Procedure Title: Collaborative Research and Reliance Agreements

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	03/31/2017	**Executive Lead:**	Chief Research Officer
Effective:	03/31/2017	**Revision History:**	.01 – 07/12/2017; .02 – 10/01/2019; .03 – 11/01/2021; .04 – 1/31/2023
Approved by:	Institutional Review Board		
Procedure Number:	105.04		
Key Words:	Cooperative, Cooperative Agreement, Reliance, Reliance Agreement		
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 other entities and administration of research.

Pacific Northwest University of Health Sciences acknowledges that each institution that is engaged in multi-institutional, collaborative research is responsible for safeguarding the rights and welfare of Human Subjects and for complying with applicable federal regulations.

With respect to such collaborative research, PNWU and the other institutions may choose to provide concurrent review within their own jurisdictions. Alternatively, the PNWU IRB may enter into a written agreement per which the PNWU IRB relies on the review of another qualified IRB or vice versa. The collaborative sites shall enter into formal written agreements that specify the roles and responsibilities of each party for all non-exempt research and exempt research with identifiable data requiring limited IRB review..

This SOP must be used as a guide in parallel with OSA Policy 1.0 to comply with proper reimbursement of human subject compensation. 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:

- Approving and requiring modifications to secure approval, or disapprove all research activities overseen and conducted under the auspices of PNWU, regardless of location of the research activities.
- Requiring that informed consent be obtained and documented in accordance with regulatory requirements unless the criteria for the waiver or alteration of such requirements has been satisfied and approved by the IRB.

        - The IRB may require that information, in addition to that specifically mentioned in the regulations, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.
    - Conducting continuing review of research at intervals appropriate to the degree of risk of the research.

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

- Supporting investigators in helping determine activities subject to human subject protection.
- Monitoring compliance with this SOP.
- Posting this SOP for the PNWU community.
- Providing the necessary support to investigators and the IRB.
- Assisting in the processing of the IRB cooperative agreements.

The Investigator is responsible for:

- Asking the OSA if their activity is subject to human research protections.
- Communicating with IRB members and OSA staff in a timely fashion.
- Seeking support from OSA and the IRB on proper protocol development and submission.
- Working with OSA on the processing of the IRB collaborative agreement
- Obtaining information from the outside institution to facilitate appropriate documentation for the IRB of record.

Definitions

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

- Federal Wide Assurance
- IRB
- Cooperative Agreement
- IRB Authorization Agreement
- Non-federally funded sub-contractor
- Vendor
- Subcontractor
- Federally funded sub-contractor

Procedure:

1. If a determination is made that the outside institution is engaged in human subjects research and the outside institution is receiving federal funds through a subcontract with PNWU, the Office of Scholarly Activity (OSA) requires documentation that the outside institution holds an FWA through the subcontract process. If the outside institution does not hold its own FWA, PNWU requires that they obtain one prior to finalization of the subcontract. Engagement Determination Checklist.

2. If this is the case and the other institution obtains its own FWA, there are a few methods of IRB oversight that the PNWU IRB would consider acceptable based on the circumstances of the project and the role of the other institution. The PNWU IRB may accept the other institution's IRB as the IRB of record for the project. This would be in cases where the PNWU IRB determines that the outside institution's IRB review will provide more appropriate expertise, oversight, and/or knowledge of local context for the PNWU role in the study. This agreement is formalized using an IRB Authorization Agreement or other equivalent agreement.

3. If the outside institution does not hold its own Federal Wide Assurance, under limited circumstances, when PNWU is able to assure understanding of local context in relation to the proposed research and has sufficient resources to provide appropriate oversight during the conduct of the research, may choose to extend its Federal Wide Assurance to cover the outside institution's role in a single project.

4. In the conduct of cooperative research projects, each institution (or entity) is responsible for safeguarding the rights and welfare of human subjects and for complying with any applicable regulations. Federal regulations from the Department of Health and Human Services and the Food and Drug Administration (45 CFR 46.114 and 21 CFR 56.114) allow for cooperative research projects, which involve more than one institution. To avoid duplication of review efforts by IRBs, PNWU can choose to conduct joint reviews, rely upon the review of another qualified IRB, or make other arrangements to establish oversight responsibilities. The PNWU IRB makes a determination about whether or not a cooperating outside institution is also engaged in human subjects research in collaboration with the university. This determination is made by the PNWU IRB Chair based on the outside institution's role and whether that role meets any of the criteria for "engaged in research" as defined in Office for Human Research Protections guidance of October 16, 2008.

5. When an outside institution is engaged, the PNWU IRB may oversee research for an outside institution only when the PNWU IRB is able to assure understanding of local context in relation to the proposed research and has sufficient resources to provide appropriate oversight during the conduct of the research.

