THE OHIO STATE UNIVERSITY

# IRB Reliance Agreements

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# IRB Reliance Agreements: External IRB review, sIRB of Record, Ceded Reviews, Individual Investigators

**Short Summary:** This workshop provides a description of possible IRB reliance models for researchers working with external partners. IRB reliance models include:

- Single IRB (sIRB) of Record
- Ceded Reviews
- Central IRBs
- Individual Investigator Agreements

Descriptions are provided for obtaining Institutional Authorization Agreements (IAAs) and Individual Investigator Agreements (IIAs), and how to navigate the associated Buck-IRB submission processes

# Important Terminology

- **Ceded Review** - an IRB reliance model in which one or more participating institutions transfers IRB review and oversight authority to, and relies on another participating institution's IRB, that accepts IRB review and oversight responsibility

- **Central IRB (cIRB**) – a single IRB that may or may not be affiliated with an institution, which has been granted authority to oversee research of some or all participating sites of a multi-site study

## Important Terminology (Cont.)

- **Individual Investigator Agreement** - a written agreement between an institution and a collaborating external investigator who will be engaged in non-exempt human subjects research. It describes each party's responsibilities for research conduct and oversight

- **IRB Authorization Agreement** - a written agreement between institutions defining each institution's responsibilities for IRB review and research oversight

# Important Terminology (Cont.)

- **IRB of Record** - A lead IRB has agreed to assume authority for IRB review and oversight for at least one other participating institution

- **Relying IRB** - The IRB that has chosen to cede review to a lead IRB (IRB of Record) for review and oversight of research in which the institution is participating

- **sIRB of Record** - defined by the National Institutes of Health (NIH) as the single IRB of Record (see also Central IRB) that has been selected to carry out the IRB review requirements at 45 CFR Part 46 for all participating sites of a multi-site study

# IRB Review Models for Researchers Working with External Partners: Every site obtains IRB review?

**Ohio State IRB review is always an option-except …**
**When is a reliance agreement appropriate?**

- Ohio State will not cede EXEMPT research
- NIH has mandated sIRB of Record effective May 25, 2017 for NIH funded non-exempt human subjects research
- Ohio State/NCH longstanding reliance agreement
- Western IRB (WIRB)
- NCI cIRB

# IRB Review Models for Researchers Working with External Partners: Ohio State is the IRB of Record

## When can Ohio State serve as the IRB of Record for non-Ohio State entities?

- When Ohio State is the prime awardee on the award/contract and/or is designated as the sIRB of Record (i.e. per the NIH Policy)
- For non-affiliated institutions when an IRB Authorization Agreement (IAA) is completed and the non-affiliated institution agrees to cede review
- For non-affiliated investigator if the individual signs an Individual Investigator Agreement (IIA) and completes Ohio State's CITI training and eCOI form

# The Central/External IRB Model

# IRB Review Models for Researchers Working with External Partners: Central/External IRB (Ohio State cedes)

**When another external IRB is the IRB of Record, Ohio State is still responsible….**

Other university-based reviews/obligations are not transferred to the external IRB and must still be satisfied:

- HIPAA
- Conflict of interest (COI)/ CITI training requirement
- Radiation safety review
- Institutional Biosafety Committee (IBC) review
- Maternal Fetal Welfare and CSRC reviews
- Informed consent template/language
  -subject injury language, HIPAA, Ohio State contacts
- Data Use /Material Transfer Agreement (DUA//MTA)

# IRB Review Models for Researchers Working with External Partners: Central/External IRB (Ohio State cedes)

## What does the central IRB (other external IRB) review cover?

- Initial Review
- Modifications (amendments)
- Continuing Reviews
- Reportable Events
- Noncompliance

