

## IRBNet Abbreviations and Terms

### *Abbreviation Glossary*

- BE: College of Business
- CITI: Collaborative Institutional Training Initiative
- COI: Conflict of Interest
- Co-PI: Co-Principal Investigator
- DHHS: Department of Health and Human Services
- E: Exempt
- EPA: Environmental Protection Agency
- ER: Expedited
- FDA: Food and Drug Administration
- IRB: Institutional Review Board
- LA: Liberal Arts
- NH: College of Nursing and Health Professions
- OPRA: Office of Planning, Research, and Assessment
- OSPRA: Office of Sponsored Projects and Research Administration
- PI: Principal Investigator
- RCR: Responsible Conduct of Research
- SEE: Pott College of Science, Engineering, & Education
- UD: University Division

### *Definitions*

- **Anonymous:** Information obtained that is not and has never been traceable to the contributing individual.
- **Assent:** A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
- **Coded:** The information does not contain the identity of the contributing individual, but has a specific code that links back to the individual's identity. There may be several unique codes between the information and the contributing individual's identity.
- **Confidentiality:** The ethical principle or legal right that a physician or other health professional will hold secret all information relating to a patient, unless the patient gives consent permitting disclosure.
- **Conflict of Interest:** Any interest that could reasonably be expected to affect the objectivity of an IRB member with regard to a research project. A conflict of interest includes financial interests and may include nonfinancial interests, such as personal or ethical beliefs, or other factors.
- **Consent Document:** A structured, written description in lay terms of relevant research project information. The written consent document is not consent itself; it is the record of what has been communicated to a prospective subject. It is the document, based on a template provided by the IRB and approved by the IRB, to ensure that all regulatory elements are present and

communicated to a potential subject. When signed by the potential subject, the consent document is a record of the receipt of research-related information by the subject. It also serves as reference material for the subject as the research project progresses. It is not legally binding, and the subject may choose to withdraw consent at any time.

- **Continuing Review:** Periodic review of research activities at intervals appropriate to the degree of risk, but not less than once per year. The criteria for approval are defined by federal regulations.
- **De-Identified:** Information that at one point was identifiable, either directly or through a code, but has been stripped of all identifiers and codes. The information can no longer be traced back to the contributing individual.
- **Disseminated:** published, presented or shared, ex. Journal article, conference presentation, thesis/dissertation, course paper or presentation.
- **Documentation:** The act or an instance of furnishing or authenticating with documents. Documentation of informed consent includes use of a written consent form, approved by the IRB and signed and dated by the subject or the subject's legally authorized representative.
- **Engaged in Human Research:** In general, an institution is considered *engaged* in a particular non-exempt human subjects research project when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.
- **Exempt Review:** A review of research involving human subjects and minimal risk by only one IRB reviewer.
- **Existing Data:** Data that has been previously collected but not published.
- **Expedited Review:** A review of research involving human subjects by the IRB chair or by one or more experienced reviewers from among members of the IRB.
- **Expired Study:** When continuing review of the research does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. The study expires on the date specified on the approval letter and the consent document. No activities can occur after the expiration date.
- **Full Committee Review:** Studies reviewed by the full, convened IRB committee with a recorded vote and corresponding minutes to document the discussion.
- **Human Research:** Any activity that:
  - studies in which a substance or stimulus is administered to a subject, or responses or states are measured;
  - studies that involve changes in the subject's physical or psychological state or environment, or changes in diet;
  - interviews, surveys, tests, inquiries, and observations designed to elicit or obtain nonpublic information; and
  - studies of existing records where the identity of the subjects is known or could be readily ascertained by the investigator.

