Procedure Title: Public Health Practice vs. Research

Associated Policy:	Human Research Protection Policy (OSA Policy 1.0)		
Responsible Unit:	Office of Scholarly Activity		
Created:	06/03/2020	**Executive Lead:**	Chief Research Officer
Effective:	06/30/2020	**Revision History:**	.00 – 6/03/2020; .01 – 1/25/2023
Approved by:	Institutional Review Board		
Procedure Number:	147.01		
Key Words:	Research, Principal Investigator (PI), Project Director (PD), Public Health, Public Health Practice, Public Health Surveillance, Generalizable		
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 Federalwide Assurances (FWAs)		

Process:
This SOP serves to inform all agents, offices, departments, and affiliate sites of PNWU regarding when public health practice may be human subjects research.

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:
Public health surveillance activities that are authorized, conducted, required, or supported by a public health authority (federal, state, local, or tribal) are not research per the Common Rule (45 CFR 46.102(l)(2)). Surveillance activities may be carried out by a public health authority or under a contract or grant of authority from the agency. According to the Common Rule, "public health surveillance activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, and patterns in diseases or injuries)."[2]

However, the regulations do not clearly define the difference between research and public health practice. Research and public health practice have similar characteristics that often intersect. Common characteristics include: use of scientific methods, systematic collection of personally identifiable health data, interpretation and analysis of data, and dissemination of findings. Because of the similarities, the distinction between research and public health practice can be difficult.

The key difference between research and public health practice is the intent or purpose of the activity. According to the federal regulations, research is *designed* to develop or contribute to generalizable knowledge. Public health practice is *designed* to prevent disease, identify a health problem, control disease,

prevent injury, or improve a public health service or existing program and is done at the request of a public health jurisdiction. Both activities may result in publication of findings.

The Health Insurance Portability and Accountability Act (HIPAA) applies whether the activity is public health practice or research. The HIPAA rule allows covered entities to disclose protected health information to public health authorities for specific health purposes without authorization. These purposes include child abuse or neglect, persons at risk of contracting or spreading a disease, and workplace medical surveillance.

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.

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

- Supporting the investigator in the development of scholarly activity;
- Providing guidance regarding public health practice vs. 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.
- Protecting participant autonomy and privacy in research and/or public health activities.
- Ensuring compliance with the IRB-approved protocol, federal regulations, state laws, good clinical practice, and applicable FDA guidance.
- Ensuring the health, safety, and welfare of individual participants in research and/or public health activities.
- Seeking support from OSA and the IRB when questions arise.

Definitions

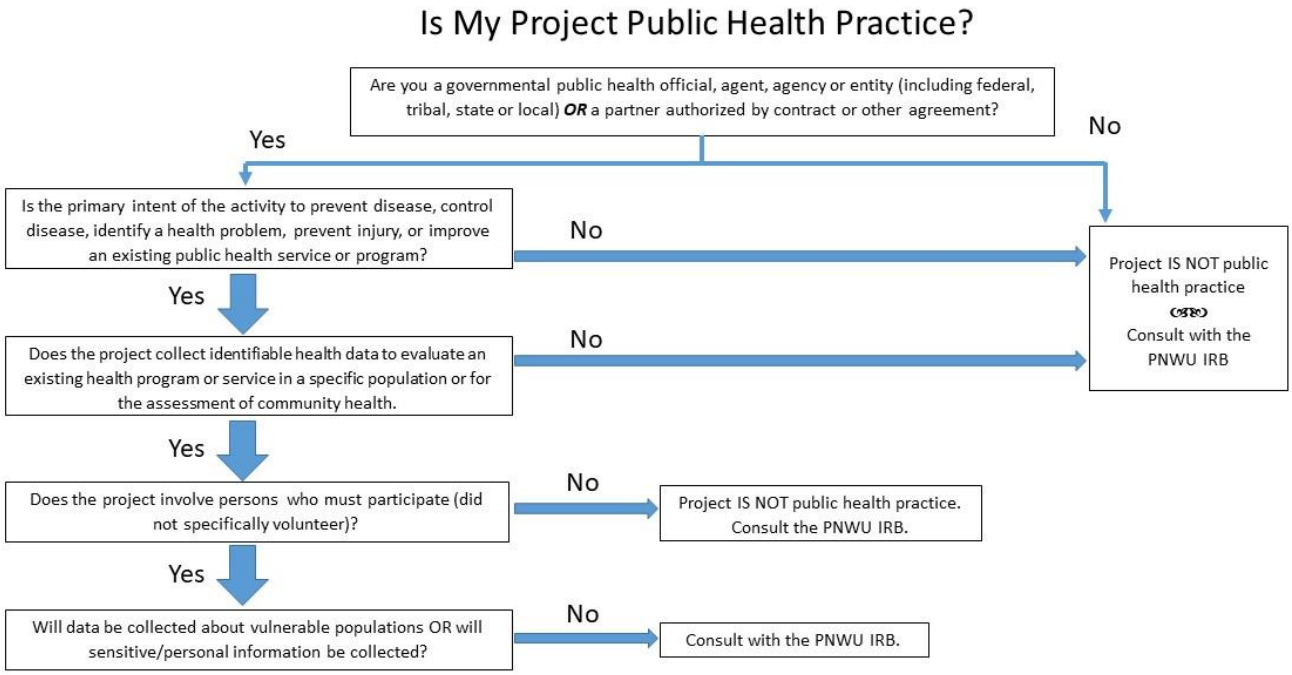
Please reference the Glossary for complete definitions of the following terms and additional terms not listed.

