Welcome to our November METS

- Please make sure your microphones are muted
- There will be a Q&A session after this presentation
  - Please reserve your questions until then
  OR
  - Put any/all questions in the chat and we will address them after the presentation
- This session may be recorded
Overview

- Introduction
- sIRB Background
- Establishing an sIRB Reliance
- sIRB Submission Processes
- Questions
sIRB: An Introduction
What is a **Single IRB (sIRB)**?

A **Single IRB** is the reviewing IRB (IRB of Record), selected on a study-by-study basis, which provides the ethical and regulatory review for all relying sites participating in a multi-site/multi-center study.
What is a Reliance Agreement?

A reliance agreement is a legal document establishing the ability for one IRB (the “Relying IRB”) to cede review to another IRB (the “IRB of Record”)

The two scenarios are:

• WCM (Relying IRB) may cede review to an external IRB (IRB of Record)

• External IRB (Relying IRB) may cede review to WCM (IRB of Record)

WCM is not the IRB of record

WCM is the IRB of record
What is an Individual Investigator Agreement?

Individual Investigator Agreement (IIA): an agreement between WCM and an individual collaborator who is unaffiliated with WCM and is not covered under a Federalwide Assurance (FWA)*.

Common scenarios:

- Researcher leaves WCM but wishes to continue their research and did not move to a new institution with an FWA
- Researcher who is part of a clinic/institution which does not have an FWA but will conduct human subject research as part of a WCM study

*FWA: an agreement with the federal government through which the institution commits to follow the laws governing human subjects research.
How do I Establish a sIRB Reliance?

Submit an IRB Reliance Request Form in Qualtrics

- Study Title
- WCM and Lead PI names
- Funding source: e.g., Federal, Institutional, Industry
- Protocol activities at WCM and sites

Note: At WCM the same reliance request form is used for requesting either an academic IRB or a commercial IRB.
sIRB Background
sIRB Regulations (2 separate mandates)

NIH sIRB Policy applies to (1/25/2018):

• NIH-sponsored multi-site studies, where the same protocol is used at multiple sites
• Domestic research only
• Non-exempt research only

Revised Common Rule sIRB Policy applies to (1/20/2020):

• Cooperative non-exempt studies (receiving initial IRB approval on or after 1/20/2020)
• Domestic research only
• Institutions need not performing the same research activities
Exceptions to use sIRB

- Exempt research
- International sites
- Studies conducted under career development research training or fellowship awards (rec’d IRB approval before 1/20/2020)
- Prohibited by a Federal, Tribal or State law, Regulation or Policy
- Exception requests made to NIH [compelling justification required]
Use of Reliance

Use of a single IRB reliance requires documentation confirming reliance from the IRBs (or equivalent office) at all participating sites.

Reliance on a single IRB typically occurs with:

- Multicenter, federally-funded research which require use of a single IRB
- Industry-sponsored clinical trials
- Multicenter studies with NYP and CTSC partner institutions.
Decision Tree

Is this a multi-site study?

Yes

Does your study meet one of the exemption criteria?

Yes

IRB reliance not allowed. WCM IRB review and approval required

No

IRB Reliance Required

Yes

IRB reliance not applicable. WCM IRB determination of exemption required

No

IRB Reliance upon request; please contact sIRB@med.cornell.edu

Is your study federally-sponsored?

No

Is your study Industry or Consortium sponsored?

Yes

IRB Reliance recommended or required

No
Establishing Reliance
Requesting sIRB Review

- WCM and External IRBs will collect and review basic information about the planned collaboration
- Initiate an IRB Reliance Request via the WCM Qualtrics Portal.
- Any questions contact the WCM Reliance Team at singleIRB@med.cornell.edu
IRB Reliance Request Form

https://weillcornell.az1.qualtrics.com/jfe/form/SV_9sQ5rUvSSFd7abH
Reliance Documentation

- WCM PI or designee responsibilities:
  - Complete the Reliance Request form
  - Obtain WCM reliance agreement memo
  - WCM Reliance Team will provide next steps prior to study submission to WCM IRB
  - Scientific review by PRMC or CTSC is required.
  - Ancillary Committee Reviews- COI review, Biosafety (IBC), Radiation Safety- if applicable

- Any questions or status updates please contact the WCM Reliance Team at singleIRB@med.cornell.edu
Existing Institutional Agreements

WCM IRB has executed master reliance agreements

• Cornell U-Ithaca
• NYP-BMH
• NYP-Queens
• Columbia University
• MSKCC

Existing Commercial IRBs

• Biomedical Research Alliance of New York (BRANY) IRB
• Advarra IRB
• WCG IRB (formerly Western IRB)

