



SOP: Definitions

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1 PURPOSE

- 1.1 This policy establishes the definitions followed by the human research protection program.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 Allegation of Non-Compliance: An unproved assertion of Non-Compliance.
- 3.2 Clinical Trial: A biomedical or behavioral research study of human subjects designed to answer specific questions about diagnostic procedures or therapeutic interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new diagnostic procedures or therapeutic interventions are safe, efficacious, and effective.
- 3.3 Conflicting Interest: An individual involved in research review is automatically considered to have a conflicting interest when the individual or the individual's spouse, domestic partner, children, and dependents have any of the following interests in the sponsor, product or service being tested, or competitor of the sponsor held by the individual or the individual's immediate family:
- 3.3.1 Involvement in the design, conduct, or reporting of the research.
- 3.3.2 Ownership interest, stock options, or other ownership interest of any value exclusive of interests in publicly-traded, diversified mutual funds.
- 3.3.3 Compensation of any amount in the past year or of any amount expected in the next year, including compensation for costs directly related to conducting research.
- 3.3.4 Proprietary interest including, but not limited to, a patent, trademark, copyright or licensing agreement.
- 3.3.5 Board or executive relationship, regardless of compensation.
- 3.3.6 Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center.
- 3.3.7 Any other reason for which the individual believes that he or she cannot be independent.
- 3.4 Continuing Non-Compliance: A pattern of Non-Compliance that suggests the likelihood that, without intervention, instances of Non-Compliance will recur, a repeated unwillingness to comply, or a persistent lack of knowledge of how to comply.
- 3.5 Designated Reviewer: The IRB chair or an Experienced IRB Member designated by the IRB chair to conduct Non-Committee Reviews.
- 3.6 Emancipated Minor:
- 3.7 Experienced IRB Member: An IRB member is considered experienced if the IRB chair considers the IRB member to have sufficient experience in and knowledge of conducting IRB reviews.
- 3.8 Expiration Date: The first date that the protocol is no longer approved. The date after the end date of the approval period.
- 3.9 Finding of Non-Compliance: Non-Compliance in fact.
- 3.10 Human Research: Any activity that either:¹
- 3.10.1 Is Research as Defined by DHHS and involves Human Subjects as Defined by DHHS; or
- 3.10.2 Is Research as Defined by FDA and involves Human Subjects as Defined by FDA.

¹ The terms "Human Subject Research," "Research Involving Human Subjects," "Human Subject Research," "Research Involving Human Subjects," "Clinical Research," "Clinical Investigation," "Clinical Study" and similar phrases are considered to be synonyms for the term Human Research.



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- 3.10.3 Is Research as Defined by one of the above and adheres to Pennsylvania's definition of a proxy.
- 3.11 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. For the purpose of this definition:
- 3.11.1 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.
- 3.11.2 Interaction: Communication or interpersonal contact between investigator and subject.
- 3.11.3 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).
- 3.11.4 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).
- 3.12 Human Subject as Defined by FDA: 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.
- 3.13 Immediate Family: Spouse, domestic partner; and dependent children.
- 3.14 Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research that 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.²
- 3.14.1 For research involving prisoners Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.
- 3.15 Minor:
- 3.16 Non-Committee Review: Any of the following:
- 3.16.1 Determination of whether an activity is Human Research.
- 3.16.2 Determination of whether Human Research is exempt from regulation.
- 3.16.3 Reviews of non-exempt research using the expedited procedure.
- 3.16.4 Determinations of which subjects can continue in expired research.
- 3.17 Non-Compliance: Failure to follow the regulations, or the requirements or determinations of the IRB.
- 3.17.1 In the case of research funded or conducted by the Department of Defense (DOD), Non-Compliance includes failure of a person, group, or institution to act in accordance with Department of Defense (DOD) instruction 3216.02, its references, or applicable requirements

² The phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests" should not be interpreted to include the inherent risks certain categories of subjects face in their everyday life. For example, the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).



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- 3.17.2 In the case of research funded or conducted by the Department of the Navy (DOD), Non-Compliance includes failure to comply with the Department of the Navy instructions regarding protection of Human Subjects.
- 3.18 Organizational Official: Senior Associate Vice Provost for Research Administration
- 3.19 Physician Extender: a health care provider who is not a physician but who performs medical activities typically performed by a physician. It is most commonly a nurse practitioner or physician assistant.
- 3.20 Prisoner: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.
- 3.20.1 For Department of Defense (DOD) research the term includes military personnel in either civilian or military custody.
- 3.21 Related to the Research: A financial interest is Related to the Research when the interest is in:
- 3.21.1 A sponsor of the research;
- 3.21.2 A competitor of the sponsor of the research;
- 3.21.3 A product or service being tested; or
- 3.21.4 A competitor of the product or service being tested.
- 3.22 Research as Defined by DHHS: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- 3.23 Research as Defined by FDA: Any experiment that involves a test article and one or more Human Subjects, and that meets any one of the following:
- 3.23.1 Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;
- 3.23.2 Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR
- 3.23.3 Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.
- 3.24 Restricted: Applies to investigators who are delinquent in meeting IRB requirements.
- 3.25 Serious Non-Compliance: Non-Compliance that adversely affects the rights or welfare of subjects.
- 3.25.1 For Department of Defense (DOD) research Serious Non-Compliance includes failure of a person, group, or institution to act in accordance with Department of Defense (DOD) Instruction 3216.02 and its references such that the failure could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.
- 3.26 Suspension of IRB Approval: An action of the IRB, IRB designee, Organizational Official, or designee of the Organizational Official to temporarily or permanently withdraw IRB approval of some or all research procedures short of a Termination of IRB Approval. Suspended studies remain open and are subject to continuing review.
- 3.27 Termination of IRB Approval: An action of the IRB, IRB designee, Organizational Official, or designee of the Organizational Official to permanently withdraw IRB approval of all research procedures. Terminated studies are permanently closed and no longer require continuing review.
- 3.28 Unanticipated Problem Involving Risks to Subjects or Others: Any information that is (1) unanticipated and (2) indicates that subjects or others are at increased risk of harm.

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3.28.1 For Department of Defense (DOD) research the term Unanticipated Problem Involving Risks to Subjects or Others includes any incident, experience, or outcome that meets ALL three of the following conditions:

3.28.1.1 Is unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g., the IRB-approved research protocol and informed consent document) and the characteristics of the human subject population being studied.

3.28.1.2 Is related or possibly related to participation in the research (in this Instruction, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).

3.28.1.3 Suggests that the research places human subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.

4 RESPONSIBILITIES

4.1 Individuals writing policies and procedures are to indicate terms defined in this policy with a double underline.

4.2 Individuals using policies and procedures are to consult this policy for the definitions of double underlined terms.

5 PROCEDURE

5.1 None

6 MATERIALS

6.1 None

7 REFERENCES

7.1 45 CFR §46.102.

7.2 21 CFR §50.3, 21 CFR §56.102, 21 CFR §312.3, 21 CFR §812.2(a), 21 CFR §812.3(p)