WRIGHT STATE UNIVERSITY

PUBLIC HEALTH SURVEILLANCE GUIDANCE

The Wright State University Institutional Review Board (IRB) frequently receives inquiries regarding whether projects involving public health surveillance constitutes human subjects research. Like research, public health surveillance activities are generally data driven and involve human participants. Unlike human subjects' research, public health surveillance activities generally do not require submission to the IRB for review. However, due to the systematic nature of some these projects, there may be overlap with research methods and determining whether an activity is public health surveillance, research, or both can be challenging.

The purpose of this guidance to:

- Clarify the regulatory requirements associated with public health surveillance projects and when they fall under the purview of the IRB

DEFINITION

There is no regulatory definition, however, it states that those activities include "the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority."

Examples of such data may include information about:

- The spread and control of communicable diseases
- Injuries and conditions
- Population vital statistics
- Tracking of health risk factors and outcomes
- Monitoring of environmental hazards and conditions that threaten access to safe workplaces and housing, and clean air, water, and uncontaminated food sources.

To be considered a public health surveillance activity, these data must be collected, shared and used for health-related policy making, advocacy, and to prepare system responses to new threats.

IRB REVIEW NOT REQUIRED

Research, as defined by DHHS at 45CFR46.102(d), means a "systematic investigation", including research development, testing and evaluation, designed to develop or contribute to "generalizable knowledge," such that conclusions will be drawn that can be applied to populations outside of the specific study population. The reason for this determination is that DHHS "recognizes that the requirements of 45 CFR 46 should not impede a public health authority's ability to accomplish its mandated mission to protect and maintain the health and welfare of the population(s) for which it is responsible. The study results are limited to a specific population and not being generalized to other populations; thus, IRB review is generally not required.

The following criteria must be met to qualify as Public Health Surveillance:

1. the activity must be conducted, supported, requested, ordered, required, or authorized by a **public health authority**;
    a) academic institutions, health care organizations, and non-profit entities, **do not** constitute public health authorities.
    b) Examples of public health authorities: Centers for Disease Control (CDC), Ohio Department of Public Health, county public health departments
        1. Can includes employees, agents, entities, or contractors
2. the activity must be a **public health surveillance activity**; and
    a) Must generally involve collecting, testing, analyzing, and using information or biospecimens to improve public health and prevent disease;

WRIGHT STATE UNIVERSITY

PUBLIC HEALTH SURVEILLANCE GUIDANCE

1. Must serve the purpose **of informing a public health authority** on taking certain action, such as disseminating information to the public, or issuing orders or guidance

3. the activity must be limited to *only* that **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.

WHEN PUBLIC HEALTH SURVEILLANCE REQUIRES IRB REVIEW

In some instances, public health surveillance activities are designed to accomplish a research purpose, as well as the purpose of improving public health. In such cases, IRB review and approval must be in place BEFORE project initiation. The major difference between research and non-research lies in the purpose of the activity. The purpose of research is to generate or contribute to generalizable knowledge. The purpose of non-research in public health is to prevent or control disease or injury and improve health, or to improve a public health program or service.

Examples of Public Health Research:

- Activities where data are gathered for public health surveillance AND the results will be generalized across multiple populations should be viewed as research.
- Activities where the research will contribute to new knowledge about the health condition;
- Activities involve longitudinal designs (such as follow up surveys) that allow for hypothesis testing;
- If the scope of data collected is broad and includes more information than the occurrence of a health condition;
- If cases are identified in order to be included in subsequent studies;
    - While secondary research can be carried out concurrently with a public health surveillance activity, that portion of the project that is not public health surveillance is not subject to the research exclusion.

CHARACTERISTICS OF PUBLIC HEALTH PRACTICE VESUS RESEARCH

This table is intended to help in determining whether a project requires submission to the IRB as a research project involving human subjects.

Common Elements	
Public Health Practice	**Research**
Involves direct performance or oversight by a governmental public health authority (or its authorized agent) and has public accountability	Often conducted by academic centers and institutions which have experience conducting research
Primary intent is to prevent or control a disease or injury	Main aims are to research and draw conclusions about a hypothesis in order to contribute to the field at large
Focused on improving the health of a specific population or group	Focused on generating knowledge that can be disseminated and applied broadly
Benefits and risks are primarily designed to accrue to the participating community	Benefits are intended to apply beyond the participating community who bear the risks
May legitimately involve persons who did not specifically volunteer to participate	Involves research subjects who voluntarily consent to participate

Table developed by Emory University IRB