1. PURPOSE
   1. This policy establishes definitions followed by George Washington University (GW) Office of Human Research (OHR).
2. POLICY
   1. <Allegation of Noncompliance>: An unproven assertion of <Noncompliance>
   2. <Children>: Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted
   3. <Classified Research>: Research involving any information or material, regardless of its physical form or characteristics, that is owned by the United States Government, and determined pursuant to Executive Order 12356, April 2, 1982 or prior orders to require protection against unauthorized disclosure, and is so designated
   4. <Clinical Investigation>: A synonym for <Research as Defined by FDA>
   5. <Clinical Trial>: Any investigation in human subjects intended to discover or verify the effects of a drug or device, or to identify any adverse reactions to a drug or device, or to study physiology of a drug or device to ascertain its safety or efficacy.
   6. <Committee Review>: All review processes that require a convened IRB.
   7. <Compassionate Use>: The use of an unapproved device on an individual in a serious situation in which the device does not have an IDE, no generally acceptable alternative for the condition exists, and in which there is not sufficient time to obtain IRB approval.
   8. <Conflicting Interest>: An IRB member or consultant has a conflicting interest if any of the following are true for the member/consultant or an individual in the member’s <Immediate Family>:
      1. Involvement in the design, conduct, or reporting of the research
      2. Equity interest <Related to the Research>, exclusive of interests through mutual funds
      3. Compensation <Related to the Research> in the preceding 12 months
      4. Proprietary interest <Related to the Research>, including copyrights, or patents, trademarks
      5. Any other reason for which the IRB member believes that he or she cannot be objective
   9. <Continuing Noncompliance>: A pattern of <Noncompliance> that is likely to continue without intervention or failure to work with the IRB to resolve <Noncompliance>
   10. <Designated Reviewer>: An <Experienced IRB member> designated by the IRB Chair to conduct <Non-Committee> review.
   11. <Emergency Use>: The use of an unapproved drug, biologic, or device on an individual in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.
   12. <End Approval Date>: The last date that a study is IRB approved and the last date that a study can be conducted without undergoing continuing review
   13. <Expiration Date>: The first date that the protocol is no longer approved. The date after the <End Approval Date>.
   14. <Experienced IRB Member>: An IRB member who in the opinion of the IRB chair has gained over a period of time sufficient experience in and knowledge of conducting IRB reviews to serve as <Designated Reviewer>.
   15. <Experimental Subject as Defined by DOD>: An activity, for research purposes, where there is an <Intervention> or <Interaction> with a living individual for the primary purpose of obtaining data regarding the effect of the <Intervention> or <Interaction>
   16. <Expiration Date>: The day after the <End Approval Date>
   17. <Fetus>: The product of conception from implantation until delivery
   18. <Guardian>: An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care
   19. <Human Research>: Any activity that either:[[1]](#footnote-1)
       1. Is <Research as Defined by HHS> and involves <Human Subjects as Defined by DHHS>; or
       2. Is <Research as Defined by FDA> and involves <Human Subjects as Defined by FDA>.
   20. <Human Subject as Defined by FDA>: An individual who is or becomes a participant in <Research as Defined by FDA>, either as a recipient of the test article or as a control, or an individual on whose specimen an investigational device is used
   21. <Human Subject as Defined by HHS>: A living individual about whom an investigator conducting <Research as Defined by HHS> obtains (1) data through <Intervention> or <Interaction> with the individual, or (2) information that is both <Identifiable Information> and <Private Information>.
   22. <Identifiable Information>: The identity of the subject is or may be ascertained by the investigator or associated with the information by the investigator, either directly if subjects’ identities are present on research records, or indirectly if there is a key or code linking their identity to the research records.
       1. Identifiable information includes: names; postal address information (other than town or city, state and zip code); telephone numbers, fax numbers, e-mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate /license numbers; vehicle identifiers and serial numbers, including license plant numbers; device identifiers and serial numbers; internet protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full face photographic images and any comparable images.
       2. Identifiable information under the HIPAA Privacy Rule also include all geographic identifiers smaller than a state, including street address, city, county, precinct, zip code, and their equivalent postal codes, except for the initial three digits of a zip code; all elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death.
