Weill Cornell Medicine

Welcome!

- The session will begin shortly; for those that are joining via Zoom, please take a moment to make sure your microphone is muted.
- The presentation portion of this session will be recorded.
- Please hold your questions to the end of the presentation.
- Not registered? Please register now using the QR code.

Weill Cornell Medicine

Single IRB: How does it impact you?

Presented by
German Jimenez
Human Research Compliance and Reliance Administrator

Office of Human Research Protection & Compliance
Melissa Epstein, PhD, MBE, CIP *Executive Director*

https://research.weill.cornell.edu/irb

German Jimenez, BS

Reliance Administrator for WCM IRB

10+ years experience in regulatory oversight for biomedical and social behavioral research.

Business degree from Kean University.

Joined WCM in 2021.

Overview

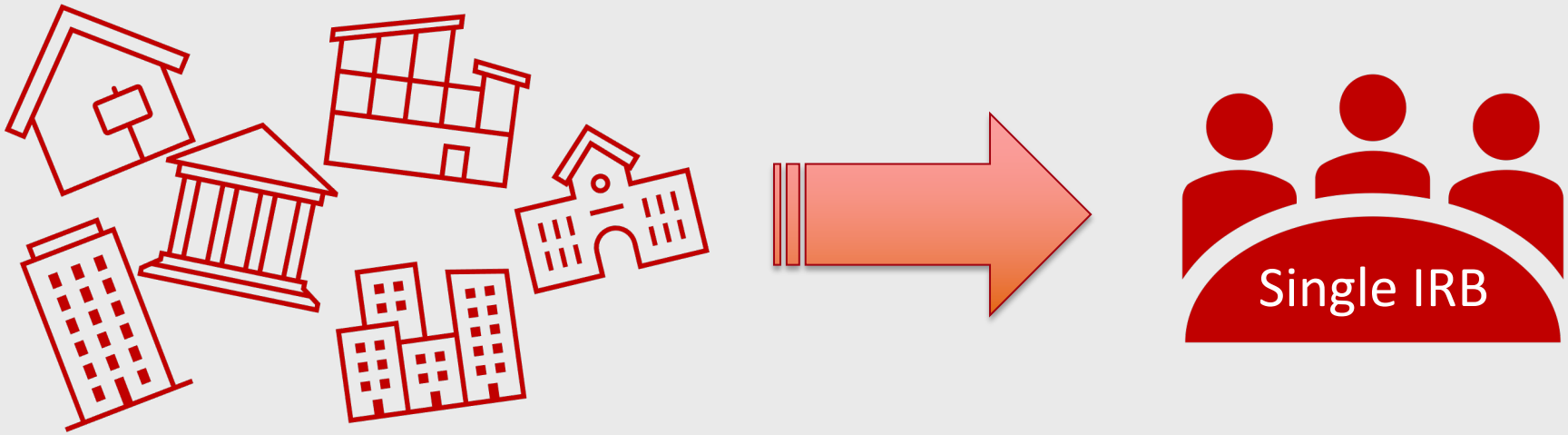
- Single IRB Introduction
- Engaged in Human Subject Research
- Reliance Agreements
- Single IRB Process: WCM as Relying site/Reviewing IRB
- Takeaways/Questions

Weill Cornell Medicine

Single IRB Introduction

What is a Single IRB (sIRB)?

A Single IRB is the Reviewing IRB or (IRB of Record), that provides the ethical and regulatory review for all relying sites participating in a multisite/multi-center study.



Weill Cornell Medicine

Why the need for sIRB?

- **Problem:** To the launch a new multi-site research study took too long. A major contributor to the delay was that too many institutional review boards (IRBs) were reviewing the protocol and consent documents for the same study, often with no added benefit in terms of the protections for research participants.
- **Solution:** To address this bottleneck, new policies/regulations were created:
  - NIH sIRB Policy (2018)
  - Common Rule Cooperative Research Provision (2020) *45CFR46.114(b)*
- These sIRB mandates seek to end duplicative reviews that delay the start of research projects.

When is sIRB required?

NIH sIRB Policy (2018)

- NIH sponsored multi-site studies
- Same protocol activities
- U.S. Domestic research only
- Non-exempt research only

Common Rule Cooperative Research Provision (2020)

- Non-exempt federally funded research
- U.S. Domestic research only
- *Need not* perform same protocol

FDA sIRB Policy (???)

