

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 IRB Protocol Analysts to determine that a submission for IRB review is complete, including the required materials, copies, 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 an OSU IRB or for review of changes to previously approved research. Except as noted, submission requirements are the same for reviews performed by the convened IRBs and for reviews using expedited procedures.

3.1 Initial Review

- A. When submitting protocols for initial review, investigators will provide all applicable information required in the application form, *Initial Review of Human Subjects Research*.
- B. In addition to the application form (and relevant appendices) investigators will submit the following information, when applicable:
 - 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) 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 participants)
 - Other committee approvals/letters of support

- Research protocol
- Complete grant application
- 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).

- C. Submissions for convened IRB review will include five collated copies of all materials. One copy must contain original signatures. Three copies are distributed to the assigned reviewers, the original is retained in the protocol file in the Office of Responsible Research Practices, and one copy is used to prepare the composite of materials distributed to all IRB members.
- D. One copy with original signatures is required for submissions undergoing expedited review.

3.2 Continuing Review

- A. When submitting protocols for continuing review, investigators will provide all applicable information required in the application form, *Continuing Review of Human Subjects Research*.
- B. In addition to the application form (and relevant appendices) investigators will submit the following information, when applicable:
- Currently approved consent form(s), assent form(s), permission form(s), and verbal script(s), including translated documents
 - HIPAA research authorization form(s)
 - Recruitment materials (e.g., ads, flyers, telephone or other oral script, radio/TV scripts, internet solicitations) if still being used
 - Script(s) or information sheet(s), including debriefing materials
 - Instruments (e.g., questionnaires or surveys completed by participants) if still being used
 - Current IRB approvals from non-OSU sites
 - Research protocol (full description of the research with changes incorporated since initial IRB approval)
 - Complete grant application (new or revised grants only)
 - Data and safety monitoring reports or multi-center clinical trial reports
 - Other supporting documentation and/or materials.

- C. Submissions for convened IRB review will include five collated copies of all materials. One copy must contain original signatures. Two copies are distributed to the assigned reviewers, the original is retained in the protocol file in ORRP, and one copy is used to prepare the composite of materials distributed to all IRB members. The unused copy is kept for any IRB member requesting the complete information provided to the assigned reviewers.
- D. One copy with original signatures is required for submissions undergoing expedited review.

3.3 Amendments

- A. When submitting amendments for IRB review, investigators will provide all applicable information required in the application form, *Amendment/Changes to Research*, including one or more of the appropriate appendices.
- B. In addition to the application form (and relevant appendices) investigators will submit the following information, when applicable:
 - Current version of the document(s) being modified
 - Proposed changes underlined (or "tracked changes") within the document(s)
 - Proposed changes incorporated ("clean" copy) within the document(s)
- C. When submitting an amendment(s) in conjunction with an application for continuing review, only the relevant appendices are required. The application form, *Amendment/Changes to Research* is not needed.
- D. Submissions for convened IRB review will include five collated copies of all materials. One copy must contain original signatures. Two copies are distributed to the assigned reviewers, the original is retained in the protocol file in ORRP, and one copy is used to prepare the composite of materials distributed to all IRB members. The unused copy is kept for any IRB member requesting the complete information provided to the assigned reviewers.
- E. One copy with original signatures is required for submissions undergoing expedited review.

4. Pre-review Procedures

- A. Upon receipt of a submission for IRB review, IRB Protocol Analysts pre-review the materials to verify whether the application is complete as described above.
- B. In addition, ORRP staff members verify the following:

- All necessary signatures are present (e.g., signatures of the Principal Investigator, Co-Investigator(s), and Department Chair or signatory official)
- 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 is notified by ORRP staff. If no response is received within 30 days, a reminder is sent, with subsequent reminders at 60 and 90 days. 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 ORRP in accordance with OSU HRPP policy [[IRB Recordkeeping](#)].

5. Reviewer Assignment

Once a submission is complete, the IRB Protocol Analyst assigns 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 OSU 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” (01/15/07), OHRP “Guidance on Written IRB Procedures” (01/15/07)