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

Jessica Evans, MHA, CHRC, CIP
Office of Responsible Research Practices
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Workshop Overview

- Regulatory context
- Definitions
- IRB reliance models-examples
- BuckIRB and Agreements “How to…”
- SMART IRB navigation
- Current External IRB Relationships
The Regulations are Changing
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
OSU Active Protocol Data Summary
June 2017

Who is Reviewing OSU Research?

<table>
<thead>
<tr>
<th>Board Name</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Cancer Institute Central IRB (CIRB) (Y)</td>
<td>122</td>
</tr>
<tr>
<td>Nationwide Children's Hospital IRB (N)</td>
<td>125</td>
</tr>
<tr>
<td>Ohio CTSA Consortium (X)</td>
<td>4</td>
</tr>
<tr>
<td>Ohio State IRB Behavioral IRB (B)</td>
<td>1367</td>
</tr>
<tr>
<td>Ohio State IRB Biomedical IRB (H)</td>
<td>1571</td>
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<tr>
<td>Ohio State IRB Cancer IRB (C)</td>
<td>891</td>
</tr>
<tr>
<td>Other external IRB (X)</td>
<td>97</td>
</tr>
<tr>
<td>Western IRB (WIRB) (W)</td>
<td>686</td>
</tr>
<tr>
<td>Grand Total</td>
<td>4863</td>
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</tbody>
</table>
OSU Active Protocol Data Summary
June 2017

INTERNAL VS CEDEd REVIEW

External IRBs 21%
Ohio State IRBs 79%

Ohio State Board(s) = 3829/ External Boards Ceded Review=1034
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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</thead>
<tbody>
<tr>
<td>OSU IRB Reviews</td>
<td>External IRB Reviews</td>
<td>None</td>
</tr>
<tr>
<td>OSU IRB Reviews</td>
<td>External Collaborator Relies on OSU IRB</td>
<td>IAA or IIA</td>
</tr>
<tr>
<td>OSU IRB Relies on External Collaborator’s IRB</td>
<td>External IRB Reviews</td>
<td>IAA</td>
</tr>
</tbody>
</table>
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 (e.g., per the NIH policy)
OSU IRB reviews (IRB of Record)

**IRB of Record**-reviews, approves, and 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)-industry-sponsored clinical trials
• Sponsor-mandated central IRB (e.g., 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
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

• Human Subject Radiation Committee (HSRC)
• Institutional Biosafety Committee (IBC)
• Maternal Fetal Welfare Committee
• Cancer Scientific Review Committee (CSRC)
IRB Review Models

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, and HIPAA
Buck-IRB

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

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

In Buck-IRB 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
Uploaded by Eric Tesk on 03/02/17
Buck-IRB Considerations

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

In Buck-IRB 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](mailto:irbinfo@osu.edu) or 614-688-8457 for more information.

All fields marked with an "*" are required.

### EXTERNAL COLLABORATORS

**Key Personnel - Jessica Evans**

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

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

In Buck-IRB 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” Buck-IRB 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
- [x] 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” Buck-IRB 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 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” Buck-IRB 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” Buck-IRB 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 the 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


Institution Providing IRB Review (IRB of Record):
The Ohio State University

IRB of Record Registration #:
IRB0000485

IRB of Record Federalwide Assurance # (FWA):
FWA0000578

Relaying Institution:

Relaying Institution’s Federalwide Assurance #:

The officials signing below agree that the designated IRB of Record may rely on the designated IRB of Record for review and continuing oversight of its human subjects research described below.

This agreement is limited to the following specific protocol(s):

Name of Research Project:
OSU#:

Funding Agency (Award Number):

Point of Contact:

Ohio State Primary Investigator:

Ohio State IRB Point of Contact:
Jessica Evans, MHA
614-292-9832
Diana fares@osu.edu

Relaying Institution Co-Investigator:

Relaying Institution IRB Point of Contact:

The review performed by The Ohio State University will meet the human subject protection requirements of the relaying institution’s OHRP-approved FWA. The IRB at The Ohio State may serve as the IRB’s privacy board as necessary. The IRB at The Ohio State University will follow standard procedures for reporting its findings and actions to appropriate officials at the relaying institution. Relevant minutes of IRB meetings will be made available to the relaying institution upon request. The relaying institution remains responsible for ensuring compliance with the IRB’s determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official of Relaying Institution:

[Signature]

Date

Signature of Signatory Official of the Ohio State University (IRB of Records):

[Signature]

Date
Individual Investigator Agreement (IIA)

An external collaborator is an **individual investigator** if:
- Not a faculty, student, or staff of Ohio State
- 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 Federalwide Assurance #, 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
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: [http://orrp.osu.edu/irb/training-requirements/citi/citiinstructions/](http://orrp.osu.edu/irb/training-requirements/citi/citiinstructions/)

- To access CITI, log on [http://go.osu.edu/citi](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://go.osu.edu/coi
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 250+ participating institutions
OSU is a SMART IRB participating institution

- A national reliance agreement signed by 250+ 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”
# The Reliance System Is...

<table>
<thead>
<tr>
<th>For Investigators</th>
<th>For Institutions</th>
</tr>
</thead>
<tbody>
<tr>
<td>(or their designees)</td>
<td>A platform to review reliance requests and determine and record appropriate reliance arrangements for each study</td>
</tr>
<tr>
<td>A centralized mechanism to request single IRB review for their studies and track the status of those requests</td>
<td></td>
</tr>
</tbody>
</table>

# The Reliance System Is NOT...

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</thead>
<tbody>
<tr>
<td>A mechanism to submit an application for IRB review and approval</td>
<td>A document management system</td>
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</table>
Funded by the NIH Clinical and Translational Science Awards (CTSA) Program grant number UL1TR001102-04S1

Learn more at smartirb.org
FAQs and References

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:
Who to Contact

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

IRB reliance and investigator agreement help:
Jessica Evans, MHA, CHRC, CIP
Office of Responsible Research Practices
1960 Kenny Road, 3rd Floor
email: evans.309@osu.edu and IRBAgreements@osu.edu
direct phone: 614-292-9832
Questions?

IRB APPROVED MY RESEARCH PROJECT

FIRST TRY