- *Coming soon!*
- FDA-regulated cooperative research
- Reduce costs

When sIRB is not required:

- Non-federally-funded research
- Exempt research
- Prohibited by federal, tribal, or state law, regulation, or policy
- Foreign sites
- Exception requests to the National Institutes of Health (NIH)
- 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

Weill Cornell Medicine

Who can serve as Single IRB?

- Any IRB with a federalwide assurance (FWA), or federal registration can serve as Single IRB.
- Selecting a sIRB is a responsibility for the lead PI/site, however WCM IRB should be consulted in the selection process when involved in a planned collaboration.

Do NOT enter into Reliance commitments without first discussing with WCM IRB.

WCM may agree to serve as Single IRB (limited case by case basis) depending on:

- Coordinating Capacity
- Federally Funded
- Minimal Risk
- No more than 3 sites

Weill Cornell Medicine

Cost of Single IRB Review

The additional costs associated with sIRB review may be charged to grants or contracts as direct costs provided that such costs are well-justified and consistently treated as either direct or indirect costs according to applicable cost principles in the NIH Grants Policy Statement and the FAR 31.202 (Direct Costs) and FAR 31.203 (Indirect Costs)

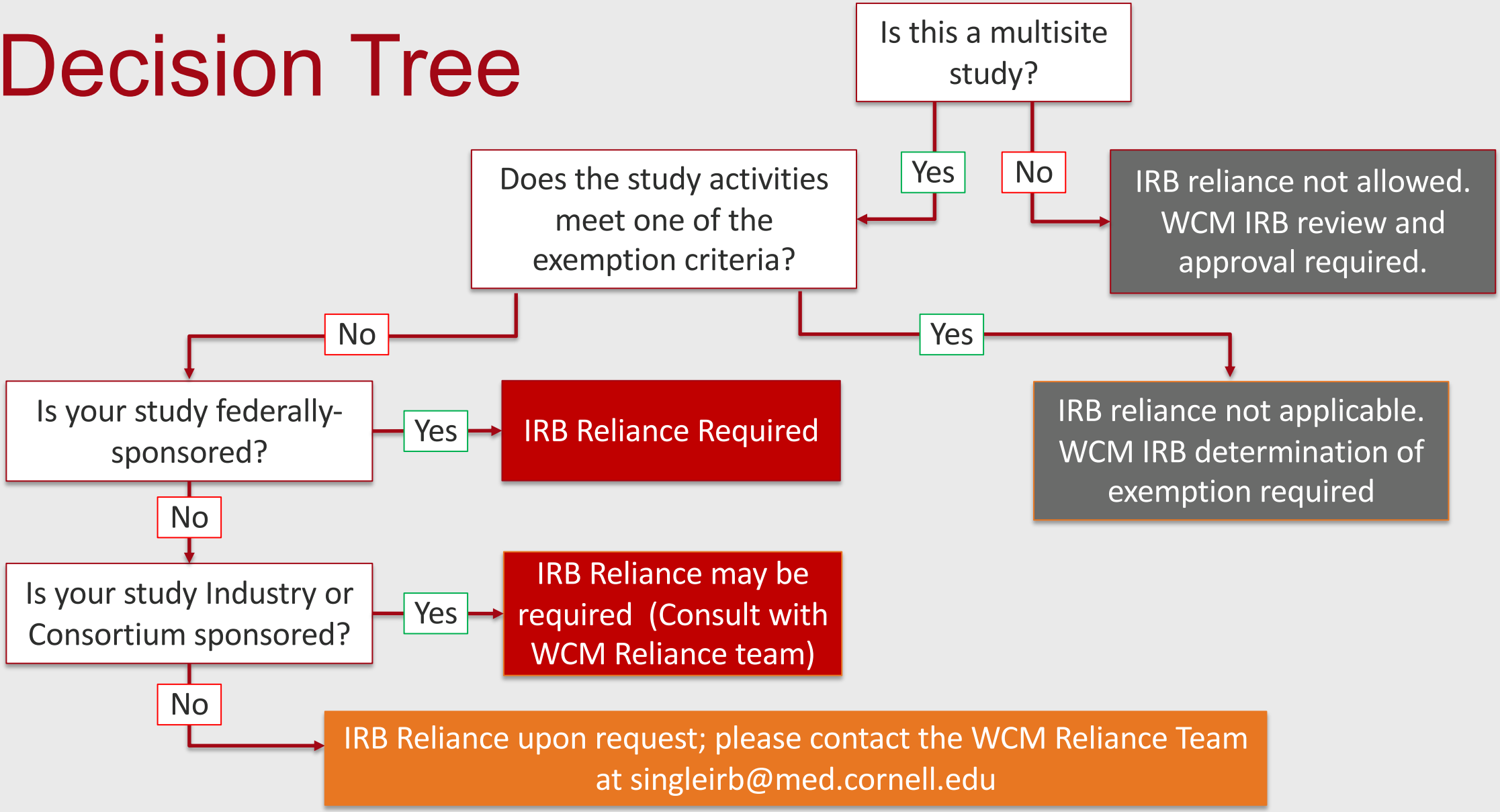
Primary activities: Activities associated with conducting the ethical review of the proposed research protocol that will be carried out at all sites.

