1. PURPOSE

1.1. This policy establishes definitions followed by the [Organization].

2. POLICY

2.1. <Allegation of Noncompliance>: An unproven assertion of <Noncompliance>.

2.2. <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.

2.3. <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.

2.4. <Clinical Investigation>: A synonym for <Research as Defined by FDA>.

2.5. <Clinical Trial as Defined by 45 CFR §46>: 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.

2.6. <Committee Review>: All review processes that require a convened IRB.

2.7. <Compassionate Use>: The use of an unapproved device on an individual who has a life-threatening or serious disease or condition and no generally acceptable alternative treatment for the condition exists.

2.8. <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>:

- 2.8.1. Involvement in the design, conduct, or reporting of the research,
- 2.8.2. Equity interest <Related to the Research>, exclusive of interests through mutual funds,
- 2.8.3. Compensation <Related to the Research> in the preceding 12 months,
- 2.8.4. Proprietary interest <Related to the Research>, including copyrights, or patents, trademarks,
- 2.8.5. Any other reason for which the IRB member believes that he or she cannot be objective.

2.9. <Continuing Noncompliance>: A pattern of <Noncompliance> that is likely to continue without intervention or failure to work with the IRB to resolve <Noncompliance>.

2.10. <Designated Reviewer>: An <Experienced IRB member> designated by the [IRB Executive Chair] to conduct <Non-Committee> review.

2.11. <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.

2.12. <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.

2.13. <Experienced IRB Member>: An IRB member who based on professional competence in the opinion of the [IRB Executive Chair] has gained over a period of time sufficient knowledge and skill in conducting IRB reviews to serve as <Designated Reviewer>.

2.14. <Expiration Date>: The day after the <End Approval Date>.

2.15. <Fetus>: The product of conception from implantation until delivery.

2.16. <Guardian>: An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

2.17. <Human Research as Defined by FDA>: Any activity that is <Research as Defined by FDA> and involves <Human Subjects as Defined by FDA>.

2.18. <Human Research as Defined by HHS>: Any activity that is <Research as Defined by HHS> and involves <Human Subjects as Defined by HHS>.

2.19. <Human Research>: Any activity that is <Human Research as Defined by HHS> or <Human Research as Defined by FDA>.

2.20. <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.

2.21. <Human Subject as Defined by HHS>:

2.21.1. For <Research as Defined by HHS> subject to the <Original Rule>: 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>.

2.21.2. For <Research as Defined by HHS> subject to the <Revised Rule> or the <Hybrid Rule>: A living individual about whom an investigator conducting <Research as Defined by HHS>:

2.21.2.1. Obtains information or biospecimens through <Intervention> or <Interaction> with the individual, and uses, studies, or analyzes the information or biospecimens; or

2.21.2.2. Obtains, uses, studies, analyzes, or generates <Identifiable Private Information> or <Identifiable Biospecimens>.

2.22. <Hybrid Rule>: A set of requirements adopted by the [Organization] that follows the <Revised Rule>, unless the <Original Rule> is substantially less restrictive, in which case the <Original Rule> is followed. See Table in references for a detailed description.

2.23. <Identifiable Information>:

2.23.1. For <Research as Defined by HHS> subject to the <Original Rule>: Information for which the identity of the subject is or may readily be ascertained by the investigator or readily be associated with the information.

2.23.2. For <Research as Defined by HHS> subject to the <Revised Rule> or the <Hybrid Rule>: Information or a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or readily be associated with the information.

2.24. <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.

2.25. <Identifiable Biospecimen>: A biospecimen for which the identity of the <Human Subject as Defined by HHS> is or may readily be ascertained by the investigator or associated with the biospecimen.

2.26. <Immediate Family>: Spouse and dependent children.

2.27. <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.

2.28. <Interaction>: Communication or interpersonal contact between investigator and subject

2.29. <Intervention>: Physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

2.30. <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.

2.30.1. For <Research as Defined by HHS> subject to the <Revised Rule> or the <Hybrid Rule>, but NOT subject to FDA regulations: Where there is no applicable law addressing this issue, legally authorized representative also means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective <Human Subject as Defined

by HHS> to the <Human Subject's> participation in the procedure(s) involved in the research.

2.31. <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>.

2.32. <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

2.32.1. 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).

2.32.2. For <Human Research as Defined by HHS> that involves <Prisoners> as <Human Subjects as Defined by HHS>: 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.

2.32.3. 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.

2.33. <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.

2.34. <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.

2.35. <Non-significant Risk Device>: An investigational device that is not a <Significant Risk Device>.

2.36. <Noncompliance>: Failure to follow the regulations or the requirements or determinations of the IRB.

2.37. <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.

