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1. PURPOSE

1.1. This policy establishes the definitions followed by the Institutional Review Board.

2. REVISIONS FROM PREVIOUS VERSION

2.1. None

3. POLICY

3.1. **Adverse Effect:** An undesirable and unintended, although not necessarily unexpected, result of research or other intervention (*e.g.*, headache following spinal tap or intestinal bleeding associated with aspirin therapy).

3.2. **Assent:** Agreement by an individual not competent to give legally valid informed consent (*e.g.*, a child or cognitively impaired person) to participate in research.

3.3. **Assurance:** A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved [Federal Policy § __.103].

3.4. **Authorized Institutional Official:** An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research.


3.5. **Authorization Agreement:** Also called a Reliance Request, is the agreement that documents respective authorities, roles, responsibilities, and communication between an institution/organization providing the ethical review and a participating institution relying on the ethical review.

3.6. **Clinical Trial:** A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

3.7. **Confidentiality:** The treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.


3.8. **Cooperative Research:** Also called collaborative study in which two or more institutions coordinate, with each institution completing a portion of the research activities outlined in a specific protocol.

3.9. **Expedited Review:** Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research [Federal Policy § __.110] The research must involve no more than minimal risk and fit one or more of the

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categories for expedited review procedures as specified in the regulations [45 C.F.R. § 46.110 and 21 C.F.R. § 56.110].

- 3.10. **Full Board Review:** Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting [Federal Policy § __.108].
- 3.11. **Human Subject:** A living individual about whom an investigator (whether professional or student) is conducting research:
- (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
 - (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
- 3.12. **Informed Consent:** A person’s voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution, or agents thereof from liability for negligence [Federal Policy § 116; 21 C.F.R. §§ 50.20 and 50.25].
- 3.13. **Institutional Review Board:** A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research [Federal Policy §§ __.102(g), __.108, __.109].
- 3.14. **Interaction:** includes communication or interpersonal contact between investigator and subject.
- 3.15. **Intervention:** includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
- 3.16. **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. (45 C.F.R. § 46.102(i))
- 3.16.1. 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.
- 3.16.2. When following Department of Defense regulations, the definition of minimal risk based on the phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests” shall not

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be interpreted to include the inherent risks certain categories of human participants face in their everyday life. For example, the risks imposed in research involving human participants focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

- 3.17. **Office for Human Research Protections (OHRP):** The office within the Department of Health and Human Services, responsible for implementing DHHS regulations (45 C.F.R. Part 46) governing research involving human subjects.
- 3.18. **Principal Investigator (PI):** The scientist or scholar with primary responsibility for the design and conduct of a research project.
- 3.19. **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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
- 3.19.1. **Identifiable Private Information:** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
- 3.19.2. **Identifiable Biospecimen:** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
- 3.20. **Protocol:** The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.
- 3.21. **Reliance Request:**
- 3.22. **Research:** 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. For purposes of this rule, the following activities are deemed not to be research:
- (i) 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.

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- (ii) 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).
- (iii) 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.
- (iv) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

3.23. **Risk:** The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only “minimal risk.”

3.24. **Voluntary:** Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject’s decision to participate (or to continue to participate) in a research activity.