IRB101: Single IRB
An Overview

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https://research.weill.cornell.edu/irb
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)**, that provides the ethical and regulatory review for all relying sites participating in a multisite/multi-center study.
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)
What is an **Individual Investigator Agreement (IIA)**?

(IIA): an agreement between WCM and an individual collaborator who is:

- unaffiliated with WCM & 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.
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
Budgeting considerations for Single IRB

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.
Exceptions to use Single IRB (sIRB)

- Exempt research
- Foreign 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]
Establishing Reliance
Who will serve as Single IRB (IRB of Record)

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

WCM IRB and External IRBs will collect and review basic information about the planned collaboration

WCM IRB may agree to serve as the Reviewing IRB on limited case by case basis, depending on:

- Funding source (*federally funded*)
- Risk level (*minimal risk*)
- Number of sites (*no more than 3 domestic sites involved*)
How Do I Establish sIRB Reliance?

Submit a **WCM Reliance Request Form** in Qualtrics

- WCM and Lead PI names
- Propose Reviewing IRB
- Funding source: e.g., Federal, Institutional, Industry
- Protocol activities at WCM and External Site(s)

*Note: The same reliance request form is used to request either an academic IRB or a commercial IRB to serve as IRB of Record.*
IRB Reliance Request Form

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

WCM PI or designee responsibilities:

- Complete the WCM Reliance Request form
- Obtain reliance agreement memo
- Submit IRB submission in WRG-HS
- Scientific review by PRMC 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
Lead PI responsibilities

The Lead PI will be responsible for the following:

• Ultimate responsibility for conduct of the research
• Effectively serving as a regulatory coordinating center
• Oversee and manage IRB reporting for ALL sites
• Compliance with each participating institution’s policies
• Lead PI is responsible for ensuring coordinator/staff are aware of new responsibilities and policies.
SMART IRB
Streamlined, Multi-site, Accelerated Resources for Trials

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

SMART IRB will be our preferred mechanism in establishing reliance
- Flexibility/Faster
- 1000+ participating institutions
- Peace of mind

For more information on SMART IRB, please visit smartirb.org
sIRB Submissions
# WCM IRB as Reviewing IRB (Single IRB)

<table>
<thead>
<tr>
<th>STEP 1</th>
<th>STEP 2</th>
<th>STEP 3</th>
<th>STEP 4</th>
<th>STEP 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submit <strong>WCM Reliance Request form</strong></td>
<td>Submit a <strong>WCM IRB application</strong></td>
<td><strong>WCM IRB approves initial study</strong></td>
<td><strong>Submit Amendment to add external site(s)</strong></td>
<td><strong>WCM IRB approves amendment</strong></td>
</tr>
<tr>
<td><strong>- WCM Reliance team confirms reliance</strong></td>
<td><strong>- Local WCM documents per normal practice</strong></td>
<td><strong>- WCM IRB will only approve WCM activities</strong></td>
<td><strong>- IRA- listing sites and their involvement</strong></td>
<td><strong>- Issues Amendment NOA for external site(s)</strong></td>
</tr>
<tr>
<td><strong>- Teams are provided with Reliance agreement, Local Context Form and next steps</strong></td>
<td><strong>- Protocol IRA</strong></td>
<td><strong>- Approval letter/email will inform PI to submit an amendment (to add external site)</strong></td>
<td><strong>- WCM Local Context Form for each site(s)</strong></td>
<td><strong>- Provides stamped materials to be used at external site(s)</strong></td>
</tr>
<tr>
<td><strong>- WCM documentation</strong></td>
<td><strong>- Research materials</strong></td>
<td><strong>- Reliance agreement</strong></td>
<td><strong>- Protocol</strong></td>
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When WCM is relying on a new External IRB:

- Submits a WCM Reliance Request Form
- Obtain reliance agreement

- Submit a Non-WCM Initial submission in WRG for local context review
  - Include any local context form (LCF) to be completed
  - WCM Reliance team will complete LCF and send back submission

- Provide completed local context form to Reviewing IRB
  - After Reviewing IRB approves WCM as a site, re-submit Non-WCM submission for final acknowledgement

- Additional agreements, such as Data Use Agreement (DUA) or Clinical Trial Agreement (CTA), are needed for the given collaboration

Note:
- Study documents submitted will not receive a WCM IRB stamp
- Centralizes the completion of LCF(s) and local context considerations via WRG-HS
- External IRBs familiar with WCM’s local context considerations and do not require LCF(s) to be completed may only require a one-time submission to WCM IRB. Example: BRANY
Annual Reviews when WCM is the relying IRB

Continuing Review or Post Approval Monitoring Annual Report (PAMAR)

- Check initial Reviewing IRB approval letter
- Submit within 5 business days of receiving Reviewing IRB approval.

If continuing review has been approved by the Reviewing IRB, then research activities may continue uninterrupted unless directed otherwise.
Amendments when WCM is the relying IRB

Changes to WCM Key Personnel
• Must submit to WCM IRB first for acknowledgement

Major changes (submit within 5 business days of receiving Reviewing IRB approval):
• Impact or alter risk level at WCM
• Changes to ICF(s)
• Addition of vulnerable population

Minor changes (during Annual Review- memo listing changes, updated docs and approval letters)
• No change to risk level
• Changes to recruitment materials

You may begin using updated documents approved by the Reviewing IRB while you are pending local acknowledgement
System Integrations – Key Personnel

- Study assignment to OnCore and Epic is granted by assigning personnel one of the following roles/responsibilities in HS:
  - PI or Co-Investigator/Sub-Investigator
  - Research Nurse
  - Study Coordinator/Data Management

- **Admin Contact Only** assigns the Regulatory Coordinator role in OnCore. This allows submission to the PRMC but does not give access to Epic.

- Any changes to the study personnel must be submitted to the WCM-IRB in a timely manner to ensure the responsibilities in other systems can continue.
List of Document Types accepted by OnCore

• Assent Form (ages 7-11)
• Assent Form (ages 12-17)
• Assent Script (under 7)
• Blood/Tissue Consent
• Donor Blood/Tissue Consent
• Donor Main Consent
• HIPAA Research Authorization - Oral Consent Only
• Main Consent
• Oral Consent Script
• Parental Consent
• Screening Consent

ICF document types cross the interface to be used for subject registration in OnCore
Reportable Events when WCM is the relying IRB.

- 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
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

Relying IRB Established
- Agree to cede review to sIRB selected 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 Acknowledgement
Study documents, IRB of Record approval, and local ICF reviewed and acknowledged

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

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

• Discuss with WCM Reliance Team before making Reliance commitments
• Only applies to NON-EXEMPT research
• First step is to submit a Reliance Request Form in Qualtrics
• Use of SMART IRB agreement is preferred, when possible
• Approval of the parent protocol is NOT global approval for any site to begin research
• NIH policy allows reviewing IRBs to charge for IRB review for relying Institutions
• Must follow WCM policies as well as any policies enforced by Reviewing IRB
• Communication is key!!
For More Information

Email the WCM Reliance Team: singleIRB@med.cornell.edu

Request Consult: https://weillcornell.az1.qualtrics.com/jfe/form/SV_8B8nCOcC8q7pUN0

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

WCM Reliance Request Form: https://weillcornell.az1.qualtrics.com/jfe/form/SV_9sQ5rUvSSFd7abH

SMART IRB: Smartirb.org
Questions?