Procedure Title: Scope and Authority of the Institutional Review Board

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	02/22/2017	**Executive Lead:**	Chief Research Officer
Effective:	02/22/2017	**Revision History:**	.01 – 07/06/2017; .02 – 06/22/2018; .03 – 10/01/2019; .04 – 01/28/2020; .05 – 1/23/2023; .05 – 1/24/2023
Approved by:	Institutional Review Board		
Procedure Number:	104.06		
Key Words:	IRB, Authority		
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 scope and authority of the 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 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
- Investigator
- Federal Wide Assurance
- IRB

Procedure:

1. Scope - The PNWU IRB reviews protocols for research involving human participants when conducted by or under the direction of any employee, student, or agent of PNWU in connection with his or her institutional responsibilities or using any institutional property or facility. Also, the IRB reviews research protocols of non-PNWU investigators when PNWU faculty, staff, or students are involved.
2. Authority - The authority conveyed to the IRB includes:
    a. Review/approval of new/continuing research protocols involving human participants and associated informed consent documents (ICD) prior to initiation/continuation of research.
    b. Require from investigators revisions in research protocols and ICDs as a condition for initial or continuation approval (as applicable).
    c. Disapprove the initiation of new research projects.
    d. Monitoring of approved projects including regularly scheduled continuing review as applicable to the common rule (45 CFR 46).
        a. Full board studies as well as expedited and exempt limited review studies determined to need continuing review, will undergo continuing review at least every twelve (12) months outside of data analysis only stage.
        b. Expedited studies not required to complete annual continuing review will submit an annual check-in report to the IRB.
    e. Require an annual check-in report for any studies determined to be exempt that meet one or more of the exemption criteria found in 45 CFR 46.
    f. Verification of compliance with approved research protocols and informed consent procedures.
    g. Review of all planned changes to approved protocols prior to implementation.
    h. Review of all adverse events occurring in approved projects, or in other projects related in context to the approved projects.
    i. Restriction of approved research activities to protect participants when necessary.
    j. Suspension/termination of previously approved protocols for non-compliance with established SOPs and policies.
    k. Be available to research subjects' questions or concerns.
    l. IRB has the authority to make determinations as to whether data gathered without IRB approval may be used for research.
3. Authority of Institutional Officials - The designated Institutional Official (IO) has the authority to review decisions of the IRB.
4. 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.

5. The PNWU IRB will meet monthly for official business meetings and for professional development as it relates to HRPP.
6. 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. International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines(http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073122.pdf)
2. 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
3. The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research.

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 / 2-22-2017	M. McCarroll	New Standard Operating Procedure
.01 / 07-06-2017	M. McCarroll	• Policy statement section 5.1 revised to be more specific to purpose of an SOP; • Section 6.2 revised adding a bullet to the end of the section regarding the authority of the IRB to make determinations about data gathered without IRB Approval; • Section 6.3 revised to include a statement that the IO cannot override a decision made by the IRB; • Section 6.5 updated to make the frequency of the meetings less specific.
.02 / 06-22-2018	M. McCarroll	Minor changes for clarification
.03 / 10-01-2019	C. Case	Put into the new PNWU SOP Format
.04 / 1-28-2020	C. Case	Fixed typographical error item 1; Revised language in item 2.k. to make sense.
.05 / 1-23-2023	C. Case	• Modified 2d adding information to clarify continuing review based on the review type. • Added item 2e regarding annual check-in for exempt studies. • Added The Belmont Report in the reference section.
.06 / 1.24.2023	C. Case	• Reworded item 2e to make it more apparent that it is a board requirement.

Appendices:
None