Let’s Work Together:
IRB Oversight of Collaborative Research: Part I
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Objectives

• Provide overview of single IRB (sIRB) for multi-site research
• Describe typical steps for research collaboration using a sIRB
• Explain roles and responsibilities for the study team, sIRB and relying institutions
Overview of Single IRB
Common Terminology

- Single IRB (sIRB)
- Central IRB (cIRB)
- IRB of Record
- Reviewing IRB
- Relying
- Ceding
- IRB Reliance Agreement
Common Terminology

Single IRB (sIRB) vs Central IRB (cIRB)

They mean the same thing: a single IRB of record oversees all research sites participating in a multisite study.

“IRB of Record / Reviewing IRB” the IRB that is responsible for the review, approval, and regulatory oversight of a research study.
Relying vs Ceding Review

A relying institution will cede review (give it away) to an external IRB of Record

“IRB Reliance Agreement (IAA)” A reliance agreement is a document signed by two or more institutions engaged in human subjects research that defines the relationship between the Reviewing IRB and the relying institution(s). The agreement permits one or more institutions to cede review to an external IRB.
When IRB Reliance Agreement (IAA) is needed

External Institution

Engaged in Ohio State University research

Relying on Ohio State University’s IRB

Ohio State will establish itself as IRB of record via

IRB Authorization Agreements to cover these institutions and their personnel
Types of Reviewing & Relying Institutions

- Academic institutions
- Hospitals
- Research institutes
- Government agencies
- Research consortia
- Commercial IRBs
Reviewing institution provides IRB oversight for one or more relying institutions

- oversees most activities at main & relying sites
- reviews events
- reports to sponsors

- assures HS training & COI are up to date
- completes ancillary reviews, as applicable (e.g., HSRC, CSRC)
Review Models: Single IRB Review

Lead site
IRB of Record

All sub-sites cede review to IRB of record
Review Models: Multiple IRB Review

Lead site

Sub-sites ceding review to IRB of record

Independent investigator

Sub-site doing local IRB review
Review Models: IRB Oversight Documentation

- 1 lead site
- 2 sub-sites
- 1 independent investigator

IRB oversight: documentation:

- Rural hospital’s IRB
  IRB approval letter
- Ohio State’s IRB
- Ohio State’s IRB
  Independent Investigator Agreement (IIA)
What the NIH single IRB rule says:

On or after January 25, 2018, NIH expects that all sites participating in multi-site studies, which involve non-exempt human subjects research funded by the NIH, will use a single Institutional Review Board (sIRB) to conduct the ethical review required for the protection of human subjects.
NIH Requires Single IRB Review

Lead site
IRB of Record

All sub-sites cede review to IRB of record
NIH sIRB rule is applicable:

- If all sites for a particular study are conducting the same protocol
- If an award involves both domestic and foreign sites, the domestic sites would be expected to use a sIRB and the foreign sites could use their own IRBs
- Regardless of the funding mechanism (e.g., grants, cooperative agreements, contracts or other mechanisms)
NIH sIRB Proposal

What you need:

• **Letter of Support**
  Obtain approval from ORRP for OSU to be sIRB

• **sIRB Plan**
  Identify reviewing IRB
  Describe communication between lead / relying sites

• **IRB Budget proposal**
  Ensure resources to oversee site communication
  Determine whether IRB fees apply
NIH sIRB Proposal

Where to find resources:

OFFICE OF RESEARCH

Office of Responsible Research Practices

Additional Forms and Tools

- Letter of Support for Relying Institutions (Ohio State template)
- Single IRB Communication Plan (Ohio State template)
- Communication Plan for SMART IRB (SMART IRB template)
- Description of SMART IRB for Grant Applications (SMART IRB template)
- Principal Investigator/Lead Study Team Guidance and Checklist (SMART IRB)
- Initiating a request in the Online Reliance System (SMART IRB)
- SMART iRB Resources Page

https://orrp.osu.edu/irb/osuirb/policies/single-irb/
What you need to know:

When can’t OSU be the reviewing IRB?

• Exempt research
• International collaborations

When can’t OSU rely on external IRB?

• Human Gene Transfer (HGT) studies
• Planned emergency research
• Xenotransplantation
• Embryonic stem cell research

With some exceptions granted on a study by study basis
NIH sIRB Proposal

What you need to know:

Budgeting for IRB fees

• Does OSU charge for sIRB review? Not Yet

• Do other academic IRBs charge for sIRB review? Sometimes
What the new Common Rule says:

§46.114 Cooperative research (b)(1)

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.