- Generalizable Knowledge
- Public Health Practice
- Public Health Surveillance
- Research

Project Director/Principal Investigator Procedure:

1. Project director/principal investigators are encouraged to work with OSA and the IRB in the determination of public health practices versus research.
    a. Indications that the proposed activity may be research and NOT public health practice include:
        i. the project is not designed to directly inform public health decision making or action;
        ii. additional risks are imposed on the participants by adding an intervention or the collection of data beyond what is needed for public health surveillance or public health practice to make the results generalizable beyond the actual participants;

iii. the activity includes a nonstandard or experimental intervention (e.g., an approved drug being used to treat a disease for which it is not approved);



2. Investigators who would like a determination from the IRB that the project does not meet the threshold for human subjects research are encouraged to fill out and submit written documentation of the proposed activity via a request for not human subjects research (NHSR) determination to the IRB via the electronic IRB system.

IRB Procedures:

1. The IRB administrator will review all requests for not human subjects' research determination in a timely manner and request additional information about the proposed project when needed.
2. The IRB administrator will consult with the IRB chair when necessary.
3. The IRB administrator will provide determinations in writing to the individual submitting the request for not human subjects research determination.

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. Otto, J. L., Holodniy, M., & DeFraites, R. F. (2014). Public health practice is not research. American journal of public health, 104(4), 596–602. https://doi.org/10.2105/AJPH.2013.301663
4. Human Participant Protection in CDC Research. https://www.cdc.gov/os/integrity/hrpo/index.htm
5. Washington State Department of Health, Human Subjects and Public Health Practice Guidelines for Ethical Data Collection. https://www.doh.wa.gov/Portals/1/Documents/1500/HumSubjguide.pdf
6. Distinguishing Public Health Research and Public Health Nonresearch. https://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf

7. U.S. Department of Health and Human Services. The HIPAA Privacy Rule. https://www.hhs.gov/hipaa/for-professionals/privacy/index.html
8. U.S. Department of Health and Human Services. Activities Deemed Not to Be Research: Public Health Surveillance 2018 Requirements. https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-activities-deemed-not-be-research-public-health-surveillance/index.html
9. OCR HIPAA Privacy: Disclosures for Public Health Activities. https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/publichealth/publichealth.pdf
10. The Belmont Report. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

Revision History:

Version/ Effective Date	Author	Section Changed & Reason for Revision
.00 / 06-30-2020	C. Case	Original SOP
.01 / 01-25-2023	C. Case	Minor formatting revisions so the same font is used throughout the SOP; Removed the L: Drive location from the footer as all SOPs are now in the resources folder of the IRB management system;

Appendices: