Procedure Title: Membership of the Institutional Review Board

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	03/29/2017	**Executive Lead:**	Chief Research Officer
Effective:	03/31/2017	**Revision History:**	.01 – 05/30/2017; .02 – 10/07/2019; .03 – 1/31/2023
Approved by:	Institutional Review Board		
Procedure Number:	SOP 126.03		
Key Words:	Membership, Unaffiliated, Affiliated, Scientific, Non-Scientific, Alternate, Appointment		
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 structure and membership of the IRB.

This SOP must be used as a guide to comply with the purpose of maintaining structure and membership of the IRB. 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.
- Providing the necessary support to investigators and the IRB.

The Office of the President 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.

- Human Subject
- Institutional Official
- Investigator
- IRB

Procedure:

1. Consistent with the requirements of 45 CFR 46.107 and 21 CFR 56.107, the IRB must:
   - *Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.*
   - *The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.*
   - *The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.*
   - *The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.*
   - *The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.*
   - *No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.*
   - *An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.* [§__.107]

2. IRB Member Affiliation - In determining member expertise, affiliation and status as primary or alternate member, the following criteria apply:
   - Affiliated member: A PNWU employee (or a member of that person's immediate family) is considered affiliated. Affiliated members also include, but are not limited to, individuals who are at or involved with PNWU as: part- time employees; current students; trainees; members of any panel or board; paid or unpaid consultants; healthcare providers holding credentials to practice at PNWU; guest researchers; and volunteers
   - Unaffiliated member: If an individual has no affiliation with PNWU, other than as an IRB member, then s/he is considered unaffiliated. Unaffiliated members may include people whose only association with PNWU is that of a research participant, or former student, trainee, contractor, or employee immediate family members as well. Paying unaffiliated members for their services would not make the member "otherwise affiliated" or cause the member to have a conflicting interest.

3. IRB Expertise for Scientific Role - Members whose primary interests are in scientific areas:

- A member whose highest level of education/training and/or occupation is from a scientific discipline or profession, e.g. the physical sciences, biomedical sciences, social/behavioral sciences, or mathematical sciences and who would be inclined to view scientific activities from these standpoints. The IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.

4. IRB Non-Scientific Role - Member whose primary concerns are in non-scientific areas:
    - A member whose education, training, background, and occupation would incline him/her to view research activities from a standpoint other than any biomedical or behavioral scientific discipline should be considered a non- scientist.

5. Alternate members - are members who may substitute for a primary IRB member or a category of member (e.g., physician or nurse).
    - Alternate can be an alternate for more than one individual.
    - Each alternate IRB member has experience, expertise, background, professional competence and knowledge comparable to that of the primary IRB member(s) whom the alternate would replace.
    - Alternate members may perform exempt and expedited reviews.
    - The appointment process is the same as for primary members of the IRB. Alternates' names are included in the IRB's official membership roster with the designation that they are alternates, together with the name(s) of the IRB member or category of members for whom they are an alternate.
    - An alternate member may be assigned as a substitute for one or more named primary members or for a category of members. Alternates must have qualifications similar to those of the member(s) for whom they are allowed to be a substitute. Alternate members receive agenda packages for all IRB meetings and are encouraged to attend as many meetings as possible, even when not required to be present to act as an IRB member.
    - Alternate members vote on protocols or other matters at convened meetings only when one of the primary members for whom they are an alternate is not participating in the vote (e.g., because that member is absent or has a conflict of interest). They should only participate when they have, prior to the meeting, adequately reviewed the materials distributed with regard to the protocol or other matters on which they would be voting. The IRB minutes should document the alternate member's votes.
    - When an alternate member substitutes for a regular member, the alternate member's vote counts towards the quorum in the same way as the regular member's vote.
    - A designated alternate IRB member may substitute for the primary IRB member for an entire meeting or at any time during a meeting. Substitution during a meeting commonly occurs when the primary member is (a) absent from the room for part of the meeting, or (b) recused from review of certain research protocols because the primary IRB member has a conflicting interest with respect to a specific research protocol. Whenever this occurs, the minutes of the IRB meeting should indicate clearly that the alternate IRB member has replaced the designated primary IRB member.

6. Determination of members and categories:
    a. The determination of whether the nominated IRB member's primary concerns are in scientific or non-scientific areas will be made by the designated IRB Chair at the time when members are nominated for appointment. The IRB will base this designation on a review of the nominee's curriculum vitae.

b. Consistent with Office for Human Research Protections (OHRP) guidance, IRB members can only be appointed as either regular (primary) or alternate members. There is no category of non-voting member of the IRB.

7. It is the responsibility of the Institutional Official (IO), in conjunction with the IRB Chair, to ensure that the IRB's overall composition meets regulatory and OHRP requirements. Initial Appointment to the IRB.
    - Identifying members: At the discretion of the President of PNWU and the IO, they will recommend the appointment of the IRB Chair. The IRB Chair and IRB Administrator will send recommendations for IRB members to the IO (including alternate members). In making such recommendations, consideration will be given to the requirements above for IRB membership and representation.

8. Terms of Service
    a. The term of each IRB member is three years and is subject to annual reappointment by the Institutional Official.
    b. Unless reappointed, Chairs, Vice Chairs and members rotate off the Board when their terms expire and have not been renewed, when members tender their resignations, or when members are removed for cause.
    c. IRB Chairs, Vice Chairs and members may be reappointed in conformity with the rules stated above. There is no limit on the total number of years members may serve as a result of being reappointed multiple times.
    d. Chairs and Vice Chairs may serve as regular IRB members on the same IRB or another IRB after their terms as Chair and Vice Chair are completed.

9. Removal for Cause of a Member
    - To remove a member of an IRB, including the Chair or Vice Chair, before the end of that person's appointed term, just cause must be shown of that person's inability to meet his/her responsibilities as an IRB member, such as failure to attend meetings regularly; failure to follow applicable laws, regulations, and policies; mismanagement; misconduct, or an unresolved conflict of interest for which recusal is insufficient.
    - The PNWU President along with the IO, after consultation with the Chair (if the Chair is not the member in question) should prepare a written memorandum to the IO with the reasons for recommending premature termination of membership. The President makes the final decision on termination and sends a termination letter to the member, if s/he concurs with the recommendation for removal from the IRB.

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 / 3-31-2017	M. McCarroll	Original SOP
.01 / 05-30-2017	M. McCarroll	6.5 Added alternate members can alternate for more than one member and alternates can perform expedited reviews; 6.8 Added length of term of IRB Member service.
.02 / 10-07-2019	C. Case	Put into new PNWU SOP Format; Reordered 5a-5h and 5h. And modified 5.c. to be clear than alternate members have a role in performing reviews of exempt and expedited;
.03 / 2-14-2023	C. Case	• Procedure #1 modified to match the language in the revised Common Rule (this language was previously in an addendum SOP 150). • Procedure #2 removed 3rd bullet regarding statement of status of unaffiliated member that refers to Appendix A (there has never been an Appendix A). • Procedure 6a – removed member survey • Procedure 7 – reworded to make it clear that the IRB Chair and Administrator send recommendations for new members to the IO. • Procedure 8a - Revised to show that the IO reappoints members annually (not the President). • Procedure 8c – Removed last sentence stating unless PNWU Administration wishes to impose a limit. • L: Drive information in the footer of the document has been removed as all SOPs are stored in the resources folder in the IRB Management System.

Appendices:
None