Single IRB review is required when research is conducted in the U.S.
Common Rule Requires Single IRB Review

Lead site
IRB of Record

All sub-sites cede review to IRB of record
What the new Common Rule says:

§46.114 Cooperative research

(a) Cooperative research projects are those projects covered by this policy that involve more than one institution.

(b) 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.

BOTH Reviewing IRB & Relying Institution have responsibilities for human subjects protection and compliance
What the new Common Rule says:

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.

Federal agency has the ultimate say regarding sIRB selection.
Plan on Single IRB Review

Lead site
IRB of Record

All sub-sites cede review to IRB of record
IRB Submissions for sIRB Studies
IRB Applications

Submissions in multiple systems might be required

OSU is reviewing IRB application

Relying IRB application

Reliance request application
IRB Applications

Submissions in multiple systems might be required

- OSU is ceding IRB application
- Reliance request application
- Reviewing IRB application
IRB Applications

Submissions in multiple systems might be required

OSU is ceding IRB application

Reviewing IRB application
IRB Submission Process

Consider level of engagement – do you or your external collaborator need IRB review?

- Receipt of identifiable data or specimens
- Sharing personal health information (PHI)
- Interactions with subjects
- Recruitment only? **Not engaged**
- Analysis of de-identified data? **It depends**

Come back for Collaborative Research Part 2 to learn more!
IRB Applications for multi-site studies

IRB approval must be obtained for each relying site – consider submission strategies and timing for:

• Initial application
• Amendments
• Continuing review (“Status Reports”)
• Event reports of problems
IRB Applications for Multi-site Studies

Common 2-Step Strategy

1. Initial application
   Submit the generic protocol and consent materials for review by the sIRB

2. Amend to add sites
   Submit site-specific information such as external personnel, site-specific recruitment, site-specific consent, other local context information (e.g., state laws about the age of majority)

Concurrently with
   Reliance agreement request (SMARTIRB)
   Relying IRB application (ceded review)
IRB Applications for Multi-site Studies

Collect more & different information

- Local context
- Institutional profile
- PI survey
- HRP survey
- Letter of indemnification
IRB Applications for Multi-site Studies

Require additional sections in Buck-IRB

Multi-Site Study section:

Is this a multi-site study?*

Is the Ohio State PI the lead investigator or is Ohio State the lead site for collaborative research?*

Will Ohio State be IRB of record for any other institution/location?*

Describe the communication between the sites that might be relevant to the protection of participants:

Communication will take place between sites through a weekly call. It will include members of the study team at both Ohio State and relying sites in order for all parties to touch base regarding unanticipated problems, interim results, and potential protocol modifications.
IRB Applications for Multi-site Studies

Require additional sections in Buck-IRB

Location of Research section:

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<thead>
<tr>
<th>Domestic Research Sites – Non-Ohio State Locations</th>
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</thead>
<tbody>
<tr>
<td><strong>Vanderbilt University Medical Center</strong></td>
</tr>
<tr>
<td><strong>Address</strong></td>
</tr>
<tr>
<td>1211 Medical Center Dr</td>
</tr>
<tr>
<td>Nashville, TN</td>
</tr>
<tr>
<td><strong>Research activities by</strong></td>
</tr>
<tr>
<td>Site personnel only (non-Ohio State staff)</td>
</tr>
<tr>
<td><strong>Research activities</strong></td>
</tr>
<tr>
<td>Data collection/entry/coding, Access participant protected health information (PHI), Participant recruitment, Obtaining consent/parental permission/assent, Reporting results, Research interventions and subject interactions (administer questionnaires/interviews/surveys), Manuscript preparation</td>
</tr>
<tr>
<td><strong>Using OSU as IRB of record</strong></td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td><strong>Letter of support / IRB approval</strong></td>
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<td>Uploaded by Savannah Renshaw on 06/03/2019</td>
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<tr>
<td><strong>Site-specific Documents</strong></td>
</tr>
<tr>
<td>Uploaded Files</td>
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</tbody>
</table>
IRB Applications for Ceded Review

Approval to cede must be obtained prior to an OSU investigator conducting research reviewed by an external IRB

