Let’s Work Together:
IRB Oversight of Collaborative Research
Part 2

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Streaming attendees: Access handouts & session materials at http://go.osu.edu/BaV7
Session Objectives

• Review external agreement requirements and types of reliance agreements
• Introduce & practice using tip sheets and collaborative research tools
• Discuss Buck-IRB application sections and documents required for collaborative research
Scope & Purpose

Submission requirements for collaborative research reviewed by Ohio State’s IRBs (i.e., not ceded)

- More complete submissions → faster screening → faster approval
- ORRP staff use the same tools
Part 1: What is collaborative research?
Collaborative Research In a Nutshell:

Engaged + External Individual/Institution = IRB Oversight e.g., agreement
Engagement defined

1. Collaborator (individual/institution):
   • Intervenes or interacts with living individuals (e.g., to collect data or obtain consent)
   OR
   • Obtains/releases/accesses individually identifiable private information or specimens as part of the same project conducted at Ohio State.

2. Institution is federal grant primary awardee
   • Regardless of whether human subjects research is conducted at that site
We’re engaged! Now what?

IRB oversight must be documented for all collaborators:

- **Independent researcher**
  - **Individual Investigator Agreement (IIA)**

- **Institution: Local IRB review**
  - No agreement; External IRB approval

- **Institution: No local IRB review**

*Other terms: Reliance agreement, collaborative research agreement*
Review Models: IRB Oversight Documentation

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

IRB oversight: 
Rural hospital’s IRB 
IRB approval letter

Ohio State’s IRB

Ohio State’s IRB
Independent Investigator Agreement (IIA)
Part 2: Determining engagement
Common Examples

Engaged activities

- Actively recruits subjects
- Directly obtains participant consent
- Administers investigational therapy (e.g., study drug)
- Collects identifiable participant data
- Assists with analysis of identifiable data set
Common Examples

Non-engaged activities

- Forwards recruitment materials or posts flyers on behalf of study team (i.e., no active recruitment)
- Allows researchers to recruit for/conduct research in classroom
- Provides commercial service (3 criteria)
  - *e.g.*, interview transcription; *X-rays performed at radiology clinic*
- Receives, provides, and/or analyzes de-identified materials ONLY
- Releases identifiable materials from an external repository
Engagement Determination Tools:

1. Decision tree (handout)

2. Interactive PowerPoint Tool: http://go.osu.edu/HSengagement

Activity 1: Determining engagement

- Complete the quiz using the decision tree tool
- Be prepared to share your answers!

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Part 3: Collaborative research in Buck-IRB
Tools:

1. Collaborative Research Scenarios
   Decision Tree (handout)

2. Buck-IRB cheat sheet (handout)
   • Cover 8 common scenarios
   • Range: non-engaged sites to multi-site, single IRB of record studies

3. Buck-IRB screenshots (online)

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Remember…

Multiple scenarios may apply to any given study!
Scenario 1

*External personnel involved in research but not engaged in human subjects activities*

Common example:

- Coded dataset (without code key) will be shared with external collaborators, who will assist with analysis

Submission requirements:

- *No reliance agreement required*
- This collaboration does not need to be reflected in the application or study documents
Scenario 2

*Ohio State researchers conduct research at non-engaged site*

Common example:

- Observation/research at local schools

Submission requirements:

- *No reliance agreement required*
- Letter of Support from non-engaged site
- Buck-IRB application form
Scenario 3

*Multi-site: external institution is primary awardee of federal funds but not conducting human subjects research; Ohio State is IRB of record*

Common example:
- Company creates device, receives federal grant, subcontracts Ohio State to conduct clinical trial

Submission requirements:
- Grant application
- Ohio State ICF & HIPAA (if applicable)
- Buck-IRB application form
Scenario 4

Independent investigator is engaged in Ohio State research

Common example:

• Visiting Scholar

Submission requirements:

• Individual Investigator Agreement (IIA) – ORRP will facilitate
• Individual must have Ohio State guest account to complete CITI human subjects protection & RCR trainings, annual COI disclosure
• Individual’s CV or resume
• Letter of Support (if applicable)
• Buck-IRB application form
Scenario 5

Multi-site: Ohio State is lead site but not IRB of record for any sub-site

Submission requirements:

• *No reliance agreement required*
• External IRB approval(s) from sub-site(s)
• Ohio State ICF & HIPAA (if applicable)
• Buck-IRB application form
Scenario 6

Multi-site: Ohio State is not lead site & not IRB of record for any sub-site

Submission requirements:
• No reliance agreement required
• Lead site IRB approval
• Ohio State ICF & HIPAA (if applicable)
• Buck-IRB application form
Scenario 7

Multi-site: Ohio State is IRB of record for one or more sites; subjects will be enrolled at Ohio State only

Submission requirements:

- IAA for each site ceding review to Ohio State – ORRP will facilitate
- Ohio State ICF & HIPAA (if applicable)
- Buck-IRB application form
Scenario 8 (single IRB of record/sIRB)

Multi-site: Ohio State is IRB of record for one or more sites; subjects will be enrolled at sub-sites

Submission requirements:

• IAA for each site ceding review to Ohio State – ORRP will facilitate
• Ohio State ICF & HIPAA (if applicable)
• Local Context Form(s)
• Institutional Profile Form(s)
• Site-specific documents (e.g., sub-site ICF, flyers)
• Buck-IRB application form
Activity 2: Collaborative research scenarios

• Read Supplemental Questions description
• Use decision tree and cheat sheet to determine which scenario applies
• Be prepared to share answers:
  • Screening scenario #
  • Buck-IRB application pages
  • Documents required for submission

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Collaborative Research Workflow

**Identify collaborator(s)**

**Determine engagement (use flowchart)**

**Complete Buck-IRB application (use flowchart)**

- **Reliance Team drafts agreement**
  - **Route submission to Reliance Team**
  - **Confirm external engagement & screen for consistency**

- **Agreement routed for signatures**
  - **Reliance Team finalizes/uploads agreement**
  - **Screener forwards for IRB review**
Let’s Work Together: IRB Oversight of Collaborative Research – Part 1

• Recorded session: http://go.osu.edu/BaV5

Collaborative Research Office Hours

• Tuesdays, 12:30 – 4:30 p.m.
• Prior Hall, Room 259

FAQs: http://orrp.osu.edu/article-categories/human-subjects/

Agreements inbox: IRBAgreements@osu.edu

OHRP: Determining when institutions are engaged in research (2009)
OHRP FWA lookup tool

HRPP Policies
http://orrp.osu.edu/irb/osuirbpolicies/hrpppolicies/

HRPP Glossary
http://orrp.osu.edu/irb/osuirbpolicies/hrppglossary/