6. When the outside institution is engaged as described in.5 above, PNWU and the outside institution may sign an IRB Authorization/Cooperative Agreement or other equivalent agreement to make the PNWU IRB the IRB of record for that project.

7. The final determination to enter into any agreements is made by the Institutional Official.

8. When this occurs and the research is non-federally funded (e.g. private foundation), the protocol would be submitted to the PNWU IRB in normal fashion. The final determination to enter into any agreements is made by the Institutional Official.

9. If PNWU provides IRB review of research concurrently with the IRB review of the collaborative institutions' IRBs, all policies and standard operating procedures, rules, regulations and laws shall apply to PNWU's review just as they would in non-collaborative research IRB reviews.

10. With regard to any cooperative research projects that fall within the jurisdiction of the PNWU IRB, PNWU may rely on another appropriately constituted IRB for the review of the research.

11. The IO has the sole authority to make the decision whether or not to rely on another IRB. The IO is authorized to execute IRB Cooperative Agreements on PNWU's behalf and may delegate this authority provided the delegation of authority is recorded in writing. In deciding whether or not to rely on another IRB, the IO or delegate shall consider the following criteria:
    a. If the other IRB is part of an AAHRPP-accredited HRPP, then it will be presumed that PNWU standards are being met; however, accredited status does not in itself necessarily suffice as a basis for the IO's decision.
    b. If greater-than-minimal-risk research activities will take place under the direction of PNWU personnel at sites normally under PNWU IRB jurisdiction, generally PNWU will not rely on

another IRB for review unless it is a central or commercial IRB with which PNWU has a standing reliance agreement.

c. For central or commercial IRBs, PNWU will agree to rely if the central or commercial IRB for more than minimal risks studies if the reviewing IRB is AAHRPP accredited, and the terms of the reliance agreement, including procedures for communication between the two organizations, are acceptable to both the Organization and the Principal Investigator.
d. If the National Institutes of Health (NIH) requires the use of a specific central IRB for a multicenter study or group of studies, and the IRB is not AAHRPP accredited, PNWU will rely on the NIH's determination that the central IRB is qualified to review the research.
e. For minimal risk federally funded studies, the IO or delegate will ensure that the reviewing IRB has an FWA and that that IRB is registered with the Office of Human Research Protections (OHRP).
f. The IO shall ensure that delegates for both institutions appropriately sign any required cooperative agreement.
g. The agreement must set forth PNWU's FWA number and for research subject to federal regulations, the FWA of the other party to the agreement. The agreement should identify by title, respective Principal Investigators (PIs), and sponsorship the Human Subjects Research scope and clearly state which party is relying on the other for IRB review, and how the relying party will be kept informed of the reviewing IRB's actions. Further details should be included in an appropriate template for use by the PNWU IRB and IO.

12. The PNWU IRB may serve as the IRB of record for an entity that does not have its own IRB (outside of Memorandums of Understanding) if:
    a. PNWU is involved in the conduct of or funding of the Human Subjects Research at the entity; or collaborating with the entity in the conduct of the Human Subjects Research, or is providing funding for the research;
    b. The IO approves of the arrangement in advance;
    c. The PNWU IRB can develop appropriate means by which to consider the local context of the Research; and
    d. If the research involved is being supported by a federal agency and the entity is engaged in research, then the entity must have an appropriate FWA in effect. If the foregoing criteria are met, then the PNWU IRB may enter into an appropriate cooperative agreement.

13. In cases in which PNWU PIs are conducting Human Subjects Research at non- PNWU sites that do not have an FWA, then all Human Subjects Research procedures and practices must be carried out by PNWU personnel and PNWU and the non-PNWU site must not be engaged in research, with the exception of non-PNWU personnel at that site covered by a cooperative agreement in order to conduct research under the auspices of PNWU's FWA. Criteria for the extension of PNWU's FWA to cover individual investigators shall follow OHRP guidance. The PNWU IRB should obtain, via the PI, written permission from the Non- PNWU site at which the research is to take place, for PNWU investigators to conduct the Human Subjects Research at the site.

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. 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

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 /3-31-2017	M. McCarroll	New Standard Operating Procedure
.01/ 7-12-2017	M. McCarroll	Section 3.1 revised to be more specific to the purpose of this SOP
.02 / 10-01-2019	C. Case	Put into the new PNWU SOP Format
.03 / 11-01-2021	C. Case	Added clarification in paragraph 3 on page 1 that reliance agreements are for non-exempt research.
.04 / 1-31-2023	C.Case	• Fixed the inconsistent fonts so that it is the same throughout the SOP. • Added a link to the Engagement Determination checklist (item 1 in the procedure section). • Corrected minor grammatical errors. • Added the reliance agreement information for exempt studies with identifiable data required to undergo limited IRB review (3rd paragraph page 1)

Appendices:
None