IRB Amendments and Buck-IRB

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Session Objectives

• Describe the amendment process
• Review relevant HRPP policies and regulations
• Provide guidance and tips on amendment submission via Buck-IRB
• Explain how to expedite the amendment screening and review processes
Amendment:

A request to make changes to IRB-approved research that requires IRB review and approval
Federal Regulations for Amendments:

- FDA 21 CFR 56.108 states that “an IRB should ensure that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent and immediate hazard.”

- OHRP 45 CFR 46.103 “prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.”
Buck-IRB Types of Amendments

1. Personnel Change
2. Standard Amendment
Personnel Change Amendment

Expedited process reserved for addition and removal of current OSU students or paid staff when document updates are not required & for removal only of external collaborators where document updates are not required
Tips for Personnel Amendments

• **Select activities** that each *individual will actually perform* and is authorized to complete based on study approvals

• **Visiting Scholars, OSUP** staff should be added by way of standard amendment as they *require external agreements*

• **Additional contacts** can be added by the study team; *IRB review is not required*

• Personnel change requests *cannot* be used to make principal investigator changes or to add external collaborators
Standard Amendment: all other changes

- External collaborators
- Recruitment
- Funding
- Research Methods
- Addition of instruments
- Consent revisions
- Etc…
Types of Review

1. **Expedited**: minor changes, those that in the judgement of the IRB do not affect assessment of the risks and benefits of the study.

Examples:

- minor change in study documents: formatting, contact information
- clarifications in the protocol, consent language that do not introduce new procedures or information
- Increase number of participants
Types of Review (cont.)

2. **Convened**: amendments that do not meet expedited review criteria are reviewed at a convened IRB meeting.
Supplemental Questions

At the beginning of the application, you indicated changes to the research in the following areas:

- Study Personnel
- Duration
- Number of Participants
- Incentives to Participate
- Risks, Harms, and Discomforts

Be as specific as possible when describing changes. A rationale must be provided for each change made in the application form and/or uploaded documents. If the currently approved information for this aspect of the research is not shown, that information should also be provided. Note: This should be necessary only for migrated studies. Clearly distinguish what is currently approved from the proposed change(s).

All fields marked with an * are required.

Describe the change(s) to the research and provide a rationale for each change.*

You have entered 0 of 5000 characters.

A rationale summary must be provided for all changes made in the application form pages as well as uploaded documents.

Will there be any changes in the risk(s) to participants?*

Yes  |  No

Will there be any change in the benefit(s) to the participants?*

Yes  |  No

Compensation is not to be considered a benefit.

Could the proposed change(s) affect participants' willingness to take part in the research?*

Yes  |  No
You are submitting an amendment to delete questions from an approved survey instrument, what method of review will this amendment most likely go through?

A. Expedited
B. Convened
You are submitting an amendment to revise eligibility criteria (ex. accepting subject with class II cardiac disease, previously class I only). What method of IRB review would this amendment most likely go through?

A. Expedited

B. Convened
You are removing study personnel and the individual is listed on the research protocol. What type of submission is appropriate?

A. Personnel amendment

B. Standard amendment
You are adding a student enrolled at another university as research staff so they can help with the research project and get research experience during summer break. What type of IRB submission is appropriate?

A. Personnel amendment
B. Standard amendment
Tips for Amendments

- **Answer all** Buck-IRB application questions to reflect the entire study and not just the proposed changes; the application should be updated as the study evolves.
- **Reference the study application** to identify all sections that may require revision with the amendment.
- When making revisions to the application, **consider whether documents** also need to be updated. Provide clean and tracked copies of all documents being revised.
- When submitting an initial study, only provide information requested in the question; **do not provide extra information** that is answered elsewhere.
Buck-IRB Demonstration:

- How to submit an amendment
- Submission documents/upload locations
- Quirks of Buck-IRB
- Migrated studies
What requires revision?

A study team would like to change the ages of their participants from those aged 25 and over to those aged 18 and over.

If the study was completed as follows, note all areas on the following slides that would need to be revised in order to make this change.

Consider: How could this application have been completed to make amendments easier?
What requires revision? (cont.)

Summary, Background, and Objectives

Summarize the proposed research using non-technical language that can be readily understood by someone outside the discipline. Explain briefly the research design, procedures to be used, risks and anticipated benefits, and the importance of the knowledge that may reasonably be expected to result. Use complete sentences (limit 300 words).

For this study, 65 adults aged 25 and older who play the guitar professionally will answer questions about their guitar experience. They will participate in one interview during which they will answer questions about how long they have played guitar, their work history, and why they like guitar.

Research Methods & Activities

Use the boxes provided below to provide information on all interventions and activities that are to be performed in the research. Based on the selections chosen in the list of activities and components, completion of additional form pages may be necessary to provide required information for IRB review.

Identify and describe all interventions and interactions that are to be performed solely for the research study. Distinguish research (i.e., experimental) activities from non-research activities.

65 adults aged 25 and older will engage in one interview.
What requires revision?(cont.)

**Participant Population**

Specify the age(s) of the individuals who may be included in the research:

- 25 and older

Specify the participant population(s). Check all participant groups that apply:

- Adults
- Adults with decisional impairment
- Children
- Neonates (uncertain viability/nonviable)
- Non-English speaking
- Pregnant women/fetuses – only if pregnant women will be intentionally recruited and/or studied
- Prisoners
- Student research pools (e.g., psychology, linguistics)
- Unknown (e.g., research using secondary data/specimens, non-targeted surveys, program protocols)

Describe the characteristics of the proposed participants, and explain how the nature of the research requires/justifies their inclusion:

- Aged 25 and older and play guitar professionally

**Consider:** If this application only contained the required information for each question, then what would the study team need to do to submit this same amendment?
In which situation below is a change to the protocol permitted without prior IRB approval:

A. Minor changes, removing names from study documents
B. Format changes to a research brochure
C. To eliminate apparent immediate hazard to a subject
Jessica is submitting an amendment to add personnel, update participant numbers, and revise eligibility criteria. Which description is the most appropriate for the supplemental questions page (describe changes)?

A. Personnel, participant numbers, and eligibility are being revised

B. See summary of changes document

C. Three study personnel were added. Participant numbers increased from 5 to 10 to accommodate screen fails. The eligibility criteria was revised to include healthy volunteers, and the protocol and informed consent form were revised with these changes.
You need to update the study contact on recruitment materials, as several study personnel could be points of contact. Which method below would be recommended?

A. List all personnel on one document with contact information.
B. Create separate documents for each personnel
C. Create one document with designated areas to insert personnel name and contact information [e.g., For questions about this research, please contact (insert study personnel) at (personnel e-mail address and/or phone #).]
You have decided not to conduct the interview portion of your IRB approved study, but the interview is described in the informed consent form. What actions should be taken?

A. No action needed, proceed as planned

B. Submit an amendment to update IRB application and study documents to remove interviews, proceed once amendment has been approved

C. Mark out the interview section in the informed consent form and proceed
Summary Overview

- Provide all requested information
- Upload needed documents
- Use available resources/call ORRP with questions
- Obtain IRB approval before beginning activity
Contact Us!

- ORRP Website: http://orrp.osu.edu/contact/
- Sarah Hersch: hersch.5@osu.edu 688-1253
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