
Procedure Title: Creation and Management of Standard Operating Procedures

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	7/24/2017	Executive Lead:	Chief Research Officer
Effective:	7/24/2017	Revision History:	.01 – 7/3/2018; .02 10/2/2019
Approved by:	Institutional Review Board		
Procedure Number:	112.02		
Key Words:	Standard Operating Procedure, SOP,		
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 management of Standard Operating Procedures (SOPs).

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:

- Preparing, revising and implementing the SOPs to serve as a reference or guidance for the research community on appropriate research practices
- Obtaining input and discussion by investigators
- Suggesting new SOPs based on the research community need

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

- Preparing, revising and implementing the SOPs to serve as a reference or guidance for the research community on appropriate research practices
- Monitoring compliance with research SOPs at PNWU
- Posting access to these SOPs on the PNWU website
- Ensuring timely review and approval of the SOP
- Provide training to the research team members on implementing research SOPs in their particular research area

The Investigator is responsible for:

- Developing specific SOPs, as necessary but not conflicting with institutional policies, local, state, and federal laws and regulations
- Monitoring compliance with site specific SOPs

- Training research team members on implementing site-specific SOPs in their particular research area

Definitions

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

- Institutional Official
- Institutional Review Board
- Standard Operating Procedures (SOPs)

Procedure:

1. Please review the OSA SOP 200.
2. Creating a new SOP – The OSA or IRB may identify a need for a SOP. The priorities of SOPs will be based on the input from each of the IRB committee members. The OSA will determine if the SOP is best categorized as IRB committee responsibilities, research committee responsibilities, grants/finance responsibilities, and/or institutional official responsibilities.
3. IRB Meetings – During a convened IRB meeting, an SOP will be presented. IRB members will have the opportunity to either approve the SOP at the meeting or if further revisions are needed, approval of the SOP will occur via email. A majority vote is required for approval of the SOP. After approval of an SOP, versions of SOPs with minor edits, revisions, and suggestions for improvement will be made and tracked via the OSA.
4. Managing - The IRB, OSA, IO, and/or the respective committees may suggest changes once a SOP version has been approved. Only substantive changes to an SOP will be brought forth for committee approval.

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 <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073122.pdf>

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00/7-24-2017	M. McCarroll	Original SOP
.01/7-3.-018	M. McCarroll	Minor modifications to 6.3
.02/10-2-2019	C. Case	Put into the new PNWU SOP format

Appendices:
None