Procedure Title: Source and Essential Documents in Human Subjects Research

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	07/01/2020	**Executive Lead:**	Chief Research Officer
Effective:	07/24/2020	**Revision History:**	.00 – 07-01-2020; .01 – 2-21-2023
Approved by:	Institutional Review Board		
Procedure Number:	144.01		
Key Words:	Accurate, ALCOA, Attributable, Contemporaneous, Essential Documents, Legible, Original, Source Document		
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 creation and use of essential/source documents in human subjects' research.

This SOP must be used as a guide in parallel with OSA Policy 1.0. SOPs are not intended to supersede existing institutional policies, and local, state, and federal laws and regulations.

Responsible Parties

The Institutional Review Board (IRB) is responsible for:

- Protecting the rights and welfare of human research participants.
- Impartiality when reviewing human subjects research;
- Remaining unaffected and resistant to pressure from the institution's administration, the investigators whose protocols are brought before it, or other professional and nonprofessional sources.

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

- Supporting the investigator in the development of research protocols and the source documents required for the conduct of research;
- Overseeing and providing the necessary support to the IRB.
- Monitoring compliance with this SOP.
- Posting or making this SOP available to the PNWU community.

The Investigator is responsible for:

- Being a steward of a research environment that promotes the responsible conduct of research.
- Ensuring compliance with the IRB-approved protocol, federal regulations, state laws, good clinical practice, and applicable Food and Drug Administration (FDA) guidance.

- Developing source documents that adequately capture study information.
- Providing appropriate training to members of the study team.
- Ensuring research records are easily accessible for inspection by authorized institutional officials, and as applicable, the Food and Drug Administration (FDA) or other federal agencies, sponsors and sponsor agents, or funding entities; and
- Seeking support from OSA and the IRB when questions arise.

Definitions

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

- ALCOA - Attributable, Legible, Contemporaneous, Original, Accurate
- Case Report Forms (CRFs)
- Essential Documents
- Source Documents

General Information:

Investigators are required to prepare and maintain adequate and accurate essential and source documents during the course of conducting research.

Essential documents permit an evaluation of the conduct of a study and of the quality of the data produced. These include, but are not limited to: curriculum vitae, licensure, professional certifications, IRB correspondence and approvals, IRB approved consent and assent forms, approved educational materials, subject screening logs, enrollment logs, delegation of authority/duty logs, training logs, adverse and unanticipated event logs, protocol deviation and violation logs, laboratory certifications (e.g., Clinical Laboratory Improvement Amendments Certification , College of American Pathologists Certification), and laboratory normal lab values/references. FDA-regulated clinical trial essential documents also include monitoring logs, the investigator brochure, and statement of the investigator.

Source documents are documents where data regarding study subjects are first recorded. These include original documents, data, and records in all forms (e.g., clinical medical records/charts, even notes recorded on a sticky note, paper towel, or napkin) that describe or record the conduct, methods, actions taken, results of the research, or other factors that may affect the research. Source documents provide an auditable link back to the original source of the study data and can demonstrate that the data was collected in compliance with good clinical practices. These documents often include clinical report forms, demographic collection forms, laboratory reports, subject evaluations, notes to file, observation and assessment records, subject diaries, dispensing records, questionnaires, surveys, and procedure/test results (e.g., X-ray, MRI) as well as transcriptions or certified copies after verification for completion and accuracy.

Investigator Procedures:

Creating documents:

1. Create source documents that are concise, complete, and cover all information needed for the study. Source documents are best when formatted in chronological order of the study visits and procedures.

   TIPS:

   - Create a schedule of study events that breaks down the procedures for each study visit.
   - Use document headers for information such as study title, study name, as well as blanks for visit date, visit number, and subject initials or subject ID.

- Create clear labels for the data entry fields (e.g., units of measure, timing for blood draws, and instructions).
- Create a separate form for each study visit.
- Include spaces for any necessary names, signatures, initials, dates, and times.

2. The principal investigator (PI) or a qualified person the PI has delegated must create the source documents. The person(s) creating the source documents (electronic or paper) must sign and date the record.

Completing documents:

1. All entries on paper source documents must be made in non-erasable black or blue ink.
2. Source documents must be completed in a timely manner so that necessary corrections can be made in real time.
3. Source documentation must meet the ALCOA principles:
   a. Attributable—obvious who created the record.
   b. Legible—readable
   c. Contemporaneous—information is current and documented in the correct time frame.
   d. Original—first time written, original printout or certified copy.
   e. Accurate—real representation of the facts of the event being recorded.
4. Additional attributes of research data quality also include data that is:
   a. Available and accessible (easily retrievable for review by treating physician and during audits/inspections);
   b. Complete (have all the necessary or appropriate parts at the particular point in time);
   c. Consistent (done in the same way over time).
   d. Credible (based on real and reliable facts that are believable).
   e. Enduring (long lasting)
5. **Certification of copies**. Designated member(s) of the study team will certify that printed copies of documents from the medical records are exact replicas (meaning they have all of the same attributes and information as the original) by:
   a. Marking certified copy page 1 of X on the first page of the document and certified copy X of X on the last page of the document;
   b. Dating and initialing each certified copy mark.

Reports used as original source:

1. Reports such as laboratory reports utilized for the study must be reviewed for clinical significance. Determinations must be recorded (clinically significant or not clinically significant) and signed and dated by the PI or another qualified member of the study team that has been delegated to review and interpret the results.

Storing Documents:

1. Determine methods for storing and organizing essential study documents. It is recommended that the PI create regulatory binders or regulatory files for storage of all essential and source documents during the development phase of the study. It may also be helpful to create individual study folders for each study participant.
2. Study documents must be stored securely and with adequate protection of participant confidentiality. Documents should be retained for a minimum of 3years or longer according to the length of time required by the applicable regulatory requirements and/or sponsoring agency. Refer to SOP 113 Data Management and Disposition for more information on secure storage.

Editing or changing documents:

1. Corrections on paper source documents are allowable while the documentation is being completed. Corrections must never be made by erasing or using correction fluid. Instead, place a single line through the erroneous information and write the correct information in close proximity to the original information. The individual making the corrections must date and initial corrections with the date the corrections are made.
2. Past-dated source documentation in research records must not be made to resolve deficiencies. Altering past-dated records is potentially fraudulent.
3. Source documents should never be recopied. A messy source document is acceptable as long as it is legible. If an entry is illegible, the person who made the entry may write a clarifying note in the document margin, initialing and dating the note. The original entry must remain unchanged.
4. If research data are missing and those data are obtained/found at a later date, research personnel will ensure incorporation of the missing data and an explanatory note into the research record. The individual making the notation must sign, initial, and date the notation.

Training:

1. Prior to enrolling the first study subject, the principal investigator must provide and document study training to ensure that personnel are trained and that tasks are appropriately delegated.

IRB Procedures:

1. Review source documents submitted to ensure data collected matches the study protocol.

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. International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines https://www.fda.gov/scienceresearch/specialtopics/runningclinicaltrials/guidancesinformationsheetsandnotices/ucm219488.htm
4. International Conference on Harmonization (ICH) E6 (R2) Good Clinical Practice Consolidated Guidance – Sections 3.4 Records; 4.1 Investigator's Qualifications and Agreements. https://www.fda.gov/media/93884/download
5. PNWU SOP 113 Data Management and Disposition

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 / 07-24-2020	C. Case	Original SOP
.01 / 2-21-2023	C. Case	Minor grammar corrections and changed the length of records retention to 3 years to be consistent with SOP 113 Data Management and Disposition.

Appendices: