IRB Reliance Models: Workshop for OSU Researchers Collaborating with External Partners

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Office of Responsible Research Practices
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Workshop Objectives

• Overview
• Definitions
• IRB reliance Models-examples
• PI Responsibilities
• BuckIRB and Agreements “How to…”
• Current External IRB Relationships
The Regulations are Changing

Office of Responsible Research Practices

National Institutes of Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

U.S Food and Drug Administration
Important Terminology

- IRB of Record = IRB that Reviews
- Single IRB (sIRB) of Record=central IRB=IRB that Reviews
- Relying IRB
- Individual Investigator Agreement (IIA)
- Ceded review
3 IRB Review Model Options

when OSU is conducting research with an external collaborator

<table>
<thead>
<tr>
<th>OSU IRB</th>
<th>External IRB</th>
<th>IRB Agreements</th>
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<tbody>
<tr>
<td>OSU IRB Reviews</td>
<td>External IRB Reviews</td>
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<td>OSU IRB Reviews</td>
<td>External Collaborator Relies on OSU IRB</td>
<td>IAA or IIA</td>
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<tr>
<td>OSU IRB Relies on External Collaborator’s IRB</td>
<td>External IRB Reviews</td>
<td>IAA</td>
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IRB Review Models

OSU IRB Reviews (IRB of Record)

• Primary IRB for OSU faculty, staff and students
• OSU is prime awardee on the award/contract
• OSU is designated as the sIRB of Record (i.e. per the NIH policy)
OSU IRB reviews (IRB of Record)

**IRB of Record**-reviews, approves, oversees research for external researchers and institutions.
IRB Review Models

OSU IRB review is always an option-except …

• NIH sIRB of Record mandates an External IRB
• OSU/NCH longstanding reciprocity agreement applies
• Western IRB (WIRB)-sponsored clinical trials
• Sponsor mandated central IRB (i.e. NCI cIRB)
OSU Relies on an External IRB

- **OSU is a Relying Institution** when an External IRB oversees research conducted by OSU faculty, students & staff
IRB Review Models

OSU IRB may rely on an External IRB—except …

- Research determined EXEMPT by External IRB
- Planned emergency research
- Xenotransplantation research
- Gene transfer research
- Embryonic stem cell research
IRB Review Models

What does an External IRB review cover?

• Initial Review
• Modifications (amendments)
• Continuing Reviews
• Reportable Events
• Noncompliance
IRB Review Models

When an External IRB is the IRB of Record
OSU is still responsible for ancillary committee reviews

- Radiation safety committee (RAD)
- Institutional Biosafety Committee (IBC)
- Maternal Fetal Welfare Committee
- Cancer Scientific Review Committee (CSRC)
When an External IRB is the IRB of Record
OSU is still responsible for researcher training, compliance and the conduct of research

- Training-Human Subjects Protection-CITI program
- Conflict of Interest (eCOI)
- Informed Consent: template/language, subject injury language, OSU contacts, & HIPAA
PI Responsibilities

“We call him mouse model of PI.”
PI Responsibilities

Lead PI - IRB of Record

• Determine a **communication plan** between all parties: lead and relying IRBs, lead and relying site researchers

• Share IRB of Record policies and procedures with sites, including
  - Submission process
  - Reporting unanticipated problems policy
  - Noncompliance policy
  - Subject complaints policy
PI Responsibilities

Lead PI - IRB of Record

• Obtain information from relying sites prior to approval:
  ➢ Local variations in study conduct
  ➢ Local recruitment materials & processes
  ➢ Site specific consent language

• Provide sites with final IRB-approved study documents
  ➢ Consent & authorization forms
  ➢ Protocol
  ➢ Recruitment materials
PI Responsibilities

Lead PI should have thorough, detailed plans in place for:

• Training study personnel at each site
• Communicating with each site and for them to communicate back to you
• Monitoring compliance with the study protocol
PI Responsibilities

Relying site PI

- Request IRB reliance from home IRB (i.e. short application in BuckIRB)
- Ensure site ancillary reviews completed before study start
- Manage site personnel changes (submit in BuckIRB, then to IRB of Record)
PI Responsibilities

Relying site PI

• Provide site language, local contacts for consent template
• Report COI changes & COI management plans to IRB of Record (or lead PI as per communication plan)

• Report unanticipated problems, subject injuries, complaints to IRB of Record

• Report changes to research, continuing review progress reports
PI Responsibilities

Consider:

• What documents are required for submission to the IRB of Record?
  Special Application Form?
  Local Context form?

