MONTHLY IRB-INVESTIGATOR MEETING - RELIANCE

Columbia University
Human Research Protection Office

August 19, 2021

COLUMBIA | COLUMBIA UNIVERSITY IRVING MEDICAL CENTER

Agenda

- Terminology
- Reliance Scenarios
- Requirements for single IRB review
- NIH Single IRB Review Policy
- Cooperative Research (Common Rule)
- Reliance agreements
- Reliance process - basics

Terminology

- Reliance: Ceding of responsibility for IRB review
- Reviewing IRB: In a reliance situation, the IRB that is responsible for conducting the review
- Single IRB (sIRB): A Reviewing IRB that conducts the review for participating sites of a multisite study
- Central IRB (cIRB): A Reviewing IRB that conducts the review of all studies for all sites in a consortium/network
- Relying Institution: In a reliance situation, the institution that cedes responsibility for IRB review to an external IRB
- SMART IRB: a platform designed to ease common challenges associated with multisite research; NOT an IRB

Word of caution

- Reliance by CU on another IRB means that the external IRB is required to assess and document satisfaction of IRB criteria for approval (45 CFR 46.111; 21 CFR 56.111)
- CU administrative review is required to address local requirements:
  - COI, JRSC, IBC, PRMC reviews
  - Training Requirements
  - Local policies, ethical concerns

Rascal submission is ALWAYS required

Common Reliance Scenarios

- sIRB Review required for federally funded research
  - NIH sIRB Review Policy
  - DHHS requirements for cooperative research
- sIRB required by sponsor, lead institution, consortium
- sIRB or cIRB requested by sponsor, lead institution, consortium

- CU may be the Relying Institution
- CU may be the Reviewing IRB

NIH Single IRB Review Policy for Multi-site Research

- Effective date: January 25, 2018
- Requires sIRB review for:
  - 2 or more domestic sites
  - Conducting the same protocol
  - Non-exempt research
  - Minimal risk (usually expedited review) or > minimal risk (convened review)
- Very few exceptions
  - Designated single IRB of record is unable to meet the needs of specific populations
  - Local IRB review is required by federal, tribal, or state laws or regulations
  - Compelling reason
- Policy: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html

Requirements for grant submission

- Notify HRPO
  - Complete reliance request form
  - HRPO assesses applicability of policy
  - HRPO provides letter of support
- If policy applies
  - sIRB plan (no longer required in submission)
  - Propose which IRB will serve as sIRB
  - Estimate of IRB review fees
- In most cases, when CU is applicant, rely on independent IRB to serve as sIRB
  - Provides estimate

NIH sIRB Review Policy – Quick Reference:

- NIH funded or supported
- Competing grant applications (new, renewal, revision, or resubmission)
- Receipt date on or after January 25, 2018
- Non-exempt research
- Conducted at U.S. domestic sites
- Multi-site research

Common Rule "2018 Requirements"

- Published January 2017, amended January 2018, effective July 2018 for optional implementation of 3 provisions
- Compliance date for most elements = January 21, 2019
  - Informed consent requirements (e.g., key information)
  - Elimination of continuing review for certain research
  - Requirement to post consent forms for certain research
- Compliance date for single IRB review = January 20, 2020
- 20 agencies (including HHS) intend to follow the revised Common Rule (Subpart A of 45 CFR 46)
  - FDA is not considered a Common Rule agency because its regulations differ from the Common Rule.

List of Common Rule Departments and Agencies:

	DEPT. OR AGENCY	CFR CITATION (2018 REQUIREMENTS)
1	Department of Homeland Security	6 CFR Part 46
2	Department of Agriculture	7 CFR Part 1c
3	Department of Energy	10 CFR Part 745
4	National Aeronautics and Space Administration	14 CFR Part 1230
5	Department of Commerce	15 CFR Part 27
6	Social Security Administration	20 CFR Part 431
7	Agency for International Development	22 CFR Part 225
8	Department of Housing and Urban Development	24 CFR Part 60
9	Department of Justice	28 CFR Part 46
10	Department of Labor	29 CFR Part 21
11	Department of Defense	32 CFR Part 219
12	Department of Education	34 CFR Part 97
13	Department of Veterans Affairs	38 CFR Part 16
14	Environmental Protection Agency	40 CFR Part 26
15	Department of Health and Human Services	45 CFR Part 46
16	National Science Foundation	45 CFR Part 690
17	Department of Transportation	49 CFR Part 11
18	Office of the Director of National Intelligence	Follows CR because of EO 12333, as amended
19	Central Intelligence Agency	Follows CR because of EO 12333, as amended
20	Consumer Product Safety Commission	16 CFR Part 1028

