#### Definitions of Terms

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**Used in Reviewing Research**

##### Involving Human Subjects

1. *Assent* – affirmative agreement to participate in research. Mere failure to object should not be construed as assent.
2. *Engaged in Research* – institutions are “engaged” in human research whenever their employees or agents a) intervene or interact with living individuals for research purposes; or b) obtain, release, or access individually identifiable private information for research purposes. Any institution that receives an award from the Department of Health and Human Services to support human subjects research is automatically considered to be “engaged” in such research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.
3. *Exemption –* certain research activities that do not require review and instead receive certification of exemption from the IRB Chairperson. [45 CFR 46.104](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104) *(*<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>).
4. *Expedited review* – Research activities that involve no more than minimal risk, and in which the only involvement of human subjects will be in one or more specific categories may receive expedited review as authorized in [45 CFR 46.110](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1110) and described in “IRB Policies and Procedures.”
5. *Federalwide Assurance* – An assurance of protection for human subjects that formalizes an institution’s commitment to protect human subjects. Any institution engaged in research, including DHSS and each collaborating institution, must file such an assurance with the federal [Office for Human Research Protections](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).
6. *Full Board Review* – research activities that do not qualify for exemption or expedited review are reviewed by all members of the IRB.
7. *Human Protections Administrator* – has administrative responsibility for the program within an institution, and serves as the primary institutional contact person for the Office of Human Research Protections.
8. *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains 1) information or biospecimens through intervention or interaction with the individual, or 2) identifiable private information or biospecimen.

‘Intervention’ includes both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations 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’ 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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

1. *Incompetent person* – any person who has either been adjudged incompetent or who, in fact, lacks the capacity to understand what he/she is being asked to do and to thereafter give his/her consent.
2. *Informed consent* – knowing consent by a person or his/her legally authorized representative. Before giving informed consent, the person or his/her legally authorized representative must be presented with the basic elements of information about the research listed in federal regulation [45 CFR 46.116](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116), and must have sufficient opportunity to consider whether to participate.
3. *Institution* – any public or private entity or agency (including federal, state, and other agencies).
4. *Institutional Official* – the individual authorized to act for an institution, and who assumes on behalf of the institution, the obligations of the institution’s federalwide assurance. The institutional official appoints the IRB members and chair, provides the necessary resources and staff, and supports IRB authority and decisions.
5. *Institutional Review Board* – a committee charged with the responsibility to assure that all research engaged in by an institution complies with federal guidelines and regulations concerning the protection of human subjects. See “IRB Organization and Functions” for more information.
6. *Investigator* – any individual involved in the conduct of human subjects research.
7. *Legally authorized representative* – any person or judicial or other body authorized by law to consent on behalf of a prospective subject [(45 CFR 46.102(i)).](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1102)
8. *Minimal risk* – the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
9. *Minor/Child* – any person under age 18; minor is synonymous with child in the context of procedures involving human subjects.
10. *Protocol* – a detailed description of a proposed research project that includes all the elements specified under “Protocol Submission” (see IRB Form 1).
11. *Reasonably available* – a parent of a minor subject is deemed to be reasonably available if located within the county in which the study is being conducted.
12. *Research* – a systematic investigation designed to develop or contribute to generalizable knowledge. Activities that meet this definition consitute research for purposes of DHSS 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. Surveys, questionnaires and inteverviews conducted by staff qualify as research if they are used to gather data as part of a methodology to test a hypothesis, permit conclusions to be drawn, and thereby contribute to generalizable knowledge.
13. *Public Health Authority* – An agency or authority of the United States.

For purposes of this part, the following activities are deemed 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.
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 public 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 threatens public health (including natural or man-made disasters).
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 each agency) in support of intelligence, homeland security, defense, or other national security missions.
5. *Written,* or *in writing,* for purposes of this part, refers to writing on a tangible medium (*e.g.,* paper) or in an electronic format.
6. *Research Investigator* – see Investigator.
7. *Signatory Official* – A high-level institutional official who has the authority to represent the institution named in the Fedaralwide Assurance (FWA) as well as all the institutional components listed in the FWA.
8. *Unaffiliated Investigator* – an investigator who is not acting as the employee or agent of an FWA institution, for example, a physician in private practice. Such investigators must enter into an arrangement with an FWA institution under which they agree to be bound by the human protection policies of the institution and its designated IRB(s).