**Public Health Surveillance Activities: Guidance for Investigators**

The Revised Common Rule (RCR) promulgated by the U.S. Office of Human Research Protections (OHRP) explicitly deems “public health surveillance activities” not to be “research”, and thus not governed by the regulatory requirements of 45 CFR 46. 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.”[[1]](#footnote-1) This principle applies to public health authorities in the U.S. (federal, state and local) and in other countries.

Although the RCR does not define “public health surveillance”, 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.”[[2]](#footnote-2) The World Health Organization (WHO) Guidelines on Ethical Issues in Public Health Surveillance (2017) (WHO Guidelines) is a resource that may be helpful in outlining the kinds of activities that constitute “surveillance”. WHO generally defines surveillance as “the continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice.”[[3]](#footnote-3)

Examples of such data 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.

The Office of Human Research Protections (OHRP) issued draft guidance to assist researchers and Institutional Review Boards (IRBs) in determining whether a planned activity constitutes a public health surveillance activity. The Guidance provides that “[p]ublic heath surveillance uses information and biospecimens from a variety of sources, including mandatory reporting of certain conditions, routine monitoring, vital records, medical records, medical billing records, clinical specimens, and public health investigations. Further, it often uses the same analytical and laboratory techniques as epidemiological research.”[[4]](#footnote-4)

The Guidance notes that the principal difference between surveillance and research is one of purpose; for surveillance, it is “to inform the decisions or actions that must be made by a public health authority.”

There are limits to the kinds of surveillance activities that will be deemed not to be “human subjects research”: the activities must be those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onset of disease outbreaks, or conditions of public health importance.”

At Johns Hopkins University, the IRB will make the determination of whether an activity constitutes a public health surveillance activity because, as the OHRP guidance acknowledges, “the line between public health surveillance activities and research activities can be difficult to draw.” If the JHU IRB makes a “public health surveillance/not research” determination, it may also advise the investigator to adhere to relevant ethical guidelines for the conduct of the surveillance activity (such as the WHO Guidelines).

 The IRBs will ask investigators for information to determine whether the activity qualifies as a public health surveillance activity. This may include:

* Whether the activity is necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onset of disease outbreaks, or conditions of public health importance. *(Note: It is unlikely that an activity meeting the definition of “clinical trial” would fall into this category.)*
* Whether there a **direct link** between the surveillance activity and the decision-making and action by a public health authority.
* Whether the activity will be **conducted by** a public health authority [e.g. the public health authority will participate directly in the collection, testing, analysis or use of the information/biospecimens]
* Whether the activity will be supported by a public health authority [e.g. through a grant or contract]
* Confirmation that the relevant public health authority is responsible for public health matters as part of its official mandate

**Definitionsfrom the 2018 OHRP Guidance**

**Public Health Authority**: An agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, a foreign government, or a person or entity acting under a grant authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

Please Note: The definition of a “public health authority” requires that an agency’s official mandate include the responsibility for public health matters. The mandate can be responsibility for public health matters, generally, or it can be for specific public health programs. Furthermore, an agency’s official mandate does not have to be exclusively or primarily for public health. Therefore, to the extent a government agency is responsible for public health matters as part of its official mandate, OHRP considers that, for purposes of this guidance, it qualifies as a public health authority.

**Public Health Surveillance Activity:**

There is no formal regulatory definition for public health surveillance activities.

In general, public health surveillance involves collecting, testing, analyzing, and using information or biospecimens to improve public health and prevent disease. It provides timely and useful evidence, and it enables public health authorities to be more effective in their efforts to protect and promote public health. Thus, public health surveillance is an important element of public health practice.

Public health surveillance uses information and biospecimens from a variety of sources, including mandatory reporting of certain conditions, routine monitoring, vital records, medical records, medical billing records, clinical specimens, and public health investigations. Further, it often uses the same analytical and laboratory techniques as epidemiological research. **However, the difference between public health surveillance and research in this context is that the purpose of the surveillance is to inform the decisions or actions that must be made by a public health authority.**

The direct link to decision making and action by a public health authority is a hallmark of public health surveillance. In the context of public health surveillance, the collection, management, analysis, and interpretation of surveillance information or biospecimens is designed to inform a public health authority, and generally is followed by public health action or by the dissemination of information to public health programs and others to stimulate public health action.

Surveillance activities that are not undertaken for the purpose of directly informing public health decision making or action generally will not be considered public health surveillance, even if they might be considered surveillance for other purposes

**Conducted by a Public Health Authority:**

An activity is “conducted” by a public health authority when the public health authority participates directly in the collection, testing, analysis, or use of the information or biospecimens, or funds these uses through a contract.

**Supported by a Public Health Authority:**

An activity is supported by a public health authority when the activity is funded through a grant or cooperative agreement. Activities that are requested, ordered, required, or authorized by a public health authority also may be considered to be “supported by a Public Health Authority”, even if they are carried out by an entity that is not a public health authority (e.g., academic institutions, health care organizations, nonprofit entities).

1. <https://www.hhs.gov/ohrp/draft-guidance-public-health-surveillance-activities.html> [↑](#footnote-ref-1)
2. <https://www.hhs.gov/ohrp/draft-guidance-public-health-surveillance-activities.html> [↑](#footnote-ref-2)
3. <https://www.who.int/ethics/publications/public-health-surveillance/en/> [↑](#footnote-ref-3)
4. <https://www.hhs.gov/ohrp/draft-guidance-public-health-surveillance-activities.html> [↑](#footnote-ref-4)