexible

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Additional ancillary reviews

- Need to coordinate additional ancillary reviews, local context – Section (4)
  - Relationship to IRB - IRB must determine criteria for approval are met - risks are minimized, risks are reasonable, appropriate plans for safety monitoring, etc.
    - Scientific review (when not done by IRB)
    - Biosafety, radiation safety, recombinant DNA, stem cell research
    - Conflict of interest review (when not done by IRB)
  - Responsibilities defined in MOU

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Applying SMART IRB

- SMART IRB meets AAHRPP requirements
- SMART IRB is not required
- If organization applies other agreements to some research, then policies need to address Standard I-9
- (3) When relying upon an IRB or EC that is not AAHRPP-accredited, policies and procedures must also define:
  - (a) The process ensuring research is being reviewed appropriately and complies with applicable law and regulations.
  - (b) Criteria describing the extent of the review to confirm compliance with the organization's ethical standards and with applicable law and regulations. The extent of the review of the non-accredited IRB or EC can vary, depending upon the level of risk to participants in the research.

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Questions

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BRUNSWICK


Dental College of Georgia

Collaborations

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

Phoebe

UNIVERSITY OF GEORGIA

Considerations

- AAHRPP Accreditation
- Assessment
- Evaluation
- Available Resources

Unique Features

RELIANCE TEAM REVIEW

ANCILLARY REVIEW ASSESSMENT

STUDY START-UP COMPLIANCE MEETINGS

MONITORING AND OVERSIGHT

Northwell Health Background

- Health System located in the NY metropolitan area
- 23 hospitals
- Over 650 Ambulatory Care Practices
- About 2900 active clinical research studies
- 1 Research Institute

History of Reliance

- Began serving as a reviewing IRB in 2010
- Began relying on other IRBs in early 2000's

Discussion & questions

Save the date for the next SMART Talk
October 20, 2021
2:00-3:30 pm ET

Single IRB for Social, Behavioral, and Education Research

Register at smartirb.org

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

Questions?
Contact
help@smartirb.org