



IRB Guidance: Projects Not Meeting the Definition of Research

Research according to the federal regulations means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition are considered research, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

The following activities are considered not to be research:

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. For further information regarding these types of projects please see [OHRP Guidance: Scholarly and Journalistic Activities Deemed Not to be Research: 2018 Requirements](#) located on the [OHRP website](#).
2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are 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 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 threaten public health (including natural or man-made disasters). For further information regarding public health surveillance activities please see [OHRP Guidance: Activities Deemed Not to Be Research: Public Health Surveillance 2018 Requirements](#) located on the [OHRP website](#).
3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
4. Authorized operational activities (as determined by agency) in support of intelligence, homeland security, defense or other national security missions.