- Charged as indirect costs because Institution has Federally approved F&A rate and is a participating site.

Secondary activities related to the other participating sites: Activities associated with review of site-specific information, such as investigator qualifications, institutional capabilities and state/local regulatory requirements.

- May be charged as Institution's direct costs.

Decision Tree



Weill Cornell Medicine

Engaged in Human Subjects Research (HSR)?

Weill Cornell Medicine

Human Subjects Research

Department of Health and Human Services (DHHS) & Food and Drug Administration (FDA)

All Research (DHHS)
45CFR46.102(l)

Research? A systematic investigation designed to develop or contribute to generalizable knowledge

Human subject? a living individual about whom an investigator conducting research obtains:
1. Data through intervention or interaction with the individual OR
2. Identifiable private information

FDA Regulated Research
21CFR50.3(c)

Clinical Investigation? Any experiment that involves 1 or more human subjects and an FDA-regulated test article other than in the course of standard medical practice

Human Subject? An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may either be a healthy individual or a patient.

Weill Cornell Medicine

When does an institution become engaged in HSR?

OHRP Engagement of Institutions in HSR guidance (2008):

An institution is considered *engaged* in a particular non-exempt human subjects research project when its agents (*e.g., faculty, student and staff*) for the purposes of the research obtain:

- Data about the subjects of the research through intervention or interaction with them
- Identifiable private information about the subjects of the research; or
- The informed consent of subjects for the research
- Receive a direct Federal Award

Weill Cornell Medicine

When institutions are **NOT** engaged in HSR

- **ONLY assisting with recruitment of subjects**
  - Informing prospective subjects about the availability of the research or
  - Providing prospective subjects with information about the research (which may include the consent document and any other approved research materials) but do not obtain subjects' consent for the research or act as representatives of the investigators or
  - Providing prospective subjects with information about contacting investigators for information or enrollment and/or
  - Seeking or obtaining the prospective subjects' permission for investigators to contact them

- **Obtaining coded/de-identified private information or biological specimens from another institution.**

Weill Cornell Medicine

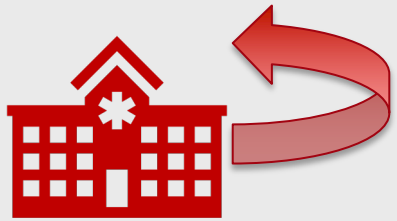
Reliance Agreements

What is a “reliance agreement”?

A reliance agreement is a legal document signed by two or more institutions (or organization, or individual) engaged in human subject research to delegate institutional review board (IRB) review to an independent IRB or an IRB of another institution.

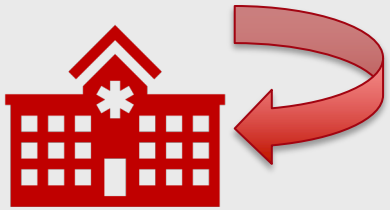
- **WCM (Relying IRB)** may cede review to an external IRB (IRB of Record)

WCM is **not** the IRB of record



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

WCM **is** the IRB of record



Weill Cornell Medicine

Roles and Responsibilities Breakdown

sIRB

- HIPAA Determination
- Conducting Initial and Continuing reviews
- Provide Informed consent documents for research
- Consider COI management plan in IRB review
- Notify Site PI and Relying Institution of Unanticipated Problems, Injuries, Complaints, Suspensions or Terminations of research
- Notify Site PI and Relying Institution of Serious or Continuing Non-Compliance
- Notify Relying Institution of Audit or Investigation related to ceded review

Site PI and Relying Institution

- Notify sIRB of Unanticipated problems or injuries
- Notify sIRB of Noncompliance or suspension restrictions of personnel's ability to conduct research
- Cooperate with Audit or Investigation

Relying Institution

- Education Training Qualifications of study team and PI
- Requiring compliance with sIRB determinations , regulations, state and local laws and institutional policy
- Notifying Research Personnel of Sites Obligations under the reliance agreement
- HIPAA Compliance and Obligations
- Provide Site Specific Information for Insertion in to Informed Consent Documents
- Conduct COI review and Notify sIRB of Conflict Management Plan
- Communicating Local Considerations to sIRB

Types of Reliance Agreements

IRB Authorization Agreement (IAA):

- An agreement between two institutions in which one institution agrees to cede IRB review to another institution's IRB. The IAA is signed by the Institutional Officials or designee at each institution.

