THE OHIO STATE UNIVERSITY

IRB SUBMISSION AND PRE-REVIEW

1. Overview

The IRBs must receive sufficient information from investigators to provide adequate review of proposed research and to make the determinations required by regulations for IRB approval. This policy describes the submission requirements and pre-review process for research requiring IRB review.

2. Definitions

Pre-review: The process performed by ORRP staff to determine that a submission for IRB review is complete, including the required materials and signatures, and that institutional requirements, such as completion of human subjects protection education and conflict of interest disclosure, have been met.

3. Submission Requirements: Materials

The information listed below includes materials that are to be submitted for initial or continuing review by the IRBs, for review of changes to previously approved research, and for review of event reports for ongoing research. Except as noted, submission requirements are the same for reviews performed by the convened IRBs and for reviews using expedited procedures.

A. Initial Review

1. Investigators will create the new research study (convened or expedited) in Buck-IRB (the electronic HRPP submission system) by logging in using his/her Ohio State user name (name.#) and password. The principal investigator is responsible for submitting all Buck-IRB submissions, with the exception of incomplete responses. Requests for signatures (i.e., co-investigator(s) and department chair or signatory official) will be routed electronically by email following submission. The ORRP website provides additional information regarding the Buck-IRB submission process.

2. When submitting protocols for initial review, investigators will provide all applicable information required in the Buck-IRB initial application.

3. In addition to completing the Buck-IRB application, investigators will upload the following information, as applicable, into the system:
    - Consent form(s), assent form(s), permission form(s), and verbal script(s), including translated documents
    - HIPAA research authorization form(s)
    - Data collection form(s) for investigator-initiated studies
    - Data collection form(s) involving protected health information
    - Recruitment materials (e.g., ads, flyers, telephone or other oral script, radio/TV scripts, internet solicitations)
    - Script(s) or information sheet(s), including debriefing materials

- Instruments (e.g., questionnaires or surveys to be completed by or administered to participants)
- Other committee approvals/letters of support
- Research protocol
- Complete grant application or funding proposal, when applicable
- Drug manufacturer's approved labeling/investigator's drug brochure
- Device manufacturer's approved labeling
- Other supporting documentation and/or materials.

For multi-center clinical trials supported by DHHS, the submission will also include:

- DHHS-approved sample informed consent document (if one exists)
- DHHS-approved protocol (if one exists).

B. Continuing Review

1. Investigators will create the continuing review submission (convened or expedited) in Buck-IRB by logging in using his/her Ohio State user name (name.#) and password. The specific research study can be located in the investigator's list of studies in either the active or archived (if study is expired) lists. Requests for signature (i.e., co-investigator(s), if added with submission) will be routed electronically by email following submission. The ORRP website provides additional information regarding the Buck-IRB submission process.

2. When submitting protocols for continuing review, investigators will provide all applicable information required in the Buck-IRB continuing review application.

3. In addition to completing the continuing review application, investigators will upload all previously approved documents into Buck-IRB, if not uploaded with a previous submission, and/or any documents being revised with the continuing review submission.

4. Continuing review applications cannot be submitted until all study team members (existing and those being added) have current CITI training and COI disclosures.

5. Buck-IRB continuing review and amendment applications cannot be submitted concurrently. If an amendment is pending, it must be approved or withdrawn and deleted before the continuing review option will become available in Buck-IRB.

6. The Buck-IRB continuing review application will become available in the study workspace 90 days prior to study expiration.

C. Amendments

1. Investigators will create an amendment submission in Buck-IRB by logging in using his/her Ohio State user name (name.#) and password. Requests for signatures (i.e., new principal investigator and any new co-investigator(s)) will be routed electronically by email following submission. The ORRP website provides additional information regarding the Buck-IRB submission process.

2. When submitting amendments for IRB review, investigators will provide all applicable information required in the Buck-IRB amendment application. The investigator must provide a rationale for all proposed changes.

3. In addition to completing the amendment application, investigators will upload the following information, as applicable:
   - Revised version of the document(s) being modified with proposed changes underlined (or "tracked changes") within the document(s)
   - Revised version of the document(s) being modified with proposed changes incorporated ("clean" copy) within the document(s)
   - Clean version of newly proposed document(s) being added.

4. Amendment submissions that include personnel changes cannot be submitted until all study team members (existing and those being added) have current CITI training and COI disclosures. Amendment submissions without personnel changes will not be screened for study team CITI and COI compliance by the Buck-IRB system.

5. Buck-IRB continuing review and amendment applications cannot be submitted concurrently. If a continuing review is pending, it must be approved or withdrawn and deleted before the amendment option will become available in Buck-IRB.

D. Personnel Change Requests

1. Amendments that add current Ohio State students and staff as co-investigators and key personnel or remove study personnel, but do not involve study document changes, can be submitted through a personnel change request rather than an amendment request. These changes can be made at any time, including while other submissions are pending. *Note: PI changes and external collaborator changes can be made by amendment request only.*

E. Event Reports

1. When submitting event reports for IRB review, investigators will provide all applicable information required in the Buck-IRB event report application. The investigator should describe the event in detail as directed by HRPP policy [Event Reporting – Unanticipated Problems Involving Risks to Subjects or Others, Adverse Events, and Other Problems].

2. In addition to completing the event report application, investigators will upload any supporting documents necessary to further describe or document the event.

4. Pre-review Procedures

A. Upon receipt of a submission for IRB review, ORRP staff pre-review the materials to verify whether the application is complete as described above.

B. In addition, ORRP staff members verify the following:
   - All individuals involved in the conduct of the research meet human subjects research education requirements

- All individuals involved in the conduct of the research meet any additional requirements, such as conflict of interest disclosure
- Review by any other committees where pre-review is required has been completed and documentation provided.

Submissions are not considered complete and are not forwarded for IRB review until the investigator has met all requirements for submission.

C. If an application is incomplete or clarifications are required, the principal investigator and additional contact are notified by ORRP staff. Weekly reminders are sent from the Buck-IRB system until a response is received. If no response is received within 90 days, the PI is notified that the submission will be withdrawn.

D. Submission materials that have been withdrawn and any related correspondence are retained by the Office of Responsible Research Practices in accordance with HRPP policy [IRB Recordkeeping].

5. Reviewer Assignment

Once a submission is complete, ORRP staff assign appropriate reviewer(s) from the applicable Board, and the submission is placed on the agenda of the next available IRB meeting or made available for expedited review as described in HRPP policy [Board Assignment and Reviewer Assignment for Convened Review] or [Expedited Review Procedures].

6. Applicable Regulations/Guidance

FDA Information Sheets: Frequently Asked Questions, OHRP "Guidance on Continuing Review" (11/10/10), OHRP "Guidance on Written IRB Procedures" (07/01/11), OHRP "Unanticipated Problems Involving Risks & Adverse Events Guidance" (01/15/07), 45 CFR 46.108, 45 CFR 46.109, 45 CFR 46.110, 21 CFR 56.108

7. History

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