

<b>SOP: 203</b> <b>Effective Date: 08/21/2020</b>	<b>DOCUMENTATION AND RECORDS MANAGEMENT</b>	<b>Supersedes Document Dated: 07/01/2019</b>
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## 1. POLICY

The IRB's files must be maintained in a manner that contains a complete history of all IRB actions related to review and approval of a protocol, including continuing reviews, amendments, adverse event reports, and reports of non-compliance. All records regarding a submitted study (regardless of whether it is approved) must be retained by the Human Research Protection Program (HRPP) in an appropriate manner as required by regulatory requirements and/or Purdue University institutional policy.

Records must be accessible for inspection and copying by authorized representatives of the sponsor, funding department or agency, regulatory agencies, and institutional auditors at reasonable times and in a reasonable manner.

Required documents must be submitted to the appropriate funding entity as required.

These policies and procedures apply to all controlled documents used in research reviewed by the IRB.

## 2. PROCEDURES

### 2.1 Document Retention

2.1.1 Study-specific documents. Adequate documentation of the IRB's activities will be prepared, maintained, and retained in a secure location. Documents to be retained include:

- (a) Copies of all original research protocols reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by Investigators, and reports of adverse events occurring to subjects, and reported deviations from the protocol;
- (b) The rationale for an expedited reviewer's determination under 45 CFR §46.110(b)(1)(i) that research appearing on the expedited review list described in § 46.110(a) is more than minimal risk (See SOP 303: Expedited Review).
- (c) Copies of all continuing review activities, including submitted monitoring reports and site visit reports;
- (d) For all human subjects research conducted at Purdue University but reviewed by an IRB operated by another institution, Purdue University and the organization operating the other IRB shall document Purdue University's reliance on the IRB for oversight of the research. The documentation can be achieved through a written agreement between Purdue University and the IRB, as set forth in a

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multi-institutional research protocol, or by implementation of a Purdue University-wide policy providing the allocation of responsibilities between Purdue University and IRBs operated by other institutions;

- (e) Copies of correspondence between the IRB and Investigators relevant to the study risks and clarifications (e.g., phone minutes, e-mail conversations, memos to file). These documents will be utilized to document resolution of controverted issues or requested revisions of the IRB. Documents must be versioned or paginated in a manner that allows obvious evidence of reconciliation of concerns expressed by a Primary and/or Expedited Reviewer;
- (f) Review worksheets will be collected from the Primary Reviewer prior to or immediately after the fully convened meeting. This collection will be conducted by the IRB Chair, IRB Administrator, or a Protocol Analyst. Expedited or exempt review sheets will be provided to an IRB office member prior to initiating an action toward revision or approval. These documents will be retained electronically or in hard copy as needed and may be considered confidential to the IRB.
- (g) Statements of significant new findings provided to subjects; and
- (h) Reports of any complaints received from subjects.

2.1.2 Administration Documents. Adequate documentation of the HRPP and IRB's internal operations will be prepared, maintained, and retained in a secure location. Documents to be retained include:

- (a) Agendas and minutes of all IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution;
- (b) A current list of the IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications or licenses sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution, for example, full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant;

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(c) Copies of all required policies and procedures of the HRPP and IRB.

## **2.2 Duration of Retention**

- 2.2.1 The HRPP must retain all records regarding a research application (regardless of whether it is approved) for at least three (3) years.
- 2.2.2 For all applications that are approved, and the research initiated, the HRPP must retain all records regarding that research for at least three (3) years after completion of the research.
- 2.2.3 The HRPP will treat denied applications as terminated files and retain records for three (3) years after the denial of the research.
- 2.2.4 For all applications that use or obtain Protected Health Information (PHI), pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the HRPP must retain all records regarding that research for at least six (6) years after the completion of the research.

## **2.3 Manner of Retention**

Federal IRB regulations permit records to be stored either electronically or in hard copy. The Purdue University HRPP maintains documentation in electronic format, but may elect to store files in hard copy as deemed necessary.

## **2.4 Destruction of Materials**

IRB Members are required to return, destroy, and/or delete all IRB-related research protocol review material that is considered confidential and in excess of the required original documentation and appropriate controlled forms. Master files are kept on file as described in Sections 2.2 and 2.3.

## **2.5 Archiving and Destruction**

All documents and materials germane to IRB applications will be retained as described in Section 2.2. After the required retention period has elapsed, archiving policies of Purdue University will determine when such archived records may be destroyed and the method of destruction.

## **2.6 Informed Consent Documentation**

For clinical trials supported by a federal agency, a copy of the IRB-approved informed consent form must be made publicly available as described in SOP 320: Informed Consent Requirements.

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### **3. PROCESS OVERVIEW**

HRPP Support Staff will log incoming applications into the IRB electronic system. Once the application has been approved, the application/protocol folder is filed in the electronic system utilized by the HRPP office. The HRPP is responsible for maintaining complete files on all research reviewed by or submitted to the IRB and for all applicable regulatory compliance requirements.

Upon closure or termination of a protocol, files are archived within the electronic system. Any hard copy files are grouped by termination month and year and are stored for three years or six years depending on the retention requirements described in Section 2.2. If an application does not receive approval and/or the Investigator withdraws the application during the review process, it the record remains in the electronic system. Files are periodically purged after expiration of the retention period, in accordance with Purdue University policy.

In the case that either the HRPP Director or Institutional Official withhold institutional approval, the files will be retained by that official until the issue is resolved (e.g., through amendment of the protocol, withdrawal of the protocol by the Investigator, or denial of the protocol by the official).

### **4. APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46.103, 46.115

21 CFR 56.115

### **5. REFERENCES TO OTHER APPLICABLE SOPs**

This SOP affects all other SOPs.