Individual Investigator Agreement (IIA):

- An agreement between an individual investigator (not affiliated with an FWA-holding organization) and the institution providing IRB oversight. The IIA is signed by the individual investigator and the Institution's Institutional Official or designee.

Master Reliance Agreements:

- An agreement among multiple institutions that any one of those institutions is generally willing to cede to any other institution's IRB.
  - ➢BRANY, Advarra, WCG
  - ➢SMART IRB agreement

What is “SMART IRB”?

SMART IRB is a platform (**not an IRB**) that enables IRB reliance among institutions who agree to collaborate under a pre-signed master SMART IRB global reliance agreement.

- An online system to facilitate reliance agreements
- Resources for researchers and IRBs

SMART IRB is WCM’s preferred mechanism for establishing reliance

- ✓ **Flexibility/Faster**
- ✓ **1000+ participating institutions**
- ✓ **Peace of mind**

For more information on SMART IRB, please visit smartirb.org

Weill Cornell Medicine

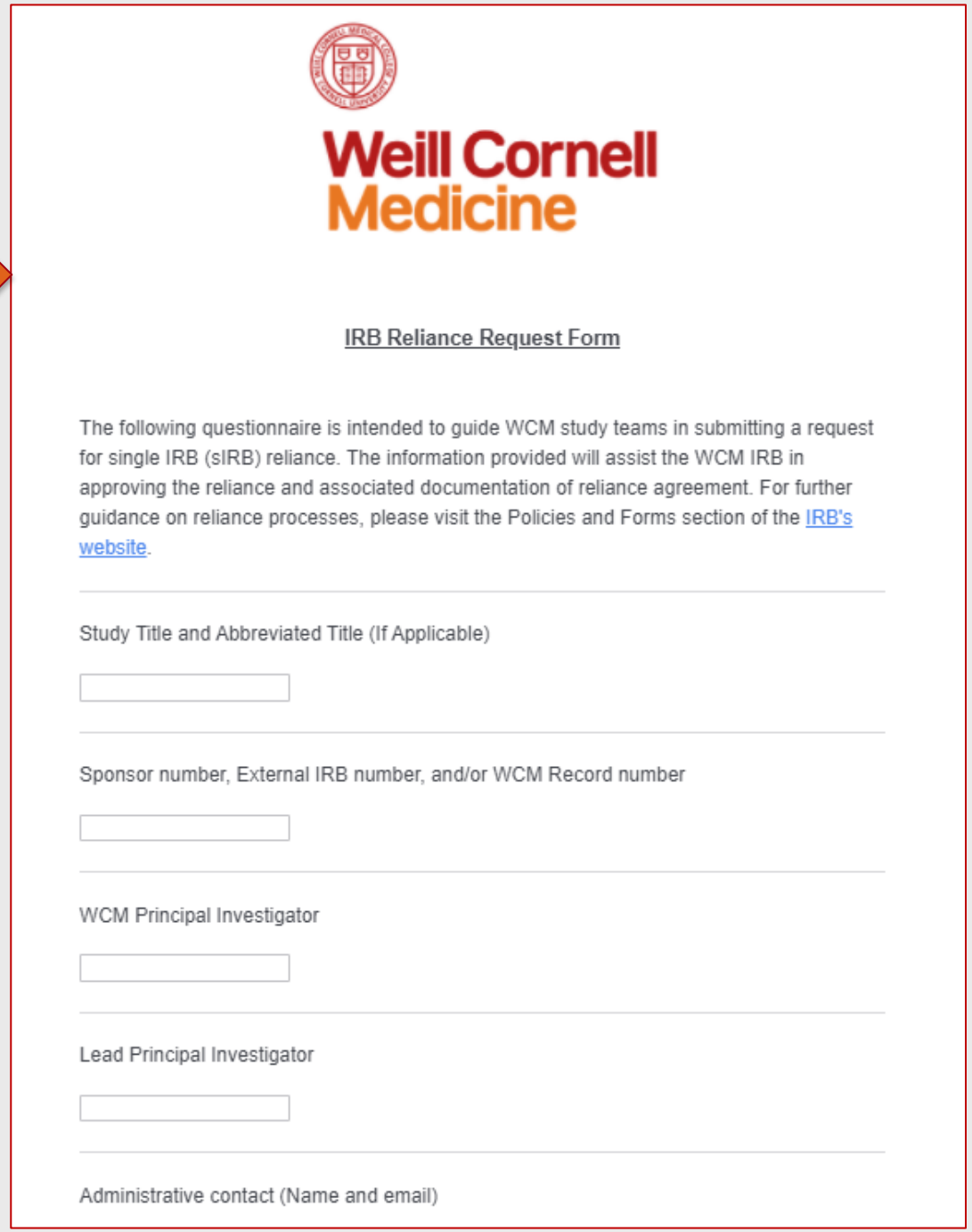
Weill Cornell Medicine

Single IRB Process: WCM as a Relying Site

How do I establish reliance?

Submit a WCM IRB Reliance Request Form

Request a consult with WCM IRB



Weill Cornell Medicine

IRB Reliance Request Form

The following questionnaire is intended to guide WCM study teams in submitting a request for single IRB (sIRB) reliance. The information provided will assist the WCM IRB in approving the reliance and associated documentation of reliance agreement. For further guidance on reliance processes, please visit the Policies and Forms section of the IRB's website.

Study Title and Abbreviated Title (If Applicable)

Sponsor number, External IRB number, and/or WCM Record number

WCM Principal Investigator

Lead Principal Investigator

Administrative contact (Name and email)

Weill Cornell Medicine

WCM as a relying site

With the Reliance Agreement in place and the Single IRB review/approval of a parent protocol, a submission in WRG-HS will be required.

The **Non-WCM Initial submission** in WRG-HS will facilitate the following:

1. Any applicable ancillary reviews (e.g., PRMC, Radiation Safety, etc.)
2. Human subjects research training confirmation
3. Conflict of Interest (COI) disclosures
4. Completion of any local context forms/questionnaires

The submission will also allow the WCM IRB to conduct a **local context review** of the study.

Weill Cornell Medicine

