HUMAN SUBJECTS RESEARCH DEFINITIONS

Human Subjects (DHHS): A living individual ***about whom*** an investigator (whether professional or student) conducting research:

(1) Obtains information or biospecimens through intervention or interaction with the individual, **AND** uses, studies, or analyzes the information or biospecimens; or

(2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens (45 CFR 46.102(e))

Living: Information or biospecimens obtained about/from individuals who are living. Research involving only information or biospecimens associated with individuals who are deceased (decedents) is not covered under the Common Rule but is still covered by HIPAA's Privacy Rule. If the project includes only information/specimens from cadavers, autopsy specimens or specimens/information from subjects, it is not considered Human Subjects.

About Whom: the information or biospecimens received from/about the living individual must be about the person.

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

Interaction: includes communication or interpersonal contact between investigator and subject

Private information or biospecimens: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record, academic records, personal journals). The opposite of this is public use data or information that is in the public domain (for example, available to the public without terms or conditions or signing an agreement or joining a membership).

Individually Identifiable: The identity of the subject is or may readily be ascertained by the investigator or associated with the information or biospecimens

Research (DHHS): A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, 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. (45 CFR 46.102(i))

A **systematic investigation** is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question.

Generalizable knowledge is knowledge from which conclusion will be drawn that can be applied to populations outside of the specific study population. This usually includes one or more of the following concepts:

(i) Knowledge that contributes to a theoretical framework of an established body of knowledge; or
(ii) The primary beneficiaries of the research are other researchers, scholars, and practitioners in the field of study; or
(iii) Dissemination of the results is intended to inform the field of study (though this alone does not make an activity constitute research "designed to contribute to generalizable knowledge"); or
(iv) The results are expected to be generalized to a larger population beyond the site of data collection; or
(v) The results are intended to be replicated in other settings.

Human Subjects (FDA): An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. (21 CFR 50.3(g))

Clinical Investigation aka Research (FDA): Any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA...or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. (21 CFR 50.3(c))

A **test article** means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Federal Food, Drug and Cosmetic Act. (21 CFR 50.3(j))

THE FOLLOWING ACTIVITIES *ARE NOT* CONSIDERED HUMAN SUBJECTS RESEARCH:

- 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.

- Public Health Surveillance Activities conducted by a public health authority, 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. This includes:

(i) the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority;

(ii) trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products; and,

(iii) 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 disaters).

- 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.

- Authorized operational activities (as determined by the relevant federal agency) in support of intelligence, homeland security, defense, or other national security missions.