

#### Procedure Title: Engagement in Research with Human Subjects

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| **Associated Policy:** | Human Research Protection Policy (OSA Policy 1.0) |
| **Responsible Unit:** | Office of Scholarly Activity |
| **Created:** | 05/21/2020 | **Executive Lead:** | Chief Research Officer |
| **Effective:** | 09/30/2020 | **Revision History:** | .00 – 05/21/2020; .01 – 3/22/2023 |
| **Approved by:** | Institutional Review Board |
| **Procedure Number:** | 149.01 |
| **Key Words:** | Agents; engaged; interaction; intervention; private information;  |
| **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 regarding the process for determining, documenting, and communicating whether PNWU (or other institution) is engaged in research with human subjects.

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**

Several institutions or individuals (e.g., investigators, students, faculty, and staff) may work together on different aspects of a research project. Employees or agents of the institution may perform institutionally-designated activities or act on behalf of the university (exercise institutional authority or responsibility) however all participating individuals or institutions may or may not be ***engaged*** in the research.

According to OHRP, an institution is ***engaged*** in research with human subjects when its employees or agents, for the purposes of a research project, obtain:

1. data about the subjects of the research through intervention or interaction with them;
2. identifiable private information about the subjects of the research or;
3. the informed consent of human subjects.

*Responsible Parties*

 The Institutional Review Board (IRB) is responsible for:

* Protecting the rights and welfare of human research participants.
* Impartiality when reviewing human subjects’ research.
* Remaining immune from pressure by the institution’s administration, the investigators whose protocols are brought before it, or other professional and nonprofessional sources.
* Providing support to investigators when determining “engagement” in research with human subjects.

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

* Supporting the investigator in determining “engagement” in human subjects’ research.
* Overseeing and providing the necessary support to the IRB.
* Monitoring compliance with this SOP.
* Posting this SOP for the PNWU community.

 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.

* Agent
* Engaged
* Federal wide Assurance
* Human Subject
* Interaction
* Intervention
* Private Health Information (PHI)
* Private Information
* Reliance Agreement
* Research

**Procedure:**

When PNWU employees or agents are engaged in the research project, the PNWU IRB must either review the project, or defer oversight to a qualified IRB. Principal investigators should fill out the Engagement Determination checklist [here](https://redcap.link/engagement_determination_checklist) and contact OSA for assistance when a reliance agreement is needed.

With respect to collaborative research, PNWU and the other institutions may choose to provide concurrent review within their own jurisdictions. Alternately, the PNWU IRB may enter into a written agreement whereby 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. Additional information about reliance agreements may be found in SOP 105 Collaborative Research and Reliance Agreements.

**Engaged Examples:**

* PNWU is a direct recipient (prime awardee) of a grant, contract, or cooperative agreement directly from the Department of Health and Human Services (HHS) or another federal entity. This may be true even when employees or agents of another institution carry out all activities.
* An employee or agent of PNWU intervenes or interacts with human subjects for the purpose of research through:
	+ Intervention: Invasive or noninvasive procedures (e.g., blood draw, collection of cells through buccal mucosa swab, administering drugs, utilizing other measurement procedures); or
	+ Interaction: Interacts with human subjects including communication or interpersonal contact between the investigator/study team member and the subject (e.g., surveying, interviewing, obtaining consent, or obtaining private identifiable information or specimens). Applies even if there is not direct interaction with the human subject.
	+ Manipulating the environment (e.g., controlling light, sound, temperature, orchestrating events or social interactions).
* An employee or agent of PNWU obtains identifiable private information or identifiable specimens (e.g., using, studying, recording, or analyzing identifiable private information or identifiable specimens provided by another institution or specimens already in the possession of the investigators) for the purposes of research.

**Not Engaged Examples:**

* When PNWU employees or agents perform commercial or other services for external researchers provided that all of the following are met:
* Services performed do not merit professional recognition (e.g., authorship).
* Services performed are typically performed by those institutions for non-research purposes.
* Services performed do not include administering any research intervention being tested or evaluated.
* When an external institution/researcher is permitted to recruit on PNWU campus or use PNWU facilities for intervention or interaction with participants.
* When a PNWU student is conducting human subjects research as an agent or affiliate of another institution (e.g., they are an employee or volunteer) AND the student will not use PNWU as their affiliation for any final publications or presentations related to the research.
* When PNWU employees or agents are involved in the design or in a consulting role but will not initiate the research and will not otherwise be conducting any human subjects’ research activities (e.g., recruitment, obtaining consent, data collection, interventions/interactions, and data analysis).
* When PNWU employees or agents are limited to informing prospective students about the research opportunity (e.g., passive distribution of recruitment materials).
* When PNWU employees or agents are limited to releasing data/samples and are not otherwise involved in the research (e.g., not involved in design of the study and/or data analysis and will not receive professional recognition).
* When the role of the PNWU employee or agent is limited to obtaining, accessing, or analyzing coded research data from another institution, and the institutions have entered into a data use agreement that prohibits any identifiers from being released to the researchers.
* When a PNWU employee or agent is involved in authoring a manuscript, journal article, or presentations describing a human subjects research project with no access to identifiers.

**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. Department of Health and Human Services Guidance: Engagement of Institutions in Human Subjects Research <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html>
4. Department of Health and Human Services Guidance: Determining When Institutions are Engaged in Research <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/determining-when-institutions-are-engaged-in-research/index.html>
5. [PNWU SOP 107 Credentialing Requirements for Human Subjects Protections](https://www.axiommentor.com/login/authkey.cfm?i=pnwu&key=78f6vuc0boOANRwGi5o4BJg69EBNGwOiyMtkJovKdxiOS3TJjIt3clqIpcV3jBZe)
6. [PNWU SOP 103 Activities Subject to Human Protections](https://www.axiommentor.com/login/authkey.cfm?i=pnwu&key=NdBwo7lFw8qlpiiMOHWguHkqwV9Pvt3JQVi8mdzv5LQk17tXsXeRdCi5jbxVxhru)
7. [PNWU SOP 105 Collaborative Research and Reliance Agreements](https://www.axiommentor.com/login/authkey.cfm?i=pnwu&key=PzsRS4xkp7xWYtYv1M3huMoG6W8%2FS0mCa6woBtUfhj4IG4HBoGBdBDkWN0s1w6iB)

**Revision History:**

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| **Version/Effective Date** | **Author** | **Section Changed & Reason for Revision**  |
| .00 / 09-30-2020 | C. Case | Original SOP |
| .01 / 3-22-2023 | C. Case | Revised first paragraph to add the link for the newly created engagement determination checklist; corrected minor punctuation errors; added PNWU SOP links in the reference section. |
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**Appendices:**