

Institutional Review Board



Defining Research

The need to distinguish between *Human Subjects Research* and *Public Health Practices* constantly arises in the planning and performance of public health activities.

Public Health Practices

Public Health Practices are about protecting the public's health. It includes the core health care activities of treatment, payment, and operations. This expands to include epidemiological investigations, surveillance, programmatic evaluations and clinical care for the population. Underlying many of these activities is the collection and analysis of identifiable health data by a public health authority for the purpose of protecting the health of a particular community. It may include:

- Specific legal authorization for conducting the activity as a public health practice at the federal, state, or local levels;
- A corresponding governmental duty to perform the activity to protect the public's health;
- Direct performance or oversight by a governmental public health authority and accountability to the public for its performance;
- Persons who did not specifically volunteer to participate;
- Principles of public health ethics that focus on populations while respecting the dignity and rights of individuals.

Human Subjects Research

Human Subjects Research is conducted for the purpose of generating knowledge that often benefits those beyond the participating community who bear the risks of participation. Research explores hypotheses, advances current knowledge, and contributes to the welfare of the persons beyond the study itself to benefit society as a whole. If an activity offers no prospect of benefit to the participants, the activity is classified as research. Characteristics include:

- Living individuals
- Data through intervention or interaction with the individual
- Identifiable private health information
- Subjects who are selected and voluntarily participate, absent a waiver of informed consent
- Principles of bioethics that focus on the interests of individuals while balancing the communal value of research.

Examples:

- Data linkage to examine pediatric obesity and its progression to chronic disease
- Records review to learn mechanisms of tuberculosis outbreak
- Survey of patient experiences with home and community-based services