Always contact WCM to discuss reliance, email: singleIRB@med.cornell.edu
SMART IRB
Streamlined, Multi-site, Accelerated Resources for Trials

- Is NOT an IRB
- An online system to facilitate reliance agreements
- WCM is a member of SMART IRB

For multi-site studies that are federal funded and do not have a master agreement in place, the SMART IRB Acknowledgement Memo may be used or a request can be made via the SMART IRB platform.
sIRB Submissions
When WCM is the IRB of Record (Reviewing IRB)

Case-by-case basis:

- Only with institutions with existing reliance agreements
- WCM IRB has determined that the study is non-exempt research
- Submit a Reliance Request Form to establish reliance
- Submit an amendment submission in WRG to add external site/investigator(s)
When using an External IRB as the Reviewing IRB

**The External IRB must approve the following:**
- Approve the research which includes WCM as a site
- ICF document(s)- if applicable
- Other research documents typically requiring IRB review

**After approval is received from External IRB (IRB of Record):**
- Submit a Non-WCM IRB submission in WRG for local context review
- WCM training and COI
- PRMC, radiation safety, biosafety, etc.

**Additional agreements may be needed:**
- Data Use Agreement (DUA) or Clinical Trial Agreement (CTA), reach out to JCTO for the given collaboration
When using an External IRB as the Reviewing IRB: A Workflow

1. Obtain reliance agreement and complete any local context form(s)/questionnaires requested by External IRB
2. Submit a Non-WCM Review and Approval (Central IRB or Single IRB) application in WRG*
3. Complete WCM training, COI and any Ancillary Committee reviews (e.g., PRMC, radiation safety, biosafety, etc.)
4. Additional agreements, such as Data Use Agreement (DUA) or Clinical Trial Agreement (CTA), are needed for the given collaboration

*Note:
- WCM IRB will provide an acknowledgment letter to capture local context review
- Study documents submitted will not receive a WCM IRB stamp (unless required)
Non-WCM Continuing Review vs PAM-AR

Non-WCM Continuing Review
- IRB of Record requires a continuing review. (check initial approval letter)
  - Submission should include all approved documents and IRB of Record CR approval letter

Post Annual Monitoring-Annual Review (PAM-AR)
- IRB of Record determined that CR is not needed- check-in/status report
- No modifications allowed with PAM-AR

Research activities may continue uninterrupted unless study has expired with the IRB of Record or if directed otherwise.
Non-WCM Amendments

Amendments to the Protocol or ICF(s) should first be approved by the IRB of Record.

- Submit a non-WCM amendment for acknowledgment within 14 days of IRB of Record approval

Amendments to research personnel at WCM

- Reviewed and approved by WCM IRB first, unless stipulated otherwise

Research activity may be implemented upon approval from the IRB of Record
Reportable Events

• All reportable events must be reported to WCM IRB and External IRBs concurrently
• WCM can place enrollment on hold, suspend or terminate the research activity, or request additional protections at the WCM site at any time
• Ensure timely submission to WCM IRB

Research activity may be implemented upon approval from the IRB of Record
Preferred Workflow for sIRB Review and Submission

Reliance Request
WCM PI requests reliance via Qualtrics or email to singleIRB@med.cornell.edu

IRB Reliance Review
- Determine reliance allowed
- Determine IRB of Record
- Determine reliance documentation to use

IRB Reliance Documentation
WCM PI obtains all local and external institutional signatures prior to study submission to the WCM IRB

IRB of Record Established
- Agree to serve as single IRB (sIRB) for study
- Sign reliance documentation

Reliance Executed
Fully signed reliance agreement provided to the IRB of Record and Relying IRB via IRB submission

Local Context Questionnaire
If provided by IRB of Record, relying Site PI and relying IRB complete local context questionnaire(s)

Ancillary Committee Review and Approval
Site PI obtains ancillary committee review and approval based on institutional requirements (e.g. PRMC)

IRB of Record Review and Approval
Study documents, participation of relying site, and local ICF for relying site reviewed and approved

Relying IRB Local Context Review and Acknowledgement
Study documents, IRB of Record approval, and local ICF reviewed and acknowledged

Weill Cornell Medicine
Questions?
For More Information

Email the sIRB Team: singleIRB@med.cornell.edu

Or

Visit the sIRB web page: https://research.weill.cornell.edu/integrity-compliance/human-subjects-research/institutional-review-board/human-research-compliance-0