2.38. <Original Rule> The Federal Policy for the Protection of Human Subjects requirements contained in 45 CFR §46 Subparts A as published in the 2016 edition of the Code of Federal Regulations.

2.39. <Pregnant Woman>: A woman during the period of time from implantation until delivery.

2.40. <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.

2.41. <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.

2.42. <Regulatory Review>: Review of administrative and regulatory issues unrelated to the regulatory criteria for approval that under the regulations must be determined by a convened IRB or reviewer using the expedited procedure.

2.43. <Regulatory Reviewer>: Individual who conducts <Regulatory Review>.

2.44. <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.

2.45. <Reliance Agreement>: Documentation describing the reliance of an institution on an IRB for the oversight of research and the responsibilities that each entity will undertake to ensure compliance with regulatory requirements, which can be embodied in a written agreement between the institution, an institution-wide policy directive, or a research protocol.

2.46. <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:

2.46.1. Act: The Federal Food, Drug, and Cosmetic Act, as amended (§§201-902, 52 Stat 1040 et. seq., as amended (21 USC 321-392))

2.46.2. 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

2.47. <Research as Defined by HHS>: A systematic investigation designed to develop or contribute to generalizable knowledge.[1]

2.48. <Restricted>: A status for investigators indicating that new submissions will not be accepted for review.

2.49. <Revised Rule>: The Federal Policy for the Protection of Human Subjects requirements contained in 45 CFR §46 Subparts A as revised January 18, 2017.

2.50. <Serious Noncompliance>: <Noncompliance> that adversely affects the rights and welfare of subjects.

2.50.1. For research conducted or supported by DOD, <Serious Noncompliance> is failure of a person, group, or institution to act in accordance with this Instruction 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.

[1] The following activities are deemed not to be <Research as Defined by HHS>: (1) 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. (2) 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). (3) 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. (4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions. Public health authority means 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.

2.51. <Significant Risk Device>: An investigational device that:

2.51.1. Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
2.51.2. 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;
2.51.3. 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
2.51.4. Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

2.52. <Single Patient Expanded Access>: Treatment with an investigational drug under an IND where the FDA granted an IND pursuant to 21 CFR §312.310
2.53. <Suspension of IRB Approval>: Temporary or permanent withdrawal of IRB approval for some or all research procedures short of <Termination of IRB Approval>.
2.54. <Termination of IRB Approval>: Withdrawal of IRB approval for all research procedures where the IRB does not anticipate re-opening the study.
2.55. <Unanticipated Problems Involving Risks to Subjects or Others>: Information that:

2.55.1. Is unexpected (inconsistent with information previously reviewed by the IRB); and
2.55.2. Indicates that subjects or others are at increased risk of harm because of the research study.

2.56. <Wards>: <Children> who are cared for and the responsibility of the state or any other agency, institution, or entity.

3. REFERENCES

3.1. 45 CFR §46.102, §46.202, §46.303, §46.402
3.2. 21 CFR §50, §56.102, §312.3, §812.3

3.3. Table of <Hybrid Rule> requirements: The <Hybrid Rule> follows the <Revised Rule>, unless the <Original Rule> is substantially less restrictive, in which case the <Original Rule> is followed. Blank lines represent sections where there are no key changes that affect the HRPP, but a policy decision was made to follow one rule or the other.

Citation	Key Change in Revised Common Rule	Hybrid Rule Follow	
		Revised Rule	Original Rule
.101	• No requirement for IRB review of grants	X	
.102	• Revised definitions	X	
.103	• Grant review no longer required • Documentation of IRB reliance through an agreement or policy	X	
.104	• Revised exempt categories[2]	X	
.105	• Modified examples of vulnerable populations	X	
.107		X	
.108		X	
.109	• Continuing review not required for certain categories of research	X	
.110	• Requirement to document rationale for determining that research falling into expedited categories is not minimal risk.		X
.110-113		X	
.114	• Requirement for single IRB review		X
.115	• Requirement that records must document the rationale for an expedited reviewer's determination that research appearing on the expedited review list is more than minimal risk • Requirement that records must document the rationale for continuing review of research where continuing review is not a requirement		X
.115	• Records must include reliance agreements or policies.	X	
.116(a)-(f)	• Reasonable person standard • Initial concise summary • Disclosure of future research without identifiers • Disclose of commercial profit • Disclose of sharing of results • Disclose of whole genome sequencing • Revised criteria for waiver of consent		X
.116(g)	• No requirement for consent for recruitment	X	
.116(h)	• Public posting of <Clinical Trial as Defined by 45 CFR §46> consent form		X
.116(i)-(j)		X	
.117	• Revised criteria for waiver of written documentation of consent	X	
.118-124		X	

[2] Requirements for broad consent and limited IRB review located in other paragraphs are considered part of 46.104 by reference.