- Public Benefit/Service Programs which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; or (b) procedures for obtaining benefits or services under those programs; or (c) possible changes in or alternatives to these programs or procedures.
- **Human Subject as Defined by DHHS:** A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through Intervention or Interaction with the individual, or (2) information that is both Private Information and Identifiable Information.
- **Human Subject as Defined by FDA:** A human subject is an individual who is or becomes a subject 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. A human subject includes an individual on whose specimen a medical device is used.
- **Identifiable:** The information contains the identity of the contributing individual.
- **Identifiable Information:** Information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).
- **Implied Consent:** Consent which is not expressly granted by a person, but rather inferred from a person's actions or lack thereof depending on a particular situation.
- **Informed Consent:** An ongoing process of communication between the subject and the investigator. Informed consent is a continual process by which a subject voluntarily confirms his or her willingness to participate in a research study, after having been informed and can demonstrate understanding of all aspects of the research study that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.
- **Institutional Review Board (IRB):** A specifically constituted review body established or designated by an entity to protect the rights and welfare of human subjects recruited to participate in biomedical or behavioral or social science research.
- **Intervention:** Physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
- **Interaction:** Communication or interpersonal contact between investigator and subject.
- **Investigator:** The investigator is the person responsible for the conduct of the Human Research at one or more sites. If the Human Research is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.
- **Minimal Risk:** 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.
- **Modification:** Any change to an IRB-approved study protocol regardless of the level of review it receives initially.
- **Oral (Verbal) Consent:** A spoken presentation of the elements of informed consent to the prospective subject or their legally authorized representative. The presentation may be based on information contained within an oral consent script or the written consent document. Oral consent is often associated with waiving the documentation of consent. Oral consent is usually recorded in the research project files.

- **Package:** Each project submitted to IRB Net is a package. Each package has its own unique package number. Each time a new submission is made, you submit it under the same package number, but the submission number will change. For example “123456-1” is an Initial Application. If you submitted an Amendment, the number would change to “123456-2.”
- **Principal Investigator:** See ‘Investigator’
- **Privacy:** The quality or state of being apart from company or observation. Freedom from unauthorized intrusion.
- **Privacy vs. Confidentiality:** Privacy is about people and their choice to share personal information. It is a right in health care and research. Confidentiality is about data. It is the investigator's obligation to protect subjects' information.
- **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 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).
- **Protocol:** Set of standardized procedures for obtaining and storing data, specified in submitted application.
- **Recruitment:** Recruitment, a component of the consent process, is the process of distributing or presenting information that describes the research project and eligibility criteria so that a prospective subject may consider enrollment.
- **Research:** For IRB purposes, *research* is defined as a systematic investigation, inquiry, or analysis—such as scholarly or critical study or inquiry or scientific investigation, development, testing, or evaluation—designed to develop or contribute to generalizable knowledge. Research includes activities that aim to test a hypothesis, discover or collate facts, principles, or effects, reach new conclusions, or reexamine information by the critical study of a subject or by a course of scientific inquiry.
- **Research Activities:** Research activity includes all contact with the research subject (such as enrolling subjects, intervention or interaction), data collection and data analysis.
- **Secondary Data:** Data that has already been collected (by someone other than the PI) and published, and is readily available from other sources.
- **Site Verification:** Signed letter of permission on appropriate letterhead from site where research will be taking place. Acknowledges and approves researcher to use secondary data, conduct research, interview patients/employees, etc. Required if research is taking place anywhere other than USI.
- **Study Expiration:** If IRB approval of a specific study expires before continuing review and approval occur, investigators must stop all research activities involving human subjects related to that study except where they judge that it is in the best interests of already enrolled subjects to continue to participate. When investigators make this judgment, they must promptly notify the IRB. When the IRB reviews the investigator's decision, it may decide whether it is in the best interests of already-enrolled subjects to continue to participate in the research by considering the best interests of subjects either one at a time or as a group. If an IRB determines that it is not in the best interests of already-enrolled subjects to continue to participate, investigators must stop all human subjects research activities, including intervening or interacting with subjects, or obtaining or analyzing identifiable private information about human subjects. Investigators may resume the human subjects research activity once continuing review and approval by the IRB has occurred.
- **Target Population:** The target population is the entire group a researcher is interested in; the group about which the researcher wishes to draw conclusions.