THE OHIO STATE UNIVERSITY

SUBMISSION AND PRE-REVIEW

1. Overview

Reviewers 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 review by an Ohio State IRB (i.e., Behavioral and Social Sciences, Biomedical Sciences, or Cancer), including exempt research requiring limited IRB review. The policy also describes the requirements for submissions that qualify for administrative review, such as exempt research, annual status reports, and final study reports.

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, Responsible Conduct of Research (RCR) training, and conflict of interest (COI) disclosure, have been met.

3. Submission Requirements

The information listed below includes materials that are to be submitted for initial or continuing review by the IRBs; administrative review of annual status reports, final study reports, and exempt research; 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.

Investigators will initiate all submissions in Buck-IRB (the electronic HRPP submission system) by logging in with his/her Ohio State credentials. 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.

With the exception of final study reports (FSRs) and event reports, applications cannot be submitted until all study team members (existing and those being added, if applicable) have current CITI human subjects protection and RCR training, and COI disclosures.

Buck-IRB continuing review, annual status report, amendment, and/or final status report applications cannot be submitted concurrently for the same study. For example, if an amendment is currently in process, it must either be approved or withdrawn and deleted before the option to initiate any other submission type will appear in Buck-IRB. Event reports and personnel change requests may be submitted at any time.

A. Initial IRB Review

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

2. 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. Exempt Determinations

1. When submitting protocols for exempt determinations, investigators will provide all applicable information required in the Buck-IRB exempt application.

2. 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
    - Data collection form(s)
    - 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
- Other supporting documentation and/or materials

C. Continuing IRB Review

1. The following changes to the research may be requested at the time of continuing review:
    - Change in principal investigator
    - Addition or removal of Ohio State co-investigators and key personnel
    - Increase or reduction in the number of Ohio State-approved participants
      Note: The multi-site accrual goal can be modified only by amendment
    - Change in sponsor information, such as the addition of new funding, provided such changes do not alter the conduct of the research as described in the approved protocol
    - Minor document revisions resulting from the above changes.

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 the following, as applicable, into the system:
    - Multi-site study reports and/or study summaries issued since the previous IRB review
    - Data Safety & Monitoring Committee reports issued since the previous IRB review
    - Documents being revised with the continuing review submission. The investigators should provide a revised version of the document(s) being modified with proposed changes underlined (or "tracked changes") within the document(s), as well as a version in which proposed changes have been incorporated (“clean” copy) within the document(s).

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

D. Annual Status Reports

1. Under certain conditions, the requirements for continuing IRB review can be satisfied through the completion of a brief application confirmed by a designated ORRP staff member through an administrative review, as described in HRPP policy [Expedited Review Procedures]. The annual status report is limited to questions regarding study changes over the previous year and the current study status.

2. When submitting annual status reports, investigators will provide all applicable information required in the Buck-IRB annual status report application. No additional materials need to be submitted with the report.

3. The Buck-IRB annual status report application will become available in the study workspace 90 days prior to study expiration.

E. Amendments

1. 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.

2. 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.

F. 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 additions can be made by amendment request only.*

G. 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.

H. Final Study Reports

1. When research has been completed and investigators are no longer interacting with participants and accessing identifiable information and/or biospecimens, a final study report (FSR) must be submitted via Buck-IRB to close the study. The FSR is a brief application confirmed by a designated ORRP staff member through an administrative review.

2. When submitting FSRs, investigators will provide all applicable information required in the Buck-IRB FSR application.

3. In addition to completing the FSR application, investigators will upload any supporting documents (e.g., Data Safety & Monitoring Committee reports issued since the previous IRB review), as applicable.

4. Pre-review Procedures

A. Upon receipt of a submission, 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 for all submission types except FSRs:

- 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 required ancillary committees, as applicable, is complete and documentation has been provided.

If an application is incomplete or clarifications are required, the principal investigator and additional contact(s) are notified by ORRP staff. Submissions are not considered complete and are not forwarded for IRB or administrative review until the investigator has met all requirements for submission. If no response is received within 90 days, the PI is notified that the submission will be withdrawn.

C. 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. Review Assignment

A. Once a submission is complete, ORRP staff determine whether the submission requires review by an IRB (convened, expedited, or limited) or qualifies for administrative review by ORRP staff.

B. For submissions requiring IRB review, 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].

C. Submissions that qualify for administrative review are confirmed and processed by designated ORRP staff.

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

Issued: 04/21/2008
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