Procedure Title: Disposition of Institutional Review Board (IRB) Records

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0) Release of FERPA Protected Data Housed in the Office of Institutional Effectiveness (OIE) for Research Purposes PNWU Information and Data Protection Policy PNWU Policy for Confidentiality of Records-Students PNWU Policy for Document Retention and Destruction and Procedure: Records Retention and Disposition Schedule		
Responsible Unit:	Office of Scholarly Activity		
Created:	06/7/2017	**Executive Lead:**	Chief Research Officer
Effective:	06/7/2017	**Revision History:**	.01 – 7/8/17; .02 - 4/1/19; .03 – 3/13/2020; .04 – 2/21/2023
Approved by:	Institutional Review Board		
Procedure Number:	120.04		
Key Words:	Destroy; Records; Disposition; Get Rid; Data; Shred Bin;		
Purpose:	To meet the responsibilities for protecting human subjects as issued by the Office for Human Research Protections (OHRP) requirement for individuals involved in the conduct or review of human subjects research at institutions holding OHRP-approved Federal Wide Assurances (FWAs)		

Process:

This SOP serves to inform all agents, offices, departments, and affiliate sites of PNWU regarding the process for managing Pacific Northwest University of Health Sciences PNWU) Institutional Review Board (IRB) Records. This document describes the essential records prepared and maintained by the PNWU Institutional Review Board.

Responsible Parties

The Office of Scholarly Activity (OSA) is responsible for:

- Monitoring compliance with this SOP.
- Posting this SOP for the PNWU community.
- Offering support to all investigators to ensure protected places are available to collect and store data.
- Disposing of all research related data (paper and/or electronic) as it relates to a specific protocol/study.

The Investigator is responsible for:

- Being a good steward of research data generated or acquired by faculty, staff, and students through the use of University facilities and resources.
- Communicating to the OSA regarding research data retention and disputation periods.

Definitions

Please reference the Glossary for complete definitions of the following terms and additional terms not listed.

- Administrative value
- Audit
- Confidential Information
- Data
- Data Confidentiality
- Data Management
- Fiscal value
- Historical/research value
- Human Data
- Human Subject
- Legal value
- Legislative value
- PNWU Workforce
- Principal Investigator (PI)
- Shred Bin
- Standard Operating Procedure
- Vendor

Procedure:

1. This SOP does not relate to study data and teams – Please see OSA SOP 113. Protocol/Study files (paper and electronic) are to be retained by either the PI or the Office of Scholarly Activity (OSA). Investigators should contact the OSA or the study sponsor to determine the required retention period for study records maintained by study teams.

2. IRB records required under 45 CFR 46.115 (Department of Health and Human Services) are retained for at least 3 years, and records relating to research which is conducted shall be retained for at least three years after completion of the research.

   The revised Common Rule included additional requirements for IRB records. When PNWU is engaged in human subjects research subject to the revised Common Rule the following records will be maintained in addition to those described in the PNWU SOPs.

   a. Institutional Records –
      1) For nonexempt research involving human subjects covered by the Common Rule (and exempt research with identifiable data requiring limited IRB review) that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy (e.g., in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol).

   b. IRB Records –
      1) The rationale for conducting continuing review of research that otherwise would not require continuing review.
      2) The rationale for a determination that research appearing on the expedited review list published in the Federal Register is more than minimal risk.

3. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

4. IRB records required by 21 CFR 56.115 (below) (Food and Drug Administration) are retained for at least three years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

5. Records are only destroyed by the IRB Administrator after consultation with OSA management.

6. A record of the applicable documents (paper and electronic) destroyed will be tracked via the IRB Records Management Certificate of Destruction form which is then kept in a binder in the OSA. Also, an Excel file tracking list will document the destruction of records found on the IRB SharePoint site.