   23. <Immediate Family>: Spouse, domestic partner, parents, siblings, and dependent children
   24. <Impartial Witness>: A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the entire consent process and reads the consent document and any other written information supplied to the subject as part of the consent process
   25. <Interaction>: communication or interpersonal contact between investigator and subject
   26. <Intervention>: Physical procedures by which data are gathered and manipulations of the subject or the subject’s environment that are performed for research purposes
   27. <Legally Authorized Representative>: An individual, 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
   28. <Meeting Chair>: The IRB member running a convened IRB meeting. The <Meeting Chair> may be an IRB chair, an IRB vice-chair, or an IRB member temporarily designated by a <Meeting Chair>.
   29. <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
       1. The IRB interprets the phrase “Ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests” to refer to normal healthy individuals in general and exclude the risks that certain subcategories of individuals face in their everyday life. For example, the IRB does not evaluate the risks imposed in research focused on a special population 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).
       2. For research that involves <Prisoners> as subjects: 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. For research subject to Canadian oversight: The probability and magnitude of possible harms implied by participation in the research that is no greater than those encountered by subjects in those aspects of their everyday life that relate to the research.
   30. <Neonate of Uncertain Viability>: A neonate after delivery that, although living, is uncertain to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration
   31. <Non-Committee Review>: All review processes that do not require a convened IRB including non-human research determinations, non-engagement determinations, exemption determinations, and expedited review.
   32. <Non-significant Risk Device>: An investigational device that is not a <Significant Risk Device>
   33. <Noncompliance>: Failure to follow the regulations or the requirements or determinations of the IRB
   34. <Nonviable Neonate>: A neonate after delivery that, although living, is unable to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration
   35. <Pregnant Woman>: A woman during the period of time from implantation until delivery
   36. <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 that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing
   37. <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
   38. <Protocol Deviation>: Departure from the IRB approved protocol which do not affect the scientific soundness of the research plan or the rights, safety, or welfare of human subjects.
   39. <Regulatory Review>: Review of administrative and regulatory issues unrelated to the regulatory criteria for approval
   40. <Regulatory Reviewer>: Individual who conducts <Regulatory Review> and is authorized to make exempt determinations. All OHR staff members are authorized to conduct <Regulatory Review>
   41. <Related to the Research>: A financial interest is <Related to the Research> when the financial interest is in the sponsor or the product or service being evaluated
   42. <Research as Defined by HHS>: A systematic investigation designed to develop or contribute to generalizable knowledge
       1. DOJ regulations state that implementation of Bureau of Prisons programmatic or operational initiatives made through pilot projects do not meet this definition
   43. <Research as Defined by FDA>: Any experiment that involves a test article and one or more <Human Subjects as Defined by FDA>, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but 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 Where:
       1. Act: The Federal Food, Drug, and Cosmetic Act, as amended (§§201-902, 52 Stat 1040 et. seq., as amended (21 USC 321-392))
       2. Test article: Any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 or 354-360F of the Public Health Service Act
   44. <Restricted>: A status for investigators indicating that new submissions will not be accepted for review due to being delinquent or noncompliant with IRB requirements.
   45. <Serious Noncompliance>: <Noncompliance> that may adversely affect the rights and welfare of subjects
   46. <Significant Risk Device>: An investigational device that:
       1. Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
       2. Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
       3. Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
       4. Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject
   47. <Suspension of IRB Approval>: Temporary or permanent withdrawal of IRB approval for some or all research procedures short of <Termination of IRB Approval>
   48. <Termination of IRB Approval>: Withdrawal of IRB approval for all research procedures where the IRB does not anticipate re-opening the study
   49. <Unanticipated Problems Involving Risks to Subjects or Others>: Information that:
       1. Is unexpected (inconsistent with information previously reviewed by the IRB); and
       2. Indicates that subjects or others are at increased risk of harm because of the research study
   50. <Wards>: <Children> who are cared for and the responsibility of the state or any other agency, institution, or entity
3. REFERENCES
   1. 45 CFR §46.102, §46.202, §46.303, §46.402
   2. 21 CFR §50, §56.102, §312.3, §812.3

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. [↑](#footnote-ref-1)