Local context review when WCM is a relying site

The local context review is an abbreviated review that includes assessment of completeness and consideration of local context.

- The latter will focus on determining if any state/local laws or institutional policies are invoked by the procedures that are proposed, and on the consent form to ensure local language is included

Examples include:

- Research related injury ICF language
- Site specific confidentiality language
- NYS Genetic Testing policy

Weill Cornell Medicine

Weill Cornell Medicine

Single IRB Process: WCM as Reviewing IRB

How do I establish reliance?

Submit a WCM IRB Reliance Request Form

Request a consult with WCM IRB

Weill Cornell Medicine

IRB Reliance Request Form

The following questionnaire is intended to guide WCM study teams in submitting a request for single IRB (sIRB) reliance. The information provided will assist the WCM IRB in approving the reliance and associated documentation of reliance agreement. For further guidance on reliance processes, please visit the Policies and Forms section of the IRB's website.

Study Title and Abbreviated Title (If Applicable)

Sponsor number, External IRB number, and/or WCM Record number

WCM Principal Investigator

Lead Principal Investigator

Administrative contact (Name and email)

WCM as Reviewing IRB

Once Reliance Agreements are in place with all Relying Site(s), the following steps are required in WRG-HS

STEP 1: WCM Initial submission will include local WCM documents per normal practice:

- ✓ Protocol
- ✓ IRB Review Application (IRA) form
- ✓ Research related materials
- ✓ Reliance Agreement *(Identifying WCM as Reviewing IRB)*

Once WCM IRB approves the parent protocol proceed with Step 2

STEP 2: Amendment submission to add relying site(s), which will include:

- ✓ WCM local context form (completed by relying PI and site)
- ✓ Fully executed reliance agreement
- ✓ Site specific documents (if applicable)

Weill Cornell Medicine

Local context review when WCM is Reviewing IRB

Each Relying PI/site must complete a WCM Local Context Form

Weill Cornell Medicine
Research Integrity

Human Research Protections
Researcher Checklist
Version Date: 10/1/2023

Single IRB (sIRB) Local Context Form

The Weill Cornell Medicine (WCM) Institutional Review Board (IRB) is being asked to serve as the Reviewing IRB for your site. This form is needed to verify your site's local laws, policies, etc. as they apply to the designated study.

