Procedure Title: Appeal of PNWU IRB Decisions

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	7/13/2017	**Executive Lead:**	Chief Research Officer
Effective:	7/13/2017	**Revision History:**	.01 – 10/25/2017; .02 – 10/01/2019; .03 – 1-28-2020; .04 – 09/11/2020; .05 – 3/7/2023
Approved by:	Institutional Review Board		
Procedure Number:	108.05		
Key Words:	Appeal, Decisions, IRB Decisions, IRB Determination		
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 appealing Institutional Review Board (IRB) decisions.

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:
Under the federal regulations for the protection of human subjects, research studies may not begin without IRB approval. The IRB has the authority to disapprove research, specify modifications required to secure IRB approval, suspend approval of a study, or terminate approval of any research overseen and/or conducted by PNWU. The IRB may suspend or terminate approval of research that is not conducted according with the study protocol, IRB policies, federal and state law, or is associated with unexpected serious harms to participants. Studies that are reviewed via expedited procedures may not be disapproved. A study may only be disapproved when it has undergone review by the full board at a convened IRB Meeting.

Research approved by the IRB may be subject to further review by PNWU Officials (as appropriate). Officers or agents of Pacific Northwest University may choose not to support or permit research that the IRB has approved. The institution may not approve research that has been disapproved by the IRB.

The investigator may file an appeal to request that the Board reconsider their actions. They may appeal the following:

- Revisions required by the IRB to secure approval;

- IRB determinations of noncompliance, serious noncompliance, continuing noncompliance;
- IRB disapproval of research; and
- IRB termination or suspension of an approved protocol by the IRB.

If the appeal is denied, officers or agents of the Institution or the Institutional Official cannot override the IRB decision. Documentation of appeals is kept in the electronic IRB submission and review system. The Board's determination on the appeal is final and no additional appeals are permitted.

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
- Documenting submissions for appeals and outcomes in the electronic IRB submission and review system

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

- Supporting the IRB and investigators during an appeal process
- Monitoring compliance with this SOP
- Posting this SOP for the PNWU community

Investigator Responsibilities

- Submitting written appeals to the IRB Chair
- Submitting revisions to the study per the IRB's requests

Definitions

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

- Appeal
- Conflict of Interest
- Human Subject
- Investigator
- IRB determination
- Standard Operating Procedure

Investigator Procedure for Appeal:

1. If the investigator disagrees with an IRB determination, the investigator must submit a written appeal to the IRB Chair within 30 days of being notified of the determination. The appeal should include information addressing any arguments made in the IRB reason(s) for decision. The written appeal must provide adequate justification for asking the IRB to reconsider its decision.

2. At the request of the investigator and with the acquiescence of the IRB Chair and/or Vice Chair, the investigator may also present his/her response at a convened IRB meeting. The investigator may not be present during the IRB discussion or vote on the appeal.

IRB Procedure:

1. The IRB will review the response of the investigator at a convened IRB Meeting and determine whether to uphold or vacate its original decision. The IRB will vote to accept the appeal, request revisions, or deny the appeal. The investigator is notified in writing of the decision.
2. The Board's decision on the appeal is final and no further appeal is permitted.

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
6. Department of Health and Human Services (DHHS) Guidance - Institutional Review Boards Frequently Asked Questions, January 1998

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	Minor wording change section 6.3
.02 / 10-01-2019	C. Case	Put into the new PNWU SOP Format
.03 / 1-28-2020	C. Case	Added investigator responsibilities to page 1.
.04 /10-09-2020	C. Case	Added General information section – page 1. Responsible parties section: • Investigator responsibilities – changed wording to indicate that appeals should be submitted to the IRB in writing. Procedure section:

		• Section title changed from procedure to Investigator Procedure for Appeal. • Deleted Item 1 in the Investigator procedure section. The section was about IRB procedure, not investigator procedure. • Item 2 – remove statement that investigator has a right to appeal as it is a repeat of information added to the general information section. Added that a written appeal must be submitted to the IRB within 30 days. • Item 3 – changed wording regarding presenting appeal from at the next meeting to at a convened IRB meeting. New IRB section: • Added new section to separate IRB procedures from investigator procedures. • Added that the review of the appeal will take place at a convened meeting and that the IRB will vote on the appeal. Also added that the investigator will be notified "in writing". • Item 5 (now item 2 in new IRB section) reworded to make it clear that IRB determinations are final and additional appeals are not allowed.
.05 / 4-3-2023	C. Case	• Reworded paragraph 2 in the general information section. • Removed location of SOPs at the bottom of the SOP. All SOPs are stored on the IRB SharePoint site and on the IRB Electronic system in the resources folder. • Added reference #6 to HHS Guidance – IRB Frequently Asked Questions

Appendices:
None