# IRB Review Models for Researchers Working with External Partners: PI Responsibilities

**As the PI, it is important for you to have answers to the following questions:**

- What will the IRB of Record (or reviewing IRB) require?
- How do I submit to the IRB of Record?
- What are the IRB of Record policies?
- How will information about study progress, personnel changes, and determinations be communicated?
- Who supplies the IRB-approved documents?
- Who is notified in the event of a problem?
  -IRB of Record
  -Ohio State IRB

# IRB Review Models for Researchers Working with External Partners: PI Responsibilities

**In addition, the lead PI must know the following information for every study site:**

- Applicable state laws or local institutional policies
- Any variability in study implementation
- Names of local PIs and research coordinators
- The point of contact at each site

**Finally, the lead PI must have thorough, detailed plans in place for:**

- Training study personnel at each site
- Communication plans with each site
- Monitoring compliance with the study protocol

# Buck-IRB Considerations

**Ohio State is acting as the IRB of Record:**
**Regular Buck-IRB application to Biomedical, Cancer, or BSS**

## In Buck-IRB note:

- Location of Research
- Domestic Research Sites-Non-Ohio State Locations
- International Research Sites
- External Co-Investigators & Key Personnel
  - Organization-affiliated vs independent?
  - Activities Performed-critical for engagement determination
  - CITI/COI-affiliated vs independent?
- Is this a multi-site study?
- Is the Ohio State PI the lead investigator or is Ohio State the lead site for collaborative research?
- IAA eventually will be uploaded to “other files” section of Buck-IRB application

# Buck-IRB Considerations

**Ohio State cedes review to other external IRB:**
**Complete Short Buck-IRB Application**

- To request a ceded review, start a new application in Buck-IRB
- Select “Create a New Study” and complete the application with all relevant information as requested
- Select “other external IRB”
- 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

# How to Obtain an Institutional Authorization Agreement (IAA)

## Key steps in establishing a Central/External IRB- the Reliance Agreement. How is it obtained?

- Contact ORRP to determine if a master agreement is in effect
- Contact ORRP early if the use of a central IRB is possible/likely
- It takes time for institutions to draft, review, negotiate, and approve a new reliance agreement

# How to Obtain an Individual Investigator Agreement (IIA)

**Key steps in obtaining approval for external individual investigators to participate in Ohio State research**

- To obtain the IIA document you may upload the individual's CV directly with your protocol or amendment submission in Buck-IRB. The individual's CV will be forwarded and the IIA process initiated during the IRB screening process

- An agreement will be prepared and sent to the principal investigator who is responsible for routing the IIA for signature by: the individual investigator, principal investigator, and the Ohio State department chair and dean

# How to Obtain an Individual Investigator Agreement (IIA)

## How to obtain access to CITI training and Conflict of Interest (COI) for external individual investigators:

**There are two steps for the external researcher to access Ohio State CITI coursework as follows:**

- Acquire an Ohio State guest account through the Office of Research Help Desk at orhelpdesk@osu.edu or (614) 688-8288.
- The researcher will then need to register and take the CITI training using his/her new Ohio State guest account. Instructions for new CITI users are located here: http://orrp.osu.edu/irb/training-requirements/citi/citiinstructions/ To access CITI, log on at http://go.osu.edu/citi

**An online COI disclosure will also need to be completed by the external researcher using their new guest account. Log on at: http://orc.osu.edu/regulations-policies/coi/ecoi/**

# FAQs, References, and Who to Contact

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

**OHRP Guidance:** http://www.hhs.gov/ohrp/regulations-and-policy/guidance/extension-of-institutional-fwa-via-individual-investigator-agreement/index.html#

**NIH Policy on the Use of a single IRB for Multi-Site Research:**
http://osp.od.nih.gov/sites/default/files/NIH_sIRB_Policy_Multi_site_Research_UPDATED2016.pdf

# FAQs, References, and Who to Contact

**IRB General assistance:**

phone: 614-688-8457
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


IRB APPROVED MY RESEARCH PROJECT
FIRST TRY

# Questions?


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