Procedure Title: Introduction and Purpose of the Pacific Northwest University of Health Sciences (PNWU) Institutional Review Board (IRB)

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	2/22/2017	**Executive Lead:**	Chief Research Officer
Effective:	2/22/2017; Reviewed 2/23/2023	**Revision History:**	.01 – 4/5/2017; 02 – 10/01/2019
Approved by:	Institutional Review Board		
Procedure Number:	102.02		
Key Words:	Purpose, IRB, Institutional Review Board		
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 purpose of the Pacific Northwest University of Health Sciences (PNWU) Institutional Review Board (IRB).

This SOP must be used as a guide in parallel with OSA Policy 1.0 to comply with proper reimbursement of human subject compensation. 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 conducting reviews of human subject research;
- Remaining immune from pressure by the institution's administration, the investigators whose protocols are brought before it, or other professional and non-professional sources;

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

- Serving as the Institutional Official (IO) for the Human Subject Research Protection Program;
- Overseeing the IRB;
- Monitoring compliance with this SOP;
- Posting this SOP for the PNWU community;
- Providing the necessary support to the IRB;

The Investigator is responsible for:

- Complying with the requests and recommendations of the IRB in the interest of human subject protections;
- Communicating with IRB members in a timely fashion;
- Seeking support from OSA and the IRB on proper protocol development and submission

Definitions

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

- Human Subject
- Institutional Official (IO)
- Investigator
- Federal wide Assurance
- Institutional Review Board (IRB)

Procedure:

1. The PNWU IRB will follow the Code of Federal Regulations (45 CFR 46), and additional regulations imposed by the Food and Drug Administration (FDA).
2. PNWU holds a Federal wide Assurance (FWA00014453) with the Department of Health and Human Services (HHS), which describes the principles and guidelines under which the PNWU IRB must review and approve the conduct of research involving human subjects under the oversite of the IO.
3. The PNWU IRB will apply the ethical principles embodied in the Common Rule (45 CFR 46) and the Belmont Report with regard to the protection of human research subjects.
4. The PNWU IRB will meet on the second Thursday of every month for official business meetings and for professional development as it relates to HRPP.
5. The PNWU IRB will advise investigators who conduct research involving human subjects as necessary to not only adhere to regulations, laws, sponsoring agency requirements, IRB policies, and any other institutional policies that govern human subjects' research, but to apply ethical reasoning in making determinations about research involving human subjects.

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)
4. Code of Federal Regulations, Title 45, Public Welfare, Department Of Health And Human Services Part 46, Protection Of Human Subjects, Revised January 15, 2009, Effective July 14, 2009. https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/investigator-responsibilities/index.html

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 / 2-22-2017	M. McCarroll	Original SOP
.01 / 04-05-2017	C. Case	Minor Formatting Changes Only
.02 / 10-01-2019	C. Case	Transferred to PNWU Standard SOP Template. Institutional Official added to the list of definitions. No other content changes were made.
Reviewed 2-23-2023	C. Case	

Appendices:

None