Procedure Title: Activities Subject to Human Protection

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	02/22/2017	**Executive Lead:**	Chief Research Officer
Effective:	02/22/2017;	**Revision History:**	.01 – 03-31-2017; .02 – 10-10-2017; .03 – 08-06-2018; .04 – 10-01-2019; .05 – 03-11-2021; .06 – 3-6-2023; .07 – 8-26-2024
Approved by:	Institutional Review Board		
Procedure Number:	103.07		
Key Words:	Human Subject, Human Research, Protection; Quality Improvement; Quality Assurance; Case Report; Case Series		
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 activities subject to human protections.

This SOP must be used as a guide in parallel with OSA Policy 1.0 to comply with federal regulations and institutional policies and procedures when conducting research with human subjects. 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:

- 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;

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;

The Investigator is responsible for:

- Asking 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;

Definitions

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

- Case Study
- Case Series
- Generalizable Knowledge
- Human Subject
- Investigator
- Quality Improvement
- Research
- Systematic Investigation

Procedure:

1. Research that does not meet the definition of research involving human subjects must be determined by OSA, not an individual investigator.
2. Investigators must complete a request for a Not Human Subjects Research (NHSR) determination via the electronic IRB system including a summary of the project and any applicable documents. Note: Projects that will collect data about human participants must be submitted and reviewed prior to beginning data collection.
3. NHSR determinations are made by an OSA staff member, typically the IRB Administrator, who may consult with the IRB Chair, if necessary.
4. The reviewer reviews all information submitted by the investigator and documents the determination in the electronic IRB system. Additional information may be requested, as needed.
5. If the project is verified as NHSR, the investigator is notified in writing. The investigator may request a determination letter at the time the NHSR request form is submitted in the electronic IRB system.
6. If the reviewer determines that the project meets the regulatory definition of human subjects research, the review proceeds as with any other new study application.
7. All research activities that appear to be subject to DHHS and/or FDA regulations require IRB review as with any other new study application.
8. In all cases, investigators should contact OSA to discuss the research project in question to obtain a determination of the type of IRB review that may be required.
9. Example activities typically not subject to human research protections are:
    - Class Projects, Research Practices, and Undergraduate Thesis Projects involving research methodology and course-assigned data collection. These activities generally do not constitute research because they are designed to provide training in research as part of the overall educational mission of a program and are not intended to contribute to new knowledge.
    - Quality Assurance/Quality Improvement Programs that attempt to measure the effectiveness of programs or services, including program evaluations, model curriculum, or needs assessments. Such activities are not typically designed to be generalizable to the larger community and would not be considered research if results will not be compared with other

assessments. Those responsible for such projects must be certain that the activities are not human subjects research and should contact OSA.

- Case Reports/Case Series (equal to or less than 4 subjects) utilizing private identifiable information such as medical information collected from a clinical activity. Clinical case reports are generally carried out by retrospective review of records and highlight a unique treatment, clinical case or outcome. As the collection and organization of information for such reports usually involves no data analysis or testing of a hypothesis, they do not constitute a systematic investigation. Therefore, single case reports/series would not require IRB review.
- Research on Institutions or Social Processes when the intent or focus of the research is to gain knowledge of an institution or social process (e.g., political party or labor negotiations) and this research is not intended to generate generalizable knowledge about any particular individual or groups of individuals. Often, investigators wish to collect information from individuals about institutions or social processes. Such activities are not considered human subjects research when the focus of the research is not on characteristics of an individual or groups of individuals because the information collected from the informant is not about the informant.