Instruction to Relying Site Investigator:

Please complete Sections 1 through 5. Submit the completed form to your local HRPP/IRB along with any approval documents from the WCM IRB according to your local processes. Once your HRPP/IRB completes and signs this form and agrees to the version of the consent form to be used at your site (if applicable), forward all the documents to the WCM PI/study team. They will submit to the WCM IRB for review and approval.

Instruction to Relying Site HRPP/IRB:

Your local investigator was instructed to contact your office to understand any local requirements regarding submission to your institution.

This form contains the following sections:

- General Study Information (completed by the site PI)
- Relying Site Information (completed by the site PI)
- Conflict of Interest disclosures (completed by the site PI or the local HRPP/IRB Office)
- Study Personnel (completed by the site PI)
- Conduct of the Study at the site (completed by the site PI)
- Institutional Information (completed by the local HRPP/IRB Office).

Please verify that the information reported by the relying site PI/study team is accurate. If you have any questions, please, contact the WCM Reliance Team at singleirb@med.cornell.edu.

Section 1: General Study Information

Study Title:	
WCM Protocol #:	
WCM Principal Investigator (PI):	

Section 2: Relying Site Information

Name of Relying Site:	
Local Tracking Study #, if available:	
Local PI:	

Weill Cornell Medicine

Weill Cornell Medicine

Takeaways

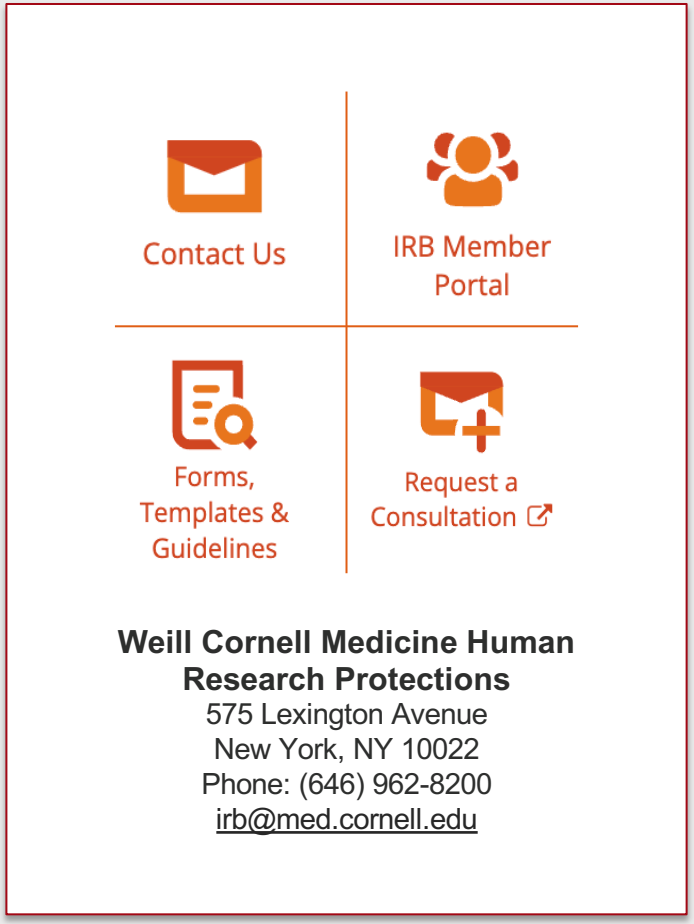
Key Takeaways:

- sIRB is required for federally funded non-exempt multisite research
- Use of Single IRB may include additional direct costs
- To avoid unnecessary burden at either site, begin discussions as early as possible. Communication is KEY!
- Use of SMART IRB agreement is preferred, when possible

Weill Cornell Medicine

Helpful Resources

- **Email the WCM Reliance Team**: singleIRB@med.cornell.edu
- **Request a Consult**: https://weillcornell.az1.qualtrics.com/jfe/form/SV_8B8nCOcC8q7pUN0
- **WCM sIRB web page**: https://hrp.weill.cornell.edu/irb/multisite-studiessingle-irb
- **WCM Reliance Request Form**: https://weillcornell.az1.qualtrics.com/jfe/form/SV_9sQ5rUvSSFd7abH
- **SMART IRB**: Smartirb.org



Weill Cornell Medicine

Questions?

Weill Cornell Medicine

Contact Us

Scan the QR code to request a consult during our on-site

Tuesday, 1/9 through Thursday 1/11

Weill Cornell Medicine

Weill
Cornell
Medicine