Procedure Title: Administration of the PNWU IRB

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	6/7/2017	**Executive Lead:**	Chief Research Officer
Effective:	6/7/2017	**Revision History:**	.01 – 07/08/17; .02 – 12/12/2017; .03 – 10/01/2019; .04 – 3/21/2023
Approved by:	Institutional Review Board		
Procedure Number:	122.04		
Key Words:	Membership, Members, Alternate Members, Duties, Operations		
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 in regards to day-to-day duties of the IRB.

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 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:

- Supporting the IRB in educational sessions to ensure professional development of the IRB members.
- Monitoring compliance with this SOP.
- Posting this SOP for the PNWU community.
- Maintain and update SOPs as they relate to the IRB.
- Providing the necessary support to investigators and the IRB.

The Office of the Provost at PNWU is responsible for:

- Appointing the necessary IRB members.

- Communicating with the Institutional Official (IO) and the IRB to support IRB membership in the arenas of affiliation and expertise.

Definitions

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

- Conflict of Interest
- Human Subject
- Investigator
- Standard Operating Procedure

Procedure:

1. Membership of the IRB is described in OSA SOP 126 Membership of the IRB
2. Duties and Responsibilities of:
    a. IRB Chair - The Chair provides leadership and promotes an environment conducive to scholarly research and activities that protect human participants who take part in research. The duties of the Chair are as follows:
        1) Preside at all meetings of the IRB.
        2) Call special meetings of the IRB.
        3) Ensure accurate records of all protocols, including relevant discussions, correspondence, modifications, and final actions.
        4) Conduct reviews of all protocols submitted to the IRB proposing use of human participants in research.
        5) Advise, and counsel investigators.
        6) Make decisions on emergency conditions as they relate to the IRB's protection of human participants in compliance with Federal regulations.
        7) Keep the IRB informed of developing problems in the area of human research on any current or pending project.
        8) Perform functions delegated to an official of the IRB in accordance with institution, State and Federal regulations.
        9) Delegate duties as applicable in OSA SOP: 115.00.
        10) Disqualify themselves from participating in the review of, or voting on any activity in which he/she has a conflict of interest or even the perception of a conflict of interest.

    b. IRB Vice Chair - The Vice Chair should be an IRB member who is a respected individual with knowledge of research ethics, regulations, guidance, and HRPP policies and procedures. The duties of the Vice Chair are as follows:
        1)Assume all the duties of the IRB Chair when the IRB Chair is unable to do so.
        2)Assist in the operation of the IRB.
        3)Disqualify themselves from participating in the review of, or voting on any activity in which he/she has a conflict of interest or even the perception of a conflict of interest.

    c. IRB members – The IRB members should be a individuals that meet the criteria defined in OSA SOP: 126.00 and are respected individuals with knowledge of research ethics, regulations, guidance, and HRPP policies and procedures or are members of the local community who bring the research participants perspective to the review process. The duties of the IRB members are as follows:
        1) Attend all meetings.

2) Review materials before each meeting and come prepared to participate in IRB business.
3) Review all introductory and regulatory documents relating to the use and protection of human participants.
4) Disqualify themselves from participating in the review of, or voting on any activity in which he/she has a conflict of interest or even the perception of a conflict of interest.
5) Contact the PNWU IRB Administrator and/or IRB Coordinator to inform the IRB Chair if unable to attend a meeting.
6) Willingly participate in subcommittee activities as time and interests allow.
7) Protect the confidentiality of the records and information provided to them.

d. IRB Alternate members – The alternate members should be a individuals that meet the criteria defined in OSA SOP: 126.00 and are respected individuals with knowledge of research ethics, regulations, guidance, and HRPP policies and procedures and may bring specific knowledge to the review process (e.g., knowledge regarding the local homeless community or medical practice). The duties of the alternate members are as follows:
    1) Attend all meetings, as available, in case the primary member is not able to attend.
    2) Assume all the duties of IRB member when the IRB member is unable to do so.
    3) Disqualify themselves from participating in the review of or voting on any activity in which he/she has a conflict of interest or even the perception of a conflict of interest.

e. IRB Consultants – In some cases, the IRB may determine that a consultant is needed to assess subject matter, procedure, etc. to fully assess the protection of human subject research protocols.
    1) The criteria for identifying and using an IRB consultant is as follows:
        - A qualified individual identified by an IRB member or Institutional Official with content expertise.
        - Available to review during the allotted time frame.
        - Signs confidentiality agreements where applicable.
        - Declares and documents no conflict of interest in reviewing the protocol.
    2) The process for using a consultant is as follows:
        - Provide the necessary documents to the consultant so the IRB can obtain the additional expertise needed to support the IRB decisions.
        - Create and disseminate a typed and signed (e-signature or actual) report from the consultant to make available to the IRB members attending the meeting.
        - Invite the consultant to the IRB meeting to provide further testimony, if necessary.

f. IRB Support Staff - The Office of Scholarly Activity shall provide the necessary staff to support the day-to-day operations of the IRB. The duties of the IRB support staff are as follows:
    1) Support all investigators and designees during the application and submission process.
    2) Take and distribute minutes of IRB meetings that record the attendance and actions of the IRB.
    3) Help maintain records of all IRB deliberations and actions during electronic, video-conferencing and in person meetings.

4) Develop and assist in the orientation and continuing education of faculty, staff and students with IRB procedures and policies.
5) Schedule meeting rooms easily accessible to all IRB members.
6) Secure the necessary technology to run the IRB meetings.
7) Confirm appropriate storage of the required documentation as outlined in OSA SOP: 113.00 Data Management and Disposition.

References:

1. National Institute of Health (NIH) Office of Human Subject Research Standard Operating Procedure for IRB Structure and Membership https://ohsr.od.nih.gov/public/SOP_2_v2_2-24-16_508.pdf
2. 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
3. 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
4. International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines(http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073122.pdf)
5. 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 / 06-07-2017	M. McCarroll	Original SOP
.01 / 07-08-2017	M. McCarroll	Name of the SOP was changed from Day to Day Duties of the IRB to Administration of the PNWU IRB
.02 / 12-12-2017	M. McCarroll	Added statement to IRB Support Staff duties regarding supporting investigators and applicants during the application process.
.03 / 10-04-2019	C. Case	Put into new PNWU SOP Format
.04 / 3-22-2023	C. Case	Removed reference to the L: Drive in the footer of the SOP as all SOPs are now stored in the electronic IRB management system; Changed responsibilities of the Office of the President to Office of the Provost; minor grammatical revisions; additional information about knowledge of community members.

Appendices:
None