



Institutional Review Board
Sponsored Programs Office
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Federalwide Assurance ID#: 00007126

Public Health Surveillance Activities Form

Following the regulations and guidance of the federal Office of Human Research Protections, certain public health surveillance activities are deemed to not be research and not require the IRB review process. However, according to the Secretary's Advisory Committee on Human Research Protections (SACHRP), such work still requires outside review to determine that it is, in fact, Public Health Surveillance. From their website:

SACHRP recommends that determinations that an activity meets the exclusion as a public health surveillance activity be clearly documented and readily available to the public to ensure transparency... In cases where the activity is limited to one or more institutions, it may be appropriate to have an institutional mechanism for making the determination, similar to exempt determinations. This could include entities such as an IRB administrator, a research office, or an institutional official. In any case, the determination should not be made by the party or parties who are offered the grant or contract to do the public health surveillance activities.

Attachment A -Public Health Authority and Surveillance Activities | HHS.gov

Those conducting public health surveillance activities should enter the project in SUNY PACS IRB. In lieu of the standard protocol, upload this template and any relevant supporting documentation.

Researcher/Project Director: _____ Phone.: _____
Department: _____ E-mail: _____
Project Title: _____
Project Dates: _____ to _____ Date of Submission: _____
Project Funding Source/Public Health Authority Requesting Project:

Description of project:

SACHRP has developed an algorithm to determine if a project meets the Public Health Surveillance exclusion. That algorithm is below. If the answer to any of the following questions is **no**, this form cannot be used.

1. Is the project conducted, supported, requested, ordered, required, or authorized by a public health authority?

If no, it does not meet the exclusion.

If yes, please explain below.

2. Does the project involve public health surveillance activities, including the collection and testing of information or biospecimens?

If no, it does not meet the exclusion.

If yes, please explain below.

3. Does the project involve only public health surveillance activities?

If no, the parts of the project that are not public health surveillance activities must be assessed separately to determine whether they are research, meet another exclusion, meet an exemption, or require IRB review.

If yes, please explain below.

4. Are the public health surveillance activities 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, patterns in diseases, or increases in injuries from using consumer products)? Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

These definitions typically do not include peer review research studies. For example, should there be intent to evaluate data for further publication this would require review by the IRB.

The OHRP draft guidance “Activities Deemed Not to Be Research: Public Health Surveillance 2018 Requirements” contains the following definitions of terms:

- *Identify* generally refers to activities that are undertaken to detect potential signals, onsets of disease outbreaks, or conditions of public health importance that had not previously been recognized.
- *Monitor* generally refers to activities that are undertaken to maintain situational awareness of an identified signal, outbreak, or condition, in order to detect changes that warrant further public health action.
- *Assess* generally refers to activities that are undertaken to evaluate the characteristics of a signal, outbreak, or condition, including its magnitude, prevalence or incidence, and the context in which a signal, outbreak, or condition occurs or has been detected, in order to inform public health action.
- *Investigate* generally refers to the range of activities that are undertaken in response to an identified or perceived threat to public health, to determine the magnitude of the problem, identify cases, or determine the cause, and to inform appropriate control measures. The problem under investigation might be a signal, an outbreak, or any other occurrence that warrants action.
- *Provide situational awareness* refers to assembling the critical information that is needed to respond to a disease outbreak or other public health emergency.
- *Potential public health signals, onsets of disease outbreaks, and conditions of public health importance* generally include conditions affecting health and safety, such as infectious and chronic diseases, injury, including those related to medical products, and mental health.

If no, the exclusion is not met.

If yes, please explain below.