Procedure Title: Review and Approval Process with Conditions

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	3/20/2018	**Executive Lead:**	Chief Research Officer
Effective:	3/20/2018	**Revision History:**	.01 – 10/07/2019; .02 – 2/21/2023; .03 – 8-26-2024
Approved by:	Institutional Review Board		
Procedure Number:	SOP 130.03		
Key Words:	Approval with conditions; Conditions of approval;		
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 approval of human subject research studies.

This SOP must be used as a guide in parallel with OSA Policy 1.0, to comply with human subject research protections. 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:

- Reviewing applications in a timely fashion.
- Assessing risk and other considerations per federal regulations in the determination of exempt versus non-exempt studies.
- Communicating with the investigator as to the application status and modifications needed to ensure protection of human subjects.

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

- Monitoring compliance with this SOP.
- Posting this SOP for the PNWU community.
- Notifying the investigator, no earlier than 60 and no later than 30 days prior to the current IRB approval expiration date and providing them instructions for submitting a request for continuing review or a closure report.
- Ensuring all required information is received prior to forwarding a request for continuing review to the convened IRB and IRB Reviewer conducting the review.

The Investigator is responsible for:

- Completing all forms required by the IRB when conditions of approval are requested.

- Responding in a timely fashion to conditions of approval.

Definitions

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

- Conditions
- Exempt
- Expedited
- Full Board
- Health Information Portability and Accountability Act (HIPAA)
- Human Subject
- Modifications
- Non-Exempt
- Principal Investigator (PI)
- Quorum
- Standard Operating Procedure

Procedure:

1. Please review PNWU IRB SOP 103, which defines the institution's process for determining Health and Human Services (HHS) conducted or supported research studies qualify as exempt or non-exempt from the HHS regulations.

2. Please review PNWU IRB SOP 115, which defines the IRB's Function on determining exempt and non-exempt study designations.

3. Please review PNWU IRB SOP 124, which defines the IRB's review and approval process of studies.

4. When reviewing a research study, an IRB may take the following actions:
   a. Approve as submitted.
   b. Approve with conditions (modifications).
   c. Require modifications to secure approval (including changing the level of review); or
   d. Disapprove the research study or proposed changes

5. When an IRB approves research with conditions (also termed "conditional approval" or "contingent approval"), the IRB requires as a condition of approval that the investigator:
   a. Make specified changes to the research protocol or informed consent document(s);
   b. Confirm specific assumptions or understandings on the part of the IRB regarding how the research will be conducted; or
   c. Submit additional documents, such that, if the conditions are satisfied, the IRB is able to make all of the determinations required for approval under the HHS regulations

6. The IRB may require the following as conditions of approval of research:
   a. Confirmation of specific assumptions or understandings on the part of the IRB regarding how the research will be conducted (e.g., confirmation that the research excludes children);
   b. Submission of additional documentation (e.g., certificate of ethics training);
   c. Precise language changes to protocol or informed consent documents; or
   d. Substantive changes to protocol or informed consent documents, along with clearly stated parameters that the changes must satisfy

7. For research projects receiving conditional approval, the PNWU IRB has in place a verification process by an individual (IRB Chair, Vice Chair, IRB administrator, or back to the primary reviewers, if full board) with "appropriate expertise or qualifications" to determine whether the investigator has satisfied all conditions of approval stipulated by the IRB. This ensures that the investigator does not initiate any research that is different from what was approved by the IRB.

8. The effective date of the initial approval is the date on which the IRB reviewed and accepted as satisfactory any revised protocol or informed consent documents, or any other response materials required by the IRB from the investigator. No research study activities involving human subjects may be initiated until the conditions have been satisfied as required by the IRB.

9. If the IRB determines that the supplemental materials do not satisfy the stipulated conditions of approval, the investigator may not proceed with the research. Instead, the investigator may submit additional revisions or materials for IRB review in an attempt to satisfy the IRB's conditions. Alternatively, the investigator may choose to submit a modified research proposal to the IRB.

10. As part of a conditional approval, an IRB may also approve some components of a proposed research study while deferring taking action on other components of the proposed study. Thus, an investigator may initiate research activities only related to those approved components.

11. If conditions on IRB approval occur at the time of continuing review, the IRB must be careful to specify whether any conditions need to be satisfied before an investigator can continue particular research activities related to those conditions.

12. To comply with federal regulations and OHRP guidance, the IRB must document the following when it approves research with conditions:
    a. All conditions that must be satisfied by the investigator;
    b. The date when the IRB determines that all conditions of IRB approval have been satisfied, the date when initial approval becomes effective and the date by which continuing review must occur;
    c. In the case of initial review, any conditions under which some research activities may be initiated; and
    d. In the case of continuing review and the review of proposed changes to previously approved research, any conditions that need to be satisfied before an investigator can continue particular research activities related to those conditions.

13. Protocol corrections that are only administrative in nature (e.g., correction of typographical and spelling errors in the protocol) would not need additional IRB review because OHRP does not consider such corrections to be changes to the research.

14. All correspondence between the IRB and the investigator regarding the conditions of approval, as well as copies of all research proposals reviewed by the IRB and approved sample consent documents (including any revised protocol or informed consent documents), must be maintained in the IRB records.

References:

1. 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

2. Department of Health and Human Services, Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection, May 5, 2004.
3. Code of Federal Regulations, Title 42 Policies of General Applicability, Department of Health and Human Services, Part 50 Subpart F – Promoting Objectivity in Research

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 / 3-20-2018	M. McCarroll	Original SOP
.01 / 10-07-2019	C. Case	Put into new PNWU SOP format
.02 / 2-21-2023	C. Case	Review of SOP and correction of punctuation
.03 / 8-26-2024	J. Simmons	Removed L:Drive reference. Removed FERPA from definitions list and references section

Appendices:
None