sIRB Requirement

- "Cooperative Research"
  - *"… are those projects covered by this policy that involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy."* 45 CFR 46.114(a)
- IRB to be designated by the funding agency
  - *"Any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research."* 45 CFR 46.114(b)

Exceptions

- 45 CFR 46.114(b)(2)
  - *(i) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or*
  - *(ii) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.*

NIH Policy vs Common Rule sIRB requirements

- NIH is an agency of the Department of Health and Human Services (DHHS)
- The Common Rule is a DHHS regulation
- Therefore, in most cases, the DHHS/Common Rule requirement for sIRB review, which is broader in scope ("cooperative research"), supersedes the requirements of the NIH sIRB Review Policy ("sites conducting the same protocol")

Summary of federal sIRB requirements

- January 25, 2018 – NIH Policy for sIRB Review for Multisite research

- January 21, 2019 – Compliance date for most Common Rule provisions (“2018 Requirements”)

- January 20, 2020 – Compliance date for sIRB review requirement for federally funded* multisite research

  **Funded by a Common Rule agency*

Other reliance situations

- Another institution asks to rely on CU for regulatory review or asks CU to rely on their IRB for regulatory review
  - Requires a reliance agreement; the OHRP template IRB Authorization Agreement (IAA) is frequently used

- An investigator is not affiliated with an institution that has an IRB or is not participating in research under their home institution's affiliation
  - Requires an Individual Authorization Agreement (IIA), which extends Columbia's IRB scope to include that individual

Reliance Agreements

- Reliance Agreement: A document that articulates the terms under which one institution will rely on the IRB review of an external IRB
- IRB Authorization Agreement (IAA): A template Reliance Agreement developed by OHRP
- Individual Investigator Agreement (IIA): A reliance agreement through which an institution agrees to provide IRB review for one individual for one or more studies
- SMART IRB Master Reliance Agreement: A Reliance Agreement through which institutions can cede review to others that have signed a Joinder

Multi-study reliance agreements

- cIRB situations, e.g.:
  - StrokeNet (Univ of Cincinnati=sIRB)
  - Perinatal Research Consortium (PRC) (CU=sIRB)
  - NeuroNext (Partners=sIRB)
- Frequent collaborations, e.g.:
  - NYSPI
  - Weill Cornell
- Service agreement w/independent IRB, e.g., WIRB

Reliance Process

- Submit a reliance request form to the IRB:

  Addresses:

  - Collaborating sites
  - Research at each site
  - Funding
- Submit as soon as potential reliance is recognized
  - During preparation of grant application if multisite
  - Prior to submission of a protocol that proposes reliance
  - When a collaborator suggests single IRB review

Reliance Process - 2

- HRPO will review and determine whether we will rely on another IRB for regulatory review or serve as the Reviewing IRB
- Negotiate and execute appropriate agreement (if one does not exist)
  - Signature by Institutional Officials
  - This can take a while!

All Reliance scenarios require a submission in Rascal!

Reliance Process - 3

- Submit protocol in Rascal
- Identify local context and local requirements
  - Provided by Relying Institution to Reviewing IRB
    - If CU is relying, HRPO will fill out the Reviewing IRB's form or, if one is not provided, provide our own
    - If CU is reviewing, each Relying Institution must provide a local context/requirements form and the CU IRB must consider the local context and requirements for each site
- Study procedures can start, for Columbia research, when the protocol has an Approval status in Rascal

Questions?

Human Research Protection Office

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