10. Example activities typically subject to human research protection are:
    - Training programs in which individual training projects remain to be selected, randomized, or designed.
    - Research, pilot or developmental studies in which the involvement of human subjects depends on such things as the completion of survey instruments or prior animal studies.
    - Institutional Support Programs where the selection of the project is the responsibility of the institution or program administrator.
    - When supporting agencies require review and certification for such programs, protocols are to be submitted to the IRB with as much information as is available.
    - Masters Theses/Doctoral Dissertation involving human subjects.
    - Pilot Studies involving human subjects.
    - Clinical Investigations including research to increase scientific understanding about normal or abnormal physiology, disease states or development and research to evaluate the safety, effectiveness, or usefulness of a medical product, drug, device, procedure, or intervention. Vaccine trial, medical device research, and cancer research are all types of clinical investigation.
    - Behavioral and Social Science Studies such as investigations on individual and group behavior, mental processes, or social constructs. These usually generate data by means of surveys, interviews, observations, studies of existing records, and/or experimental designs involving exposure to some type of stimulus or environmental intervention.
    - Epidemiological Studies such as investigations on health outcomes, interventions, disease states, and conclusions about cost-effectiveness, efficacy, efficiency, interventions, or delivery of services to affected populations. This research may be conducted through surveillance, monitoring, and reporting programs. Other methods may include retrospective review of medical, public health, and/or other records. Thus, includes meta-analysis of multiple case reports and retrospective record reviews that incorporate data collection and analysis.

11. Since journals often require proof of IRB administrative review, the “Not Human Subjects Research Determination” form on the electronic IRB system should be completed to ensure the project is not

human subject research. If, after the form is completed, the activity is determined not to be subject to human research protections, a letter from OSA can be requested by the investigator. This letter can be provided to the journal of which the information is being submitted for consideration.

References:

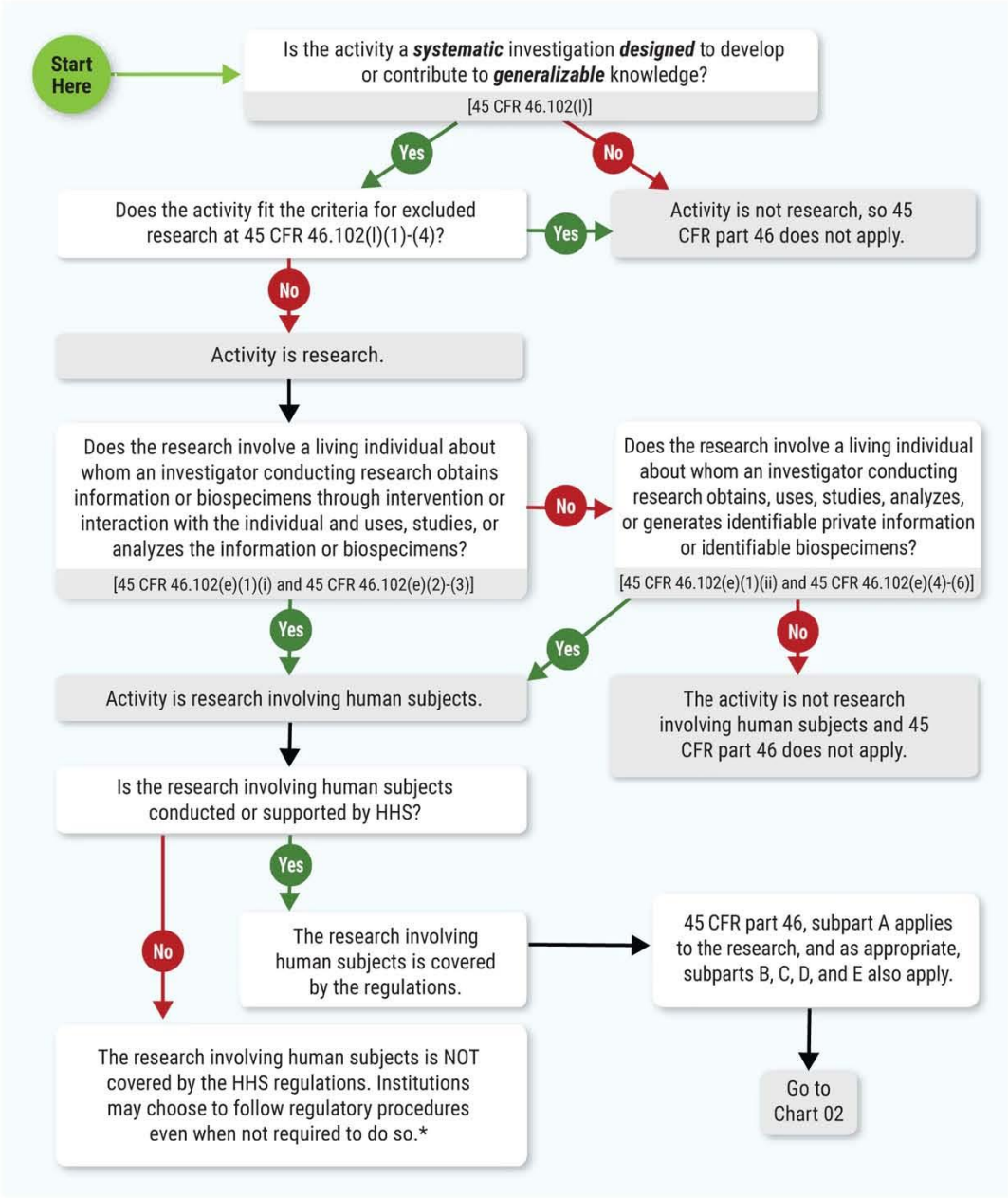
1. Human Subject Regulation Decision Charts. https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html
2. Food and Drug Administration (FDA) Federal Regulations (21 CFR 50, 54, 56, 312, 314, 600, 601, 812 and 814) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
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. U.S. Food and Drug Administration Comparison of FDA and HHS Human Subject Protection Regulations. https://www.fda.gov/science-research/good-clinical-practice-educational-materials/comparison-fda-and-hhs-human-subject-protection-regulations
7. PNWU SOP 121 Quality Improvement vs Research