Principal Investigator:
Date of Determination:
IRB Staff Contact: Jessica Evans, evans.309@osu.edu

This notification serves as documentation that IRB oversight for the research has been ceded to an external IRB as per the IRB reliance agreement. This decision applies only to the determination for Ohio State to rely and indicates completion of Ohio State requirements. The Ohio State University confirms that the investigators have satisfied all training requirements and do not have any conflicts of interest with this study. Approval to begin must be obtained from the external IRB prior to initiating study activity.
IRB Applications for Ceded Review

Relying on an external IRB

Frequently Asked Questions

What is a ceded review?
A ceded review is an administrative review performed by designated IRB staff when an Ohio State investigator requests reliance on an external IRB.

How do I request a ceded review for an external IRB?
This type of review is abbreviated but still requires a new study submission in BuckIRB. Select “Create a New Study” and complete the application. In the section titled “Review Board” select “other External IRB” and this shortens the application.

https://orrp.osu.edu/article-categories/collaborative-research-and-agreements/
IRB Applications for Ceded Review

Ceded Review Applications
Initial requests-upload to Buck-IRB:

• Protocol
• Site-specific documents for use at OSU
• Informed consent (main)
• Informed consent (OSU version if needed)
• Copy of external IRB approval OR
• Copy of external IRB application
• sIRB local context forms, IRB surveys
IRB Applications for Ceded Review

Ceded Review Applications
When are amendments needed at OSU?

• Adding or removing PI, Co-I, key personnel
• Add or removing OSU research locations
• Changes to Conflict of Interest
• Updates to external IRB about local context
• Changes to OSU boilerplate language in Informed Consent forms
• Any external forms that require IRB sign-off
IRB Reliance
IRB Reliance

How does Ohio State document IRB reliance?

- SMART IRB
- Alternative IAA agreements
SMART IRB

What is SMART IRB?

• Not an IRB
• Is a master agreement for IRB reliance

Who is using it?

• 600+ participating sites, including some commercial IRBs (Advarra, WIRB)
• OSU’s preferred IRB agreement
SMART IRB

How to initiate a SMART IRB request

• Go to smartirb.org
• Verify collaborating institution is a participating site
• Register for an account
• Login to the online reliance platform
• Submit a study-specific request
• Receive a determination letter
Other Platforms and IRB Agreements

What if my collaborator is not a SMART IRB participating site?

- Agreement can be provided by OSU or the external site
- Wet-ink / Docu-Signed and sent by email
Other Platforms and IRB Agreements

What is IREx and do we use it?

• Vanderbilt University hosts another IRB reliance platform
• Free and available for all types of research agreements
• Yes, OSU uses it (relying site only)
• Best used for large multi-site study document management
sIRB
Study Team & Site Responsibilities
Study Teams

Initial Submission to Reviewing IRB

• Who is responsible for IRB submission?
• When to submit a relying site for IRB review
• What materials will the IRB need to see?
• When can a study activate at a site?
Study Teams

Reliance Process

• When to submit to SMART IRB (if using)
• Who to contact
• What materials to provide
Study Teams

Post Approval

• Know which IRB’s policies apply to a study

• Event reporting - know what events must be reported and when (reviewing IRB requirements may differ from relying IRB)

• Don’t forget to close the study – both with the reviewing IRB and local IRB
Institution’s Responsibilities

• Conduct ancillary reviews
• Document IRB reliance
• Review state laws, regulations, and policies relevant to the study
• Manage conflict of interest (COI)
• Manage HIPAA - who does privacy board review if required (reviewing or relying IRB?)
• Confirm personnel training, qualifications
• Perform post-approval monitoring
Available Resources

- **ORRP FAQs/Collaborative Research and Agreements:** [https://orrp.osu.edu/article-categories/collaborative-research-and-agreements/](https://orrp.osu.edu/article-categories/collaborative-research-and-agreements/)
- **ORRP sIRB website** [https://orrp.osu.edu/irb/osuirbpolicies/single-irb/](https://orrp.osu.edu/irb/osuirbpolicies/single-irb/)
- **SMART IRB** [www.SMARTIRB.org](http://www.SMARTIRB.org)
- **SIRB Alliance** [https://www.sirballiance.org](https://www.sirballiance.org) Suggestions for sIRB best practices, including review of recruitment materials, conflicts of interest, and vulnerable populations