7. The electronic IRB record system is used to prepare, document, maintain and store records related to IRB activities, including, but not limited to, designated expedited reviewer and individual convened IRB member review notes, and minutes of IRB meetings documenting protocol-specific determinations and summarizing discussion of controverted issues and their resolution. Per 45 CFR 46.115: (a) An institution, or when appropriate an IRB, shall prepare, and maintain adequate documentation of IRB activities, including, but not limited to, the following:
    - Copies of all research proposals reviewed.
    - Scientific evaluations, if any, that accompany the proposals
    - Approved sample consent documents
    - Progress reports submitted by investigators.
    - Reports of injuries to subjects
    - Reportable events
    - Minutes of 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.
    - Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review §46.109(f)
    - Copies of all correspondence between the IRB and the investigators.
    - A list of IRB members in detail, identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member § 46.108(a)(23)
        - Full-time employee, part-time employee, a member of governing panel or board, stockholder, paid or unpaid consultant.
    - Written procedures for the IRB § 46.108(a)(3) and § 46.108(a)(4)
    - Statements of significant new findings provided to subjects, as required by § 46.116(c)(5)
    - The rationale for an expedited reviewer's determination under §46.110(b)(1)(i) that research appearing on the expedited review list described in §46.110(a) is more than minimal risk.
    - Documentation specifying the responsibilities that an institution [relying on another IRB] and an organization operating an IRB [the IRB of record] each will undertake to ensure compliance with the requirements of this policy, as described in §46.103(e)

8. The records required by this regulation shall be retained for at least 3 years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Food and Drug Administration at reasonable times and in a reasonable manner.

9. The Food and Drug Administration may refuse to consider a clinical investigation in support of an application for a research or marketing permit if the institution or the IRB that reviewed the investigation refuses to allow an inspection under this section.

10. In order to allow a reconstruction of a complete history of IRB actions related to the review and approval of the protocol, the IRB records include copies such as, but not limited to, as applicable:
    - Investigator brochure
    - Recruitment materials
    - Data and safety monitoring reports
    - Unanticipated problems involving risks to participants or others.
    - Documentation of non-compliance
    - IRB records for initial and continuing review of research by the expedited procedure include:
        - The justification for using the expedited procedure.
        - Justification that the criteria for approval are met.
        - Actions taken by the reviewer.
        - Justification for conducting continuing review of research that otherwise would not require continuing review.
        - Rationale for an expedited reviewer's determination under §46.110(b)(1)(i) that research appearing on the expedited review list described in §46.110(a) is more than minimal risk.
        - Any findings required by laws, regulations, codes, and guidance to be documented.

11. IRB records document the justification for Exempt determinations, as well as assessment of submitted proposals as Not Research or Not Human Subjects Research.

12. The IRB Management System is used to provide the most recent/active versions of IRB SOPs. A link on the PNWU website under the OSA helps PNWU investigators with direct access to the OSA SOPs.

13. Versions of SOPs with tracking and dates can be found in the resources folder in the electronic IRB management system.

14. New research applications that are in the pre-submission state, or are withdrawn, with no IRB review history or activity for one year will be deleted from the IRB Management system or completed as withdrawn.

15. IRB records relating to the orientation, training, and qualifications of members of the IRB will be kept indefinitely. These include, but are not limited to, membership rosters, curriculum vitae, and training documents for members of the IRB.

16. When the IRB Administrator has determined that IRB records have reached or have exceeded the legal retention period, and that the records have no further administrative, legal, or historical value, the OSA shall arrange for the disposal of those records (paper and/or electronic) through PNWU approved shred bins (paper) and via confirmed electronic deletion (electronic).

References:

1. Food and Drug Administration (FDA) Federal Regulations (21 CFR 50, 54, 56, 312, 314, 600, 601, 812 and 814) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
2. Department of Health and Human Services (DHHS) Regulations (45 CFR 46 Subparts A, B, C, and D) http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html
3. PNWU Student Catalog.
4. PNWU Information and Data Protection Policy. https://secure.compliancebridge.com/pnwu/public/index.php?fuseaction=print.preview&docID=80
5. PNWU Document Retention and Destruction Policy. https://secure.compliancebridge.com/pnwu/public/index.php?fuseaction=print.preview&docID=1390
6. The U.S. Department of Health & Human Services Guidance on Satisfying the Safe Harbor Method. https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html
7. PNWU Data Use Agreement.
8. U.S. Department of Health and Human Services Guidance for Industry - Computerized Systems Used in Clinical Investigations (May 2007) and U.S. Department of Health and Human Services Guidance for Industry - Part 11, Electronic Records; Electronic Signatures – Scope and Application, August 28, 2003.