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 / 02-22-2017	M. McCarroll	New Standard Operating Procedure
.01 / 03-31-2017	M. McCarroll	Minor changes made per HRP Review
.02 /10-10-2017	M. McCarroll	Minor formatting and content changes 5.0 and 6.1
.03 /08-06-2018	M. McCarroll	Added 6.12
.04 /10-01-2019	C. Case	Put into new PNWU SOP Format
.05 /04-27-2021	C. Case	• Added language in procedures about the Not Human Subjects Research request form in the electronic IRB System. • Deleted definitions not used in this SOP. • Added the requirement to submit the Not Human Subjects Research request form prior to collecting data in those projects that will collect data from human participants. • Replaced the Appendix: Human Subject Regulations Decision Charts 2018 Requirements – Chart 1 with current version. • Added reference to the U.S. Food and Drug Administration Comparison of FDA and HHS Human Subject Protection Regulations Chart. • Removed sentence about research incentives from second paragraph about process on page 1 as it was not relevant to this SOP.

.06 / 3-6-2023	C. Case	Added reference #7 to PNWU SOP 121 Quality Improvement vs research.
.07 / 8-26-2024	J. Simmons	Replaced reference to IRB Manager (previous system no long in use), replaced instances of "IRB staff" with "OSA" or "OSA staff member" (all terms were used interchangeably previously), updated name of NHSR determination form to its current one, some changes in grammar/verbiage for clarity.

Appendices:

Human Subject Regulations Decision Charts 2018 Requirements: Chart 1 – Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46. (https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c1)


Start Here
Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge?
[45 CFR 46.102(l)]
Yes
No
Does the activity fit the criteria for excluded research at 45 CFR 46.102(l)(1)-(4)?
Yes
Activity is not research, so 45 CFR part 46 does not apply.
No
Activity is research.
Does the research involve a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens?
[45 CFR 46.102(e)(1)(i) and 45 CFR 46.102(e)(2)-(3)]
No
Does the research involve a living individual about whom an investigator conducting research obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens?
[45 CFR 46.102(e)(1)(ii) and 45 CFR 46.102(e)(4)-(6)]
Yes
Yes
No
Activity is research involving human subjects.
The activity is not research involving human subjects and 45 CFR part 46 does not apply.
Is the research involving human subjects conducted or supported by HHS?
Yes
No
The research involving human subjects is covered by the regulations.
45 CFR part 46, subpart A applies to the research, and as appropriate, subparts B, C, D, and E also apply.
Go to Chart 02
The research involving human subjects is NOT covered by the HHS regulations. Institutions may choose to follow regulatory procedures even when not required to do so.*