• How do you submit to the IRB of Record?
  Website
  Lead research team
Buck-IRB

Online system for submitting or reporting to the IRB
Buck-IRB Considerations

Ohio State is acting as the IRB of Record-
Regular BuckIRB application to OSU IRBs

In BuckIRB note:

- Location of Research
  - Domestic Research Sites-Non-Ohio State Locations
  - International Research Sites
Location of Research

Research to be conducted at locations other than approved performance sites may require a letter of support or another institution’s approval if personnel are engaged. See OHRP Engagement Guidance or contact ORRP at irbinfo@osu.edu or 614-688-8457 for more information.

Ohio State Approved Research Sites

Physical Activity and Education Services building
305 West 17th Avenue
Columbus, OH

Domestic Research Sites – Non-Ohio State Locations

The Gahanna Jefferson Elementary School
136 Carpenter Rd
Columbus, OH
Letter of support / IRB approval

Uploaded Files

Approval from the district.pdf
Buck-IRB Considerations

Ohio State is acting as the IRB of Record- Regular BuckIRB application to OSU IRBs

In BuckIRB note:

• External Co-Investigators & Key Personnel
  Affiliated Organization vs independent investigator?
  Activities Performed?
  CITI/COI-required for independent investigators
External Co-Investigators & Key Personnel

Enter the names of external collaborators who are engaged in the research. Only external personnel whose activities will be covered by an Ohio State IRB should be included.

"Engaged" individuals are those who intervene or interact with participants in the context of the research or who will obtain individually identifiable private information for research funded, supervised, or coordinated by Ohio State University. See OHRP Engagement Guidance or contact ORRP at irbinfo@osu.edu or 614-688-8457 for more information.

All fields marked with an * are required.

External Key Personnel - Jessica Evans

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
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<tbody>
<tr>
<td>Email</td>
<td><a href="mailto:evans.309@osu.edu">evans.309@osu.edu</a></td>
</tr>
<tr>
<td>Phone</td>
<td>614-292-9832</td>
</tr>
<tr>
<td>CITI</td>
<td>Not available</td>
</tr>
<tr>
<td>GCP</td>
<td>Not available</td>
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</tbody>
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Activities Performed

- Protocol development/study design
- Recruitment
- Assess participant eligibility
- Obtain consent/parental permission/assent
- Interview participants/administer surveys
- Data collection/entry/coding
- Reporting results
- Manuscript preparation
- Access participant Protected Health Information (PHI)
Buck-IRB Considerations

Ohio State is acting as the IRB of Record -
Regular BuckIRB application to OSU IRBs

In BuckIRB note:

• Is this a multi-site study? - (often YES for collaborative research)

• Is the Ohio State PI the lead investigator or is Ohio State the lead site for collaborative research? (usually YES if OSU is IRB of Record)
Buck-IRB Considerations

Multi-site Study

A multi-site study is defined as a study conducted under a single protocol at two or more locations (often geographically diverse), involving legally separate entities and requiring IRB oversight for study activities at each location.

Is this a multi-site study?*

[ ] Yes  [ ] No

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

[ ] Yes  [ ] No

Describe the communication between sites that might be relevant to the protection of participants, such as unanticipated problems, interim results, and protocol modifications.*
Buck-IRB Considerations
OSU Relying on External IRB
“Short” BuckIRB Application

• To request a ceded review, start a new application in Buck-IRB
• Select “Create a New Study”
• Select “Type of Review”
  Must be “Expeditied or Convened Review for IRB reliance

Reminder: Exempt research cannot be ceded to an External IRB
Type of Research

Select the appropriate option below based on the type of review required for the research.

Exempt research: This option should be selected for research that involves human subjects that is not subject to regulations requiring IRB review and approval. Final determination is made by ORRP staff.

Expedited or full IRB-reviewed research: This option should be selected for review by the Biomedical Sciences, Behavioral and Social Sciences, or Cancer IRBs at Ohio State including research reviewed through either expedited or full board processes. This option should also be selected for any research which will be ceded to another non-Ohio State IRB, such as WIRB, NCI CIRB, or another external institution.

Don't know: This option should be selected if the investigator is uncertain whether the research is exempt or should be reviewed by an IRB.

What type of review is required for your project?

- Exempt research
- Expedited or full IRB-reviewed research (includes WIRB, NCI CIRB and other external IRB review)
- Don't know (screening questions to determine if exempt research)
Buck-IRB Considerations

OSU Relying on External IRB
“Short” BuckIRB Application

Next steps
• Select an external Review Board per the following choices:
  - National Cancer Institute IRB
  - NCH IRB
  - WIRB…(several other choices)
  - “Other external IRB”
Review Board

Research at Ohio State involving human subjects that requires Institutional Review Board (IRB) review is reviewed by one of three university IRBs or one of multiple external IRBs, including Western IRB (WIRB), National Cancer Institute Central IRB (CIRB), Ohio CTSA Consortium, and Nationwide Children’s Hospital (NCH) IRB. Board assignments are made to ensure that proposed research receives appropriate scientific or scholarly review by individuals with the qualifications to determine that the rights and welfare of research participants are protected. Final board assignment is determined by ORRP.

