THE OHIO STATE UNIVERSITY

IRB RECORDKEEPING

LANGUAGE IN GRAY BOXES IS ONLY APPLICABLE TO STUDIES INITIALLY APPROVED ON/AFTER JANUARY 21, 2019

1. Overview

The Office of Responsible Research Practices (ORRP) maintains records relating to research, including materials submitted by investigators for IRB review (or exemption), documentation of IRB activities, and other required records, such as IRB correspondence, rosters, and policies. All records are retained in a secure manner that allows for a review of the history of IRB actions and for inspection by authorized personnel.

The purpose of this policy is to describe recordkeeping activities and record retention for ORRP and the IRBs that comply with federal regulations, local laws, and university policy.

2. Minutes of IRB Meetings

A. Convened IRB discussions and decisions are documented by ORRP staff in IRB meeting minutes, which are reviewed and approved by the applicable IRB Chair or designee (e.g., Vice Chair) chairing the meeting. The minutes of each IRB meeting include (minimally):

- Members and alternates in attendance for each action, including their representative capacities, scientific/non-scientific status, affiliation status, etc.
- Documentation regarding whether a quorum exists
- Names of any IRB members who leave the meeting due to a conflicting interest, along with the fact that a conflicting interest is the reason for the absence (as applicable)
- Actions taken by the IRB, including the number of votes for, against, or abstaining
- Separate deliberations for each action
- Basis for requiring changes in or disapproving research
- Summary of the discussion of controverted issues (if any) and their resolution
- For initial and continuing review, determination of the risk level (minimal risk/greater than minimal risk)
- For initial and continuing review, the approval period (not to exceed one year)
- Rationale for significant/non-significant risk device determinations
- Determinations required by the regulations and protocol-specific findings justifying those determinations for the following:
    - Waiver or alteration of the consent process
    - Research involving pregnant women, human fetuses, or neonates
    - Research involving prisoners
    - Research involving children
    - Research involving participants with impaired decision-making capacity

- Waiver or alteration of HIPAA research authorization determinations required by the Privacy Rule.

- Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in DHHS-approved sample consent documents (as applicable).

B. IRB determinations made by expedited review are documented in IRB records as described below and in HRPP policy [Expedited Review Procedures].

3. IRB Records

A. In addition to IRB minutes, ORRP staff maintain other IRB records relating to research, which are organized to allow a reconstruction of IRB actions. These records include, but are not limited to (as applicable):

- All documents submitted by investigators to the IRBs, including research proposals, informed consent documents, and other materials (e.g., applications) used to request IRB review and approval
- Sponsor or multi-center protocols, including DHHS-approved protocols
- DHHS-approved sample consent documents
- Relevant grant applications
- Scientific evaluations
- Investigator's brochures
- Reports of injuries to participants and other reportable events related to the research
- Progress reports submitted by investigators
- Records of continuing review activities
- Amendments to previously approved research
- Statements of significant new findings provided to participants
- All correspondence between the IRBs and investigators
- For collaborative research, documentation specifying the responsibilities that an institution and an organization operating an IRB each will take to ensure compliance with federal and state regulations and institutional policy (e.g., collaborative research agreement).

B. For initial or continuing reviews conducted by expedited procedures, records will include the following:

- Copies of all documentation submitted
- Descriptions of the actions taken by the reviewer
- Specific category(ies) permitting review by expedited procedures
- Determinations required by the regulations and protocol-specific findings justifying those determinations for the following:
  - Waiver or alteration of the consent process
  - Research involving pregnant women, human fetuses, or neonates
  - Research involving children

- Research involving prisoners
- Research involving participants with impaired decision-making capacity
- Waiver or alteration of HIPAA research authorization determinations required by the Privacy Rule.

- The rationale for conducting continuing review of research that otherwise would not require continuing review as described in the HRPP policy [Expedited and AdministrativeReview Procedures]
- The rationale for an expedited reviewer's determination that research appearing on the expedited review list in HRPP policy [Expedited and Administrative Review Procedures] is more than minimal risk
- For collaborative research, documentation specifying the responsibilities that an institution and an organization operating an IRB each will take to ensure compliance with federal and state regulations and institutional policy (e.g., collaborative research agreement).

C. For exempt research, records will include the following:

- Copies of all documentation submitted
- Any associated correspondence between investigators and ORRP staff
- Exempt determinations, including citations of the specific category(ies) justifying the exemption
- Documentation of Privacy Board determination, if applicable
- Documentation of limited IRB review, as described in the HRPP Policy [Exempt Research].

D. For activities determined by ORRP staff members not to be research involving human subjects, records will include copies of all documentation submitted and/or correspondence between investigators and ORRP staff, as well as information documenting the determinations.

E. Other ORRP/IRB records maintained by ORRP staff include (but are not limited to) the following:

- IRB rosters and membership information
- HRPP policies and procedures
- IRB Policy Committee minutes
- ORRP desk procedures
- Administrative agreements
- General IRB/ORRP correspondence (i.e., not related to specific protocols).

4. Maintenance and Retention of Records

A. The Office of Responsible Research Practices will ensure that all records are stored confidentially in a secure location.

B. Access to IRB/ORRP records is restricted to authorized Ohio State employees. IRB records are accessible for inspection and copying by representatives of the sponsor of the research, authorized representatives of federal agencies or departments, and other

authorized agents of regulatory or accrediting organizations at reasonable times and in a reasonable manner. Records (in whole or in part) will also be made available as required under the Ohio Public Records Act (ORC 149.43) and university policy for facilitating prompt access to public records (http://compliance.osu.edu/PublicRecordsPolicy.pdf).

C. All IRB/ORRP records relating to research are retained for at least three years after completion of the research or three years after cancellation, if the research is cancelled without participant enrollment. All other IRB/ORRP records described by this policy are retained for at least three years. In some cases, a longer retention period may be required by university policy or contractual agreement. Records are stored, archived, and later destroyed as advised by the Office of Legal Affairs and University Archives (https://library.osu.edu/osu-records-management/policy).

D. When electronic records and/or data are used to meet regulatory requirements for IRB recordkeeping and retention, such records and/or data will be maintained in compliance with 21 CFR 11 and applicable FDA Guidance, Part 11, Electronic Records; Electronic Signatures - Scope and Application.

5. Applicable Regulations/Guidance

21 CFR 11, 21 CFR 56.115, Pre-2018 and Final Rule (45 CFR 46.115), FDA Guidance "Part 11, Electronic Records; Electronic Signatures – Scope and Application" (08/28/03), FDA Information Sheets: Frequently Asked Questions: "IRB Records," "Written IRB Procedures: OHRP Guidance" (08/16), ORC 149.43, "The Ohio State University Public Records Policy" (11/02/18)

6. History

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