Appendices:

PNWU Policy Records Retention Information
IRB Records Management Certificate of Destruction Form
IRB Excel File Destruction List

Version/ Effective Date	Author	Section Changed & Reason for Revision
120.00/ 6-7-2017	M. McCarroll	Original SOP
.01 / 7-8-2017	M. McCaroll	Name has been changed to better reflect the content. Bullet numbering fixed.
.02 / 4-1-2019	M. McCarroll	Updated with Revised Common Rule info, updated SOP to include all conflicts, and updated to new PNWU format
.03/3-13-2020	C. Case	Added item 15 regarding IRB Membership documentation to be retained (membership roster, CV's and training documents)
.04 / 3-3-2023	C. Case	• Added additional information required by the revised Common Rule in item 2. (This information is currently in SOP 150 which will be decommissioned once the IRB SOPs are inline with the revised Common Rule.) • Updated the information about where SOPs are stored • Moved the records retention chart to the appendices section. • Updated the information about records destruction since we no longer have a CRO.

PNWU Policy Records Retention Information

There is no single standardized record retention scheduled. Instead, a variety of retention requirements must be reviewed to be compliant. The IRB Administrators must review and comply with state and federal laws when creating a record retention and disposition plan.

PNWU Policy	Applicable	General Information
Release of FERPA Protected Data Housed in the Office of Institutional Effectiveness (OIE) for Research Purposes	• Yes	• Defaults to OSA SOPs
Information and Data Protection Policy	• Yes	• Throughout its life cycle, all institutional data shall be protected in a manner that is considered reasonable and appropriate, as defined by procedures and documentation maintained by the Data Governance Committee. • Any information system that stores, processes, or transmits institutional data shall be secured in a manner considered reasonable and appropriate, as defined by procedures and documentation maintained by Technology Services. • Individuals authorized to access institutional data shall adhere to the appropriate roles and responsibilities as defined by the Data Governance Committee. • Violations of this policy may result in suspension or loss of access to information systems. Additional administrative sanctions may apply up to and including termination of employment or contractor status with the university. Civil, criminal, and equitable remedies may apply.
Confidential Shred Bin Usage Policy	• Yes	• The PNWU workforce must undertake appropriate administrative, technical, and physical safeguards, to the extent reasonably practical, to preclude Protected Health Information (PHI), FERPA, assessment data, and other confidential information from either intentional or unintentional use or disclosure, which would violate HIPAA regulations. • Media with confidential information in hardcopy form, such as paper, must be protected against theft and unauthorized access. This includes all confidential information in hardcopy form received, created, maintained, and transmitted by PNWU personnel. Confidential information must be consistently protected and managed through its entire life cycle, form origin to destruction. PNWU shall adopt controls for hardcopy paper confidential information disposal and destruction. • The shred bins are to be used for the secure destruction of PNWU confidential information only. • The shred bins are not to be used for non-confidential documents. The shred bins are not to be utilized for the destruction of personal (that is non-PNWU) confidential information. • Once any document is placed in a shred bin, the document is to be considered destroyed and non-retrievable. Therefore placing a document in the shred bin is the equivalent of using a shredder and the document is to be considered completely destroyed. • The shred bins are not to be utilized for general recycling of non-PHI and non- confidential documents, journals, magazines, junk mail, cardboard, phone books, or any other type of non-confidential material. Other processes are available for recycling of non-confidential information. • Unlocking of Shred Bins will not be allowed. No keys will be kept on campus. • Keys and access to the shred bins shall not be available to any campus personnel.

Policy: Records Retention and Disposition and Procedure: Records Retention and Disposition Schedule	• Yes	• Records that have been contested should never be destroyed, unless the ability to reconstruct them in a legally acceptable form is preserved, or unless the issue has been resolved. • Records for which there is no legally specified period for retention must be disposed of systematically in accordance with the University's record retention and disposition schedule. • Records include those that can be accessed only with specific technology (unique computer hardware or software, etc.) • Research, Projects, and Thesis. Records documenting the culminating research, project, or thesis completed by students to satisfy degree requirements, including, but not limited to bound copy of research and/or thesis, final project (e.g., models, recordings, poster presentations, etc.), and accompanying written report.