

## 2. Clarifying Legal and Policy Issues

### Distinguishing Surveillance from Research *Supplemental Reading*

As you work with your attorneys or those for your data trading partners, you'll likely encounter the central issue of whether your program can be defined as *surveillance* or *research*. Because different laws, requirements and procedures apply to each definition, the impact on your program can be significant.

To help you prepare for these critical discussions, we suggest comparing and contrasting surveillance and research along the following dimensions: definitions, legal frameworks, and benefits and interventions. Much of the content is based on a report prepared for the Council of State and Territorial Epidemiologists (see the *Recommended Reading* list).

#### Definitions

##### Public health surveillance

The collection and analysis of identifiable health data by a public health authority for the purpose of protecting the health of a particular community where the benefits and risks are primarily designed to accrue to the participating community. The intent of public health surveillance is to improve health outcomes.

##### Public health research

The systematic collection and analysis of identifiable health data by a public health authority for the purpose of generating knowledge that may benefit those beyond the participating community who bear the risks of participation. The intent of public health research is to test a hypothesis and to generalize the findings or acquired knowledge beyond the activity's participants.

#### Legal Frameworks

##### Public health surveillance

Grounded in constitutionally-approved authority of government to protect the public's health, safety and general welfare.

##### Public health research

Grounded in the principles of the federal Common Rule that focuses on protecting individuals while pursuing knowledge through research.

#### Participant Benefits

##### Public health surveillance

The premise of public health surveillance and practice is to provide some benefit to surveillance participants or the population of which they are members. Though failures in design or implementation may limit these benefits, the objective remains to improve the health of participants and their associated populations.

##### Public health research

Public health research does not assure benefits to participants. Correspondingly, whenever risks are imposed on participants to make the results generalizable beyond the participants, the activity should be classified as public health research.



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#### Interventions

##### Public health surveillance

Public health surveillance predominantly addresses known or suspected public health problems using standard, accepted and proven interventions.

##### Public health research

Public health research interventions typically involve introducing something non-standard to the research subjects or their identifiable health data.

Depending upon your jurisdiction's policy, you may have to go through your Institutional Review Board (IRB) to make the determination of whether your program goals and methods are best characterized as surveillance or research. Because IRB policies and procedures vary widely, consult your agency attorney/legal office to learn more.