

IRB Review Requirements for Public Health Surveillance and Public Health Practice

Public Health Surveillance Not Requiring IRB Review

Public health surveillance activities do not require IRB review only if they are limited to routine activities necessary to continuously identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks or conditions of public health importance (including trends, and patterns in diseases or injuries). For instance, public health surveillance includes the collection and use of information or biospecimens to estimate the scope and magnitude of a public health problem, including the geographic and demographic distribution of a health event to inform public health interventions. Public health surveillance also includes the use of information or biospecimens to monitor changes in infectious disease agents and environmental factors, evaluate control measures and response efforts, and actively monitor, identify, and assess the safety of medical products.

The following are examples of public health surveillance activities that do not need IRB review:

- Safety and injury surveillance activities designed to enable DPH to identify, monitor, assess, and investigate potential safety signals for a specific product or class of products (e.g., the surveillance activities of FDA's Adverse Event Reporting System)
- Surveillance activities designed to enable DPH to identify unexpected changes in the incidence or prevalence of a certain disease in a defined geographic region where specific public health concerns have been raised (e.g., the U.S. influenza surveillance system)
- Surveillance activities designed to enable DPH to locate the range and source of a disease outbreak or to identify cases of a disease outbreak (including contact tracing activities)
- Surveillance activities designed to enable DPH to detect the onset of disease outbreaks or provide timely situational awareness during the course of an event or crisis that threatens the public health, such as a natural or man-made disaster

Public Health Surveillance Requiring IRB Review

Public health surveillance activities require IRB review when they involve the collection and analysis of health-related data either to generate knowledge that may apply to populations and settings other than the ones from which the data were originally collected, to contribute new knowledge about a health outcome and/or social determinants of health and/or examine relationships between an outcome and exposure/risk factor.

The following are examples of public health surveillance activities that need IRB review:

- Surveys involving interactions with human subjects such as assessing attitudes and behaviors related to a health behavior
- Adding questions to case interview protocols beyond the original surveillance intentions
- Linking primary or secondary data that is not surveillance data to an existing surveillance database

Reporting or tracking outcomes by demographic variables such as race/ethnicity would be considered surveillance whereas examining/analyzing the relationship between race/ethnicity and a health outcome would constitute research.

All public health surveillance activities involving incarcerated individuals, probationers or parolees require consultation with the Office of the IRB before implementation to receive a determination of whether the activities need IRB oversight.

Public Health Practices Not Requiring IRB Review

The following nine of the ten essential public health practices (adapted from PHAB, 2020) do not require IRB review:

1. Assessing and monitoring population health.
2. Investigating, diagnosing and addressing health hazards.
3. Communicating effectively to inform and educate.
4. Strengthening, supporting and mobilizing communities and partnerships.
5. Creating, championing and implementing policies, plans and laws.
6. Utilizing legal and regulatory actions.
7. Enabling equitable access.
8. Building a diverse and skilled workforce.
9. Building and maintaining a strong organizational infrastructure for public health.

The following are examples of public health practice activities that do not need IRB review:

- Producing community health profiles
- Public health investigations such as restaurant inspections and outbreak investigation case interviews for purpose of controlling outbreaks
- Mortality and morbidity surveillance
- Environmental investigations, e.g., pollution levels in different geographic locations

Public Health Practices Requiring IRB Review

Activities that need to come to the IRB include evaluation, research and quality improvement as well as activities deemed to be analyses of the effectiveness of any of the nine essential practices listed above. Analysis of secondary or primary data to address research questions above and beyond surveillance.

The following are examples of public health practice activities that need IRB review:

- Risk factors, root causes, predictors of mortality and morbidity
- Evaluation of public health prevention programs, e.g., mass media prevention campaign
- Continuous quality improvement of STI clinic interventions