

Human Research Protection Program

Definitions for Human Subjects Research

Clinical Investigation: Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA under Section 505(i) or 520(g) of the FDA Act, or is not subject to requirements for prior submission to the FDA under these sections of the FDA Act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of Part 58 [of Title 21 of the CFR], regarding non-clinical laboratory studies [21 CFR Section 50.3(c)].

Coded: Identifying information (such as name, Social Security number, or medical record number link) that would enable the investigator to readily ascertain the identity of the human subject to whom the private information or specimens relates has been replaced with a number, letter, symbol, or combination thereof (i.e., the code), and a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Designed: Implies intent to engage in research. If the intent of the activity is to do programmatic evaluation, quality assurance, or quality improvement, you may not be engaged in research. Intent to publish is not automatically an indication of intent to do research, but will be taken into consideration when making a determination of research.

Experiment: Any use of a drug other than the use of a marketed (FDA-approved) drug in the course of medical practice [21 CFR 312.3(b)].

Generalizable Knowledge: Knowledge from which general conclusions will be drawn from your research that will develop or contribute to a general body of knowledge (i.e., knowledge that may be applied to populations outside of the specific study population). A study that is designed to develop or contribute to **generalizable knowledge** is one that is designed to draw general conclusions, inform policy, or generate generalizable findings.

Human Subject(s): An individual who meets the definition of this term as set forth in the HHS regulations and, for projects subject to FDA regulations, the definition of this term as set forth in the FDA regulations:

1. **HHS Regulations' Definition of Human Subject:** A **living individual** about whom an investigator (whether professional or student) conducting **research** obtains: (a) data through **intervention** or **interaction** with the individual; or (b) **identifiable private information** [45 CFR Section 46.102(f).]
2. **FDA Regulations' Definition of Human Subject:** 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 human or a patient [21 CFR Section 50.3(g)]. In the case of an investigational

medical device, a human subject/participant also means a human on whose specimen an investigational medical device is used.

Intervention: Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the human subject or the human subject's environment that are performed for human subjects research purposes.

Interaction: Includes communication or interpersonal contact between an investigator and a human subject [45 CFR Section 46.102(f)].

Investigator (or Researcher): A person (whether professional or student) who conducts research.

Institutional Official (IO): The IO is the university official responsible for ensuring that the Creighton University Research and Compliance office has the resources and support necessary to comply with all federal regulations and guidelines that govern human subjects research. The IO is legally authorized to represent the institution, is the signatory official for all Assurances, and assumes the obligations of the institution's Assurance. The IO is the point of contact for correspondence addressing human subjects research with the Office of Human Research Protections (OHRP) and the Food and Drug Administration.

Human Subjects Research: A systematic investigation performed with human subjects (including development, testing, and evaluation) designed to develop or contribute generalized knowledge, regardless of the source of funding.

Individually Identifiable: Information in a form such that the identity of the human subject is or may readily be ascertained by the Investigator or be associated with the information [45 CFR Section 46.102(f)].

Living individuals: Research dealing with tissues or specimens obtained from deceased individuals or cadavers is not considered to be about living individuals. If information or data is obtained from living individuals but does not involve information about them (i.e., it's about a "what," rather than a "whom") the research might not be about living individuals.

Institutional Review Board (IRB): A convened group that meets the definition of this term as set forth in the HHS regulations and, for projects subject to FDA regulations, the definition of the term as set forth in the FDA regulations.

1. **HHS Regulations' Definition of Institutional Review Board:** An Institutional Review Board established in accord with and for the purposes expressed in the HHS Regulations. [45 CFR Section 46.102(g)].
2. **FDA Regulations' Definition of Institutional Review Board:** Any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. This term has the same meaning as the phrase "institutional review committee" as used in Section 520(g) of the FDA Act [21 CFR Section 56.102(g)].

Obtaining: Receiving or accessing identifiable private information or identifiable specimens for research purposes. OHRP interprets *obtaining* to include an investigator's use, study, or analysis for

research purposes of identifiable private information or identifiable specimens already in the possession of the investigator. **Note:** If private individually identifiable information is received by the investigator and subsequently de-identified, the study is still considered to involve human subjects.

Private Information: 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 (for example, a medical record, school grades, or height and weight measurements).

Private Information must be **Individually Identifiable** in order for obtaining such information to constitute **Human Subjects Research** [45 CFR Section 46.102(f)]. Examples of studies using private information include chart reviews, obtaining lab studies on identifiable tissues and specimens, using identifiable information from data or tissue repositories, obtaining school grades, private interviews, or surveys of opinions and attitudes.

Research is defined as “a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR 46.102 (d)). As such, research that involves human subjects must receive approval from the IRB prior to initiation. Research involving human subjects is research that involves obtaining information about a living individual that is either (1) data obtained through intervention or interaction with the individual, or (2) identifiable private information. This is the definition in the policy about the IRB.

Systematic Investigation: An activity that involves a prospective research plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a research question.

Test Article: A test article is a drug, device, or other article including a biological product used in clinical investigations involving human subjects or their specimens.

Terms for Research Involving Pregnant Women and Fetuses

Delivery: Complete separation of the fetus from the woman by expulsion or extraction or any other means.

Fetus: The product of conception from implantation until delivery.

Dead Fetus: A fetus that does not exhibit a heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, or pulsation of the umbilical cord.

Stillborn death or stillbirth: Death prior to the complete expulsion or extraction from its mother of a product of human conception, occurring after the twentieth week of pregnancy and does not include “induced termination of pregnancy.

Induced termination of pregnancy: The purposeful interruption of a pregnancy with the intention other than producing a live-born infant or removing a dead fetus that does not result in a live birth.

Neonate: A newborn