# PURPOSE

* 1. This policy establishes the definitions followed by the Human Research Ethics Board (HREB) at the State University of New York at New Paltz.

# REVISIONS FROM PREVIOUS VERSION

* 1. None

# POLICY

* 1. Allegation of Non-Compliance: An unproved assertion of Non-Compliance.
  2. Authorized Deception: Prospective agreement by the subject to participate in research where the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research. (Preamble to Revised Common Rule)
  3. Benign Behavioral Intervention: Low risk behavioral [not biomedical] interventions in conjunction with collecting information from an adult subject through oral or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and certain conditions are met. (Preamble to Revised Common Rule)
  4. Certification: The official notification by the institution to the supporting Federal department or agency component, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance. (45 CFR 46 §46.102 (a))
  5. 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. (45 CFR 46 §46.102 (b))
  6. Department or Agency Head: The head of any Federal department or agency, for example, the Secretary of HHS, and any other officer or employee of any Federal department or agency to whom the authority provided by these regulations to the department or agency head has been delegated. (45 CFR 46 §46.102 (c))
  7. Human Subject: A living individual about whom an investigator (whether professional or student) 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. (45 CFR 46 §46.102 (e)(1))
  8. Identifiable Biospecimen: A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen. (45 CFR 46 §46.102 (e)(6))
  9. Identifiable Private Information: Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. (45 CFR 46 §46.102 (e)(5))
  10. Institution: Any public or private entity or agency (including federal, state, and other agencies). (45 CFR 46 §46.102 (b))
  11. Interaction: Includes communication or interpersonal contact between investigator and subject. (45 CFR 46 §46.102 (e)(3))
  12. 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. (45 CFR 46 §46.102 (e)(2))
  13. IRB: An institutional review board established in accord with and for the purposes expressed in this policy. (45 CFR 46 §46.102 (g))
  14. IRB Approval: The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements. (45 CFR 46 §46.102 (h))
  15. Legally Authorized Representative: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject’s participation in the procedure(s) involved in the research. (45 CFR 46 §46.102 (i))
  16. Limited IRB Review: Making and documenting the determination required by 46.111(a)(7), to ensure that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens in the proposed research. (Preamble to Revised Common Rule)
  17. Minimal Risk: 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 CFR 46 §46.102 (i))
  18. 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). (45 CFR 46 §46.102 (e)(4))
  19. Public Health Authority: An agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate. (45 CFR 46 §46.102 (k))
  20. 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. (45 CFR 46 §46.102 (l))
  21. Secondary Research Use: Re-using identifiable and non-identifiable information and biospecimens that are collected for some other “primary” or “initial” activity. (Preamble to Revised Common Rule)
  22. Written or In Writing: Writing on a tangible medium (e.g., paper) or in an electronic format. (45 CFR 46 §46.102 (m))

# RESPONSIBILITIES

* 1. Individuals writing policies and procedures are to indicate terms defined in this policy with a double underline.
  2. Individuals using policies and procedures are to consult this policy for the definitions of double underlined terms.

# PROCEDURE

* 1. None

# MATERIALS

* 1. None

# REFERENCES

* 1. 45 CFR §46.102.