Procedure Title: Change and Removal of IRB Members

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	07/13/2017	**Executive Lead:**	Chief Research Officer
Effective:	07/13/2017	**Revision History:**	.01 – 10/25/2017; .02 – 10/01/2019; .03 – 3.7.2023
Approved by:	Institutional Review Board		
Procedure Number:	109.03		
Key Words:	Change, Removal, IRB Members		
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 changing and removing IRB members.

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.
- Providing input regarding IRB members to the Institutional Official (IO)

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

- Providing suggestions of IRB members to the Institutional Official (IO)
- 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. Changes to the IRB membership may occur under a variety of circumstances such as, but not limited to:
    - Change in job status.
    - Unable to commit the allotted time for meetings and reviews.
    - Leaving the institution.
    - Term expiration and unwilling to renew.
    - Refuse to be evaluated by the IRB Chair, Vice Chair, and/or designee regarding compliance with IRB standards.

2. Removal of IRB members may occur under a variety of circumstances such as, but not limited to:
    - Failure to communicate to the IRB Administrator regarding frequency of attendance.
    - Failure to comply with training requirements.
    - Failure to protect the rights of human research participants.
    - Failure to comply with attendance requirements as outlined in this document.
    - Failure to report or disclose a major conflict of interest.
    - Fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research.
    - Any breach of confidentiality (e.g. study data, participants, IRB votes etc).
    - Research fraud or abuse.
    - Failure to comply with federal regulations, institutional policies, or IRB requirements for their own ongoing research activities.

3. Notification of changes in IRB Membership (removal/changes) will be made to Office of Human Research Protections (OHRP) by the IRB Administrator. The changes will be made within 90 days of the changes occurring. Changes are made via the website at https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-registration/update-renew-registration/index.html.
4. The OSA will verify the data currently on file with OHRP on an annual basis.

References:

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

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
5. Department of Health and Human Services OHRS Website for IRB registration and renewal. https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-registration/update-renew-registration/index.html.

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00/ 7-13-2017	M. McCarroll	New Standard Operating Procedure
.01/10-25-2017	M. McCarroll	Switched the order of sections 6.1 and 6.2; Section 6.4 added frequency of the review of OHRP data.
.02 / 10-01-2019	C. Case	Put into the new PNWU SOP Format
.03 / 4/3/2023	C. Case	Changes in the responsible parties: • IRB to include making recommendations for new IRB members to the Institutional Official • OSA changed that input regarding membership of the IRB is given to the Institutional Official (not the president). • Office of the President changed to office of the Provost. Changed the language in item 3 to clarify that changes to the IRB roster are made by the IRB Administrator through the OHRP website. Added the website for changes to the IRB registration to the reference section. Removed the SOP location at the bottom of the SOP. SOPs are now kept on the IRB SharePoint site and in the reference folder of the IRB Management System.

Appendices:
None