Procedure Title: External Research Requests

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	09/01/2020	**Executive Lead:**	Chief Research Officer
Effective:	10/26/2020	**Revision History:**	.00 – 09/01/2020; .01 – 1/23/2023
Approved by:	Institutional Review Board		
Procedure Number:	151		
Key Words:	Engaged, external researcher		
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 procedures for external investigators to obtain permission to conduct research on PNWU's campus or to recruit PNWU faculty, staff, or students to participate in external research. This SOP does not cover PNWU faculty, staff or students who are collaborators with external researchers.

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.

General Information:
OHRP considers an institution engaged in human subjects' research when its employees or agents, for the purposes of research, obtain data about the subjects of the research through intervention or interaction with them; obtain identifiable private information about the subjects of the research or obtain the informed consent of human subjects. The PNWU IRB will apply the federal rules of engagement of institutions in human subjects' research to determine the appropriate review procedure for the research.

Permission is required for external researchers to conduct research on PWNU's campus or to recruit PNWU students, staff or faculty. Requests are considered on a case-by-case basis. In most cases, when proof of IRB approval is provided, PNWU will agree to post recruitment information on University internal webpages/intranet. PNWU does not release internal email lists to external investigators and typically will not forward recruitment notices to PNWU email lists. The IRB Administrator will work with the external researchers and the Office of Institutional Effectiveness when receiving requests for recruitment of PNWU constituents.

Responsible Parties

The Institutional Review Board (IRB) is responsible for:

- Protecting the rights and welfare of human research participants.
- Maintaining impartiality when reviewing human subject research.

- Remaining immune from pressure by the institution's administration, the investigators whose protocol are brought before it, or other professional and non-professional sources

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

- Overseeing and providing the necessary support to the IRB.
- Monitoring compliance with this SOP.
- Working with internal resources to determine whether or not the research is appropriate for the PNWU community.
- Posting this SOP for the PNWU community.

The IRB Administrator is responsible for:

- Working with internal resources to determine whether or not PNWU is engaged in the research.
- Collecting and storing necessary documentation of IRB review and approval of the research.
- Working with the external investigator and OIE and other internal departments when recruitment will be conducted via email.

The Investigator is responsible for:

- Being a steward of a research environment that promotes the responsible conduct of research.
- Ensuring compliance with the IRB-approved protocol, federal regulations, state laws, good clinical practice, and applicable FDA guidance.
- Seeking support from OSA and the IRB when questions arise.

Definitions

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

- Engagement
- External Researcher

Request Procedure:

1. Request permission to conduct research on the PNWU campus or to recruit PNWU students, staff, or faculty by completing the Request for External Research at PNWU.
2. Provide evidence of IRB review and approval as well as the following information about the study:
    - A copy of the IRB application packet. The following information should be included:
        - Study title
        - Study summary
        - Recruitment materials
        - Consent form
        - Intended study participants
        - The IRB reviewing the IRB Application

    Documentation of study review and approval or exemption determination.
    - Information about any equipment or facilities needed.

Approval Process:

1. The IRB Administrator receives notification of Request for External Research submission via email.
2. The IRB Administrator reviews the requests and contacts the researcher with any question and requests additional information when necessary.

3. The IRB Administrator consults with appropriate departments and individuals within the University (e.g., IRB Chair, Vice Chair, Chief Research Office, Dean of the COM, and Institutional Official). When needed, the IRB Administrator forwards any documents needed to make a determination of acceptability of the research.
4. Assuming a determination that the research is appropriate for the PNWU community, the IRB Administrator will facilitate the process of obtaining permission from appropriate departments and individuals on campus.
    a. For survey-based research, the institution typically posts recruitment materials for IRB approved studies on the University internal webpages/intranet. Requests to distribute survey links will be given consideration on a case-by-case basis. When the University agrees to distribute recruitment links, consideration will be given to distribution timing and whether or not, the requested distribution timing conflicts with scheduled internal survey-based research or other institutional projects involving the surveying of PNWU students, faculty, or staff.
    b. The IRB Administrator will work with the Office of Institutional Effectiveness to determine appropriate timing for distribution.
5. Copies of study materials and correspondence are maintained in the REDCap request form project.
6. The IRB Administrator notifies the external researcher via email of the decision.

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. Health and Human Services Engagement of Institutions in Human Subjects Research https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html
4. PNWU SOP 149 Engagement in Research with Human Subjects

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 /10-26-2020	C. Case	Original SOP
.01 / 1-23-2023	C. Case	Minor updates to change the locations that research opportunities will be posted (on internal websites) and the records for the external studies will be maintained in the REDCap project.

Appendices