## Key Definitions: Research and Human Subject

### a. Human Research

As of January 20, 2019 human research is defined by the DHHS as:

***Research*** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable* knowledge.

Four categories of activities are considered **NOT** to be research:

a. Scholarly and journalistic activities; for example;
    i. Oral history, journalism, biography, literary criticism, legal research, and historical scholarship), includes the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

b. Public health surveillance activities; for example:
    i. 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 public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products).
    ii. 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).

c. Collection of information and biospecimens for a criminal justice agency or criminal investigatory purposes; and

d. Operational activities in support of national security or intelligence missions).

*It is up to individual IRBs how to define “generalizable”.

### b. Human Subject

#### 1. A living individual about whom an investigator is conducting research

i. (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
ii. (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

§_.102(e)(1)

## Related Definitions

a. ***Clinical trial*** means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

b. ***Department or agency head*** means the head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated.

(c) ***Federal department or agency*** refers to a federal department or agency (the department or agency itself rather than its bureaus, offices or divisions) that takes appropriate administrative action to make this policy applicable to the research involving human subjects it conducts, supports, or otherwise regulates (*e.g.,* the U.S. Department of Health and Human Services, the U.S. Department of Defense, or the Central Intelligence Agency).

(d) ***Intervention*** includes both physical procedures by which information or biospecimens are gathered (*e.g.,*venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

(e) ***Interaction*** includes communication or interpersonal contact between investigator and subject.

(f) ***Private information*** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (*e.g.,*a medical record).

(g) ***Identifiable private information*** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

(h) ***An identifiable biospecimen*** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

(i) ***Institution*** means any public or private entity, or department or agency (including federal, state, and other agencies).

(j) ***Legally authorized representative*** means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, *legally authorized representative* means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

(k) ***Minimal risk*** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

(l) ***Public health authority*** means an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.