Selection of one of the three Ohio State IRBs below will connect to the initial review of human subjects research.

Selection of one of the external (non-Ohio State) IRBs will connect to an external review application which provides the necessary information for ORRP staff to perform pre-screening of the application to determine that institutional requirements have been met (e.g., COI disclosure, education) and that the research meets the conditions necessary to be forwarded for external IRB review.

Select the board to review this research.

- Ohio State Behavioral IRB
- Ohio State Biomedical IRB
- Ohio State Cancer IRB
- National Cancer Institute Central IRB (CIRB)
- Nationwide Children’s Hospital IRB
- Western IRB (WIRB)
- Ohio CTSA Consortium
- Quorum IRB
- Other external IRB

"Other" External IRB Review

An IRB Authorization Agreement is required for research ceded to an external IRB other than those listed on the last page. See HRPP policy Research Performance Sites and Collaborative Off-Site Research or contact ORRP for more information.
Buck-IRB Considerations

OSU Relying on External IRB
“Short” BuckIRB Application

Next steps

Selecting “Other external IRB” will require point of contact information for two individuals

- Collaborating external investigator (lead PI)
- External IRB point of contact
Buck-IRB Considerations

"Other" External IRB Review

An IRB Authorization Agreement is required for research ceded to an external IRB other than those listed on the last page. See HRPP policy Research Performance Sites and Collaborative Off-Site Research or contact ORRP for more information.

All fields marked with an * are required.

Specify the external IRB that will provide review.*

Ohio Community College IRB

External Investigator

Name (Last, First, MI)*

Evans, Jessica

Email*

evans.309@osu.edu

Degree*

MHA

Phone*

614-292-9832

External IRB Contact

Name (Last, First, MI)*

Evans, Jessica
Buck-IRB Considerations

OSU Relying on External IRB
“Short” BuckIRB Application

Next steps

• Upload a copy of the IRB approval and/or IRB application form from the external institution as well as the protocol and any other documents relevant to Ohio State’s participation
• ORRP will reach out to the external IRB when your application is received
IRB Agreements
IRB Agreements

Important notes

• Contact OSU IRB to determine if a master agreement with the External IRB already exists
• Contact OSU IRB early if a new central IRB Agreement is needed (takes time)
• New External IRB IAA templates need OSU legal review (takes time)
• IRB staff will draft an IAA using an approved OSU template, or fill in OSU info on External IRB template

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<tbody>
<tr>
<td><strong>Institution Providing IRB Review</strong> (Institution of Record)</td>
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<tr>
<td><strong>IRB of Record Registration #</strong></td>
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<tr>
<td><strong>IRB of Record Federally Authorized (FAWA)</strong></td>
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<tr>
<td><strong>IRB of Record Federally Authorized (FAWA)</strong></td>
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<tr>
<td><strong>Signature</strong></td>
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<td><strong>Date</strong></td>
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**Signature of IRB Official of the IRB of Record**

| **Name** | |
| **Title** | |
| **Position** | |
| **Address** | |
| **City** | |
| **State** | |
| **Zip** | |
| **Phone** | |
| **Fax** | |
| **Email** | |

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| **Phone** | |
| **Fax** | |
| **Email** | |
An external collaborator is an individual investigator if:

- Not a faculty, student or staff of OSU
- May be conducting research activities outside of OSU
- Not acting as an employee or agent of ANY institution or
- Acting as an employee or agent of a non-assured institution (no FWA#, likely no IRB)

Examples: former student, volunteer, consultant/ self-employed, local business/clinic, international researcher, survey firm
Individual Investigator Agreement (IIA)

To obtain an IIA for an external collaborator
• Upload individual’s CV in Buck-IRB with an Initial submission or Amendment
• Eligibility for IIA is determined during IRB screening
• IIA template is prepared and sent by IRB staff to the PI for signatures
Example Individual Investigator Agreement template

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**Individual Investigator Agreement**

Name of Institution with the Federalwide Assurance (FWA): The Ohio State University

Applicable FWA #: 00006378

Research Covered by this Agreement:

Protocol #: Title:

Individual Investigator’s Name:

1. I have reviewed: 1) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research at [http://www.fhi.org/ethics/humanethics/index.html](http://www.fhi.org/ethics/humanethics/index.html); 2) the U.S. Department of Health and Human Services regulations for the protection of human subjects at 45 CFR part 46 (found at [http://www.hhs.gov/ohrp/humansubjects/index.html](http://www.hhs.gov/ohrp/humansubjects/index.html)), 3) the terms of Ohio State University’s Federalwide Assurance (found at [http://osuethics.osu.edu/ehs/index.html](http://osuethics.osu.edu/ehs/index.html)); and 4) the relevant Ohio State institutional policies and procedures for the protection of human subjects (found at [http://www.osu.edu/ethics/irb/index.html](http://www.osu.edu/ethics/irb/index.html)).

