

# IRB101: Single IRB

## An Overview

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

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## Overview

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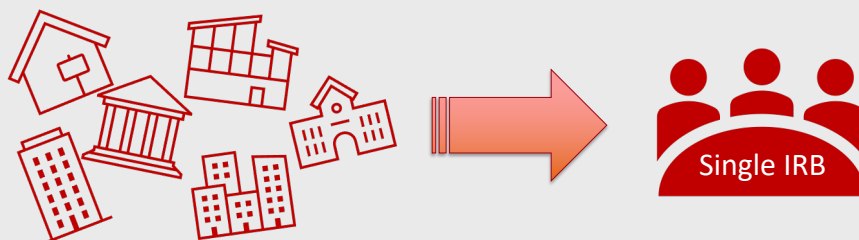
# sIRB: An Introduction



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## 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.



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## 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.***



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# sIRB Background



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## 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



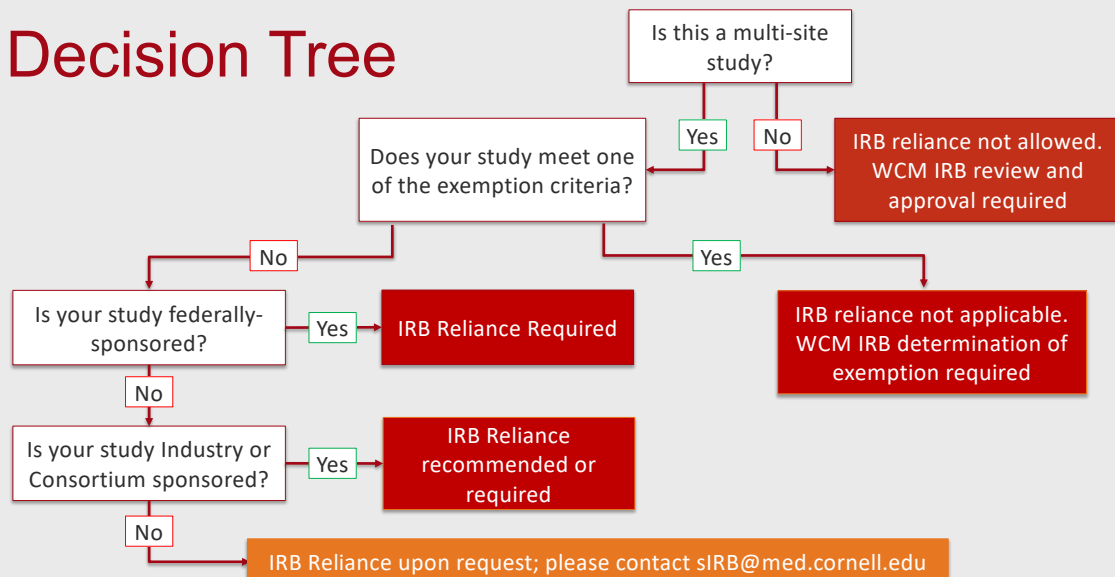
Industry-sponsored clinical trials



Multicenter studies with NYP and CTSC partner institutions.



## Decision Tree



# Establishing Reliance



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## 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](mailto:singleIRB@med.cornell.edu)



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# IRB Reliance Request Form

[https://weillcornell.az1.qualtrics.com/jfe/form/SV\\_9sQ5rUvSSFd7abH](https://weillcornell.az1.qualtrics.com/jfe/form/SV_9sQ5rUvSSFd7abH)



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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)

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## 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](mailto:singleIRB@med.cornell.edu)



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## 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](mailto:singleIRB@med.cornell.edu)



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## SMART IRB

Sstreamlined, 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**.



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# sIRB Submissions



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## 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)



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## 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

Obtain reliance agreement and complete any local context form(s)/questionnaires requested by External IRB

Submit a Non-WCM Review and Approval (Central IRB or Single IRB) application in WRG\*

Complete WCM training, COI and any Ancillary Committee reviews (e.g. PRMC, radiation safety, biosafety, etc.)

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.**



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## 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**



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## Reportable Events

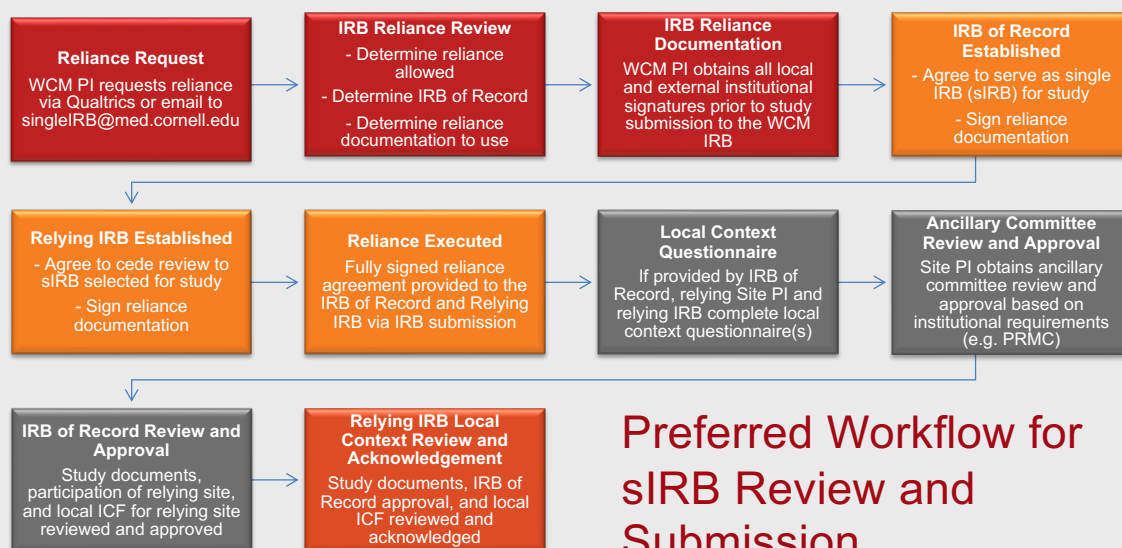
- All reportable events must be reported to WCM IRB and External IRBs concurrently
- WCM can place enrollment on hold, suspend or terminate the research activity, or request additional protections at the WCM site at any time
- Ensure timely submission to WCM IRB

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



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## Questions?



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## For More Information

Email the sIRB Team: [singleIRB@med.cornell.edu](mailto: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>



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