Session Objectives

- Provide overview of Buck-IRB functionality
- Identify documents that typically accompany a submission
- Discuss common pitfalls and tips for successful submission
- Walk through initial application for medical research
Session Scope
IRB Initial Application
IRB Approval Criteria

45 CFR §46.111 (Common Rule)

- Risks minimized
- Risk: benefit reasonable
- Equitable selection of subjects
- Consent documented or waived
- Data & safety monitoring
- Privacy & confidentiality
- Add’l safeguards*

*when appropriate
Methods of Review

Expedited
- Minimal Risk
- Fits one or more expedited categories

Convened
- > Minimal risk
- Doesn’t fit exp. category
- Risk level uncertain
IRB Application Structure

**Basic Info**
- Type of review
- Location
- Personnel

**What**
- Purpose
- Methods/activities
- Duration

**Who**
- Subject pool
- Accrual goal
- Recruit

**Consent/HIPAA**
- Process
- Forms
- Waivers

**Risk/benefit**
- Subject-specific
- Broader impacts
- Monitoring
Buck-IRB Functionality

• Supported browsers

• PI holds all the cards
• Anyone on the study team can work on the application

• Study team reminders

User Registration  
http://go.osu.edu/orregister

Conflict of Interest, CITI/RCR training
http://go.osu.edu/coi
http://go.osu.edu/citi
http://orc.osu.edu/regulations-policies/rcr/
Buck-IRB Functionality

- Initial app = basis of all subsequent submissions
- Tools
  - Look-up tools
  - Upload boxes
- Smart form: branching questions
Application Tips
#1 Use ORRP Resources

- Templates: consent, assent, parent permission, and HIPAA
- Sample research documents
- Info on special topics
- General educational information
- Recorded sessions

Explore the ORRP website: [http://orrp.osu.edu/](http://orrp.osu.edu/)
#2 Prepare documents

- Protocol
- Consent/HIPAA authorization form(s)
- Data collection form(s)
- Instruments
- Ancillary review docs (e.g., CSRC, IBC)
- Drug/device information (e.g., IND documentation, investigator’s brochures)
- Grant application – full application materials
- Recruitment materials, handouts – anything the subject might see
#2 Prepare documents

- Upload boxes appear throughout application form
  - Example: consent document(s) uploaded on Informed Consent Process page

- Individual file for each document

- Multiple cohorts? Label docs accordingly

- Refer to ORRP guidance/templates
  
  http://orrp.osu.edu/irb/investigator-guidance/
#3 Read the Instructions

**Number of Participants**

The number of participants is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are accessed, etc.) even if all do not prove to be eligible or complete the study. The total number of research participants may be increased only with prior IRB approval.

All fields marked with an * are required.

Provide the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking Ohio State University approval. *

Example: 15 healthy controls, 15 patients, 200 students, 30 teachers.
You have entered 0 of 500 characters.
#4 Answer the Prompt

- Questions designed to elicit specific info
- Don’t duplicate info provided elsewhere in Buck-IRB
- Multiple arms/cohorts? Differentiate!
- Avoid copying directly from protocol or consent form
#5 Check for Consistency

**Common Discrepancies**

- Access/use of PHI
- Risk level
- Consent by LAR
- Participant identification/recruitment
#5 Check for Consistency

### Key Personnel - Jessica Mayercin-Johnson

**Contact Information**
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- mayercin-johnson.1@osu.edu
- 614-688-1059

**Academic Information**
- IRB Protocol Analyst
- Responsible Research Practices (40260)
- Office of Academic Affairs (42000)

**Activities Performed**
- Protocol development/study design, Recruitment, Reporting results, Maintain regulatory documentation,
- **Access participant Protected Health Information (PHI)**

**CITI**
- ✔️ Expires 01/28/2019

**COI**
- ⚠️ Incomplete

**GCP**
- ✔️ Completed 01/29/2016

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Is individually identifiable Protected Health Information (PHI) subject to the [HIPAA Privacy Rule](https://www.hhs.gov/hipaa/) requirements to be accessed, used, or disclosed in the research study?*

- Yes
- ☠️ No
Upfront effort

Faster approval

Easier amendments
Buck-IRB Demonstration:

• How to submit an application for new research
• Submission documents/upload locations
• Quirks of Buck-IRB

https://orwebtst02.rf.ohio-state.edu/buck-irb/
IRB Application Structure

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Key Takeaways

Reflect on the materials thus far & complete 1-2 of the following sentence stems:

- I learned (or re-learned)…
- I realized…
- I was surprised…
- I wonder…
- I hope…
- I will apply…
- I will implement…
Summary & reminders

- Provide all requested information
- Upload needed documents
- Use available resources/call ORRP with questions
- Obtain approval before beginning activity
Time to Approval – Initial Review

<table>
<thead>
<tr>
<th>Biomedical Sciences IRB</th>
<th>Cancer IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Expedited Review</strong></td>
<td><strong>Convened Review</strong></td>
</tr>
<tr>
<td>31 day(s)</td>
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<td><strong>Convened Review</strong></td>
</tr>
<tr>
<td>34 day(s)</td>
<td>65 day(s)</td>
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*Tip: Access Time to Approval info any time by clicking the hourglass icon at the top of the page in Buck-IRB!*

*Information accurate as of 03/04/19*
Contact Us!

- ORRP Website: [http://orrp.osu.edu/contact/](http://orrp.osu.edu/contact/)

- Erin Odor: odor.3@osu.edu
  614-688-1332
Questions