2. I understand and accept responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement. I also agree to comply with any other applicable federal, international, state, and local laws, regulations, and policies that I am aware of, which provide additional protection for human subjects participating in research conducted under this Agreement.

3. I agree to abide by any determinations of the Ohio State University’s Institutional Review Boards (IRBs) designated under the above FWA to review the research conducted under this Agreement, and will accept the final authority and decisions of the IRBs, including but not limited to directives to terminate participation in designated research activities.

4. I agree to complete the CITI Basic Human Research Course required by Ohio State and its IRB to participate in the research covered under this Agreement. The CITI Basic Human Research Course is available at [http://osu.citiprograms.org](http://osu.citiprograms.org).

5. I agree to promptly report any proposed changes in the research conducted under this Agreement to the Ohio State Principal Investigator and to the IRB. I also agree not to make changes in the research without prior IRB review and approval, except unless necessary to eliminate apparent immediate hazards to subjects.

6. I agree to immediately report any unanticipated problems involving risks to subjects or others in research covered under this Agreement to the Ohio State Principal Investigator and to the IRB.

7. I will obtain, document, and maintain records of informed consent for each subject or each subject’s legally authorized representative as required under IRB regulations and as required by the IRB.

---

Signature: Date:

Principal Investigator Name: Date:

Chair Name: Date:

Dean Name: Date:

FWA Institutional Official Name: Date:

Title: Senior Associate Vice President for Research
Individual Investigators

Individual Investigators (IIA) are required to have OSU CITI training and Conflict of Interest (eCOI)

Steps for external collaborator to access OSU CITI / eCOI
• Acquire an Ohio State guest email account from orhelpdesk@osu.edu (or call (614) 688-8288)
Individual Investigators

Individual Investigators (IIA) are required to have OSU CITI training and Conflict of Interest (eCOI)

- The researcher registers for CITI training using OSU guest email address
- Instructions here: http://orrp.osu.edu/irb/training-requirements/citi/citiinstructions/
- To access CITI, log on http://go.osu.edu/citi
Individual Investigators

Individual Investigators (IIA) are required to have OSU CITI training and Conflict of Interest (eCOI)

- eCOI disclosure will also need to be completed by the external researcher using their guest email. Log on at: http://orc.osu.edu/regulations-policies/coi/ecoii/
Master IRB Agreements

Consortia

- CReATe (via U of South Florida IRB)
- Jaeb Center for Health Research Foundation
- MARCH (Midwest Area Research Consortium for Health)
- Northeast ALS Consortium (NEALS)-via Partners IRB
- NeuroNEXT Consortium-via Partners IRB
- PCORI LHSNet-via Mayo Clinic IRB
- PETAL cIRB-via Vanderbilt IRB
- StrokeNet-via University of Cincinnati IRB
Master IRB Agreements

Commercial / Government IRBs
- Western IRB (WIRB)
- Quorum IRB
- NCI CIRB - National Cancer Institute

Academic Institutions
- Nationwide Children’s Hospital
- Ohio CTSA (8 Ohio Institutions & hospitals)
- SMART IRB - National Reliance with 167+ Participating Institutions
OSU is a SMART IRB participating institution

- A national reliance agreement signed by 169+ institutions and growing.

“Designed to harmonize and streamline the IRB review process for multisite studies by using a single agreement and a process to designate and document the IRB of Record”

For more information about SMART IRB go to: https://smartirb.org/about-us/index.html
FAQs, References and Who to Contact

ORRP Website – Frequently Asked Questions:
http://orrp.osu.edu/irb/irb-faqs/

OHRP Guidance:

NIH Policy on the Use of a single IRB for Multi-Site Research:
FAQs, References and Who to Contact

IRB General assistance:
phone: 614-688-8457
press 2 for collaborative research, IRB agreements questions
email: IRBInfo@osu.edu

IRB Reliance and Investigator Agreement help:
Jessica Evans, MHA, CHRC
Office of Responsible Research Practices
1960 Kenny Road, 3rd Floor
email: evans.309@osu.edu and IRBAgreements@osu.edu
direct phone: 614-292-9832
Upcoming Education Sessions

The Informed Consent Process
• April 18th at 8 am
• 620 Prior Health Sciences Library

Waivers of Informed Consent
• May 16th at 8 am
• 620 Prior Health Sciences Library
Upcoming Education Sessions

IRB Process Overview
• June 20th at 8 am
• 620 Prior Health Sciences Library

Amendments and Buck-IRB
• July 18th at 8 am
• 620 Prior Health Sciences Library
Reminders

• Sign the registration list
• Complete the session evaluation
Questions?

IRB APPROVED MY RESEARCH PROJECT

FIRST TRY