1. PURPOSE

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

2. POLICY

2.1. Allegation of Noncompliance: An unproven assertion of Noncompliance

2.2. Children/Minors: Persons who have not attained the legal age for consent of treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. Florida law defines “minor” as any person who has not attained the age of 18 years. (§ 1.01(13), Florida Statutes). The term Minors also excludes those individuals who have otherwise been emancipated under Florida law.

2.3. Clinical Investigation: A synonym for Research as Defined by FDA

2.4. Clinical Trial: Any investigation in human subjects intended to discover or verify the effects of a drug, device, or behavioral intervention, 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.

2.5. Conflict of Interest: An IRB member or consultant has a conflict of interest if any of the following are true for the member/consultant or an individual in the member’s Immediate Family:

2.5.1. Involvement in the design conduct or reporting of the research

2.5.2. Equity interest Related to the Research, exclusive of interests through mutual funds

2.5.3. Compensation Related to the Research in the preceding 12 months

2.5.4. Proprietary interest Related to the Research, including copyrights, or patents, trademarks

2.5.5. Any other reason for which the IRB member believes that he or she cannot be objective

2.6. Continuing Noncompliance: Noncompliance (serious or non-serious) that has been previously reported by the investigator, or a pattern of ongoing activities that indicate a lack of understanding of human subjects protection requirements that may affect research participants or the validity of the research and suggest the potential for future noncompliance without intervention, particularly after the IRB has informed the investigator of the noncompliant issue.

2.7. Emergency Use: The use of an investigational drug, biological product, or medical device with a human subject 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.

2.8. Executive Reviewer: The IRB Chair or an Experienced IRB Member designated by the IRB chair to conduct Non Full Board Reviews.

2.9. Expanded Access: The use of an investigational drug when the primary purpose is to diagnose, monitor, or treat a patient rather than to obtain the kind of information about the drug that is generally derived from clinical trials. Also called Compassionate Use.

2.10. 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.

2.11. 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

2.12. Expiration Date: The first date that the protocol is no longer approved. The date after the end date of the approval period.

2.13. Full Board Review: All review processes that require a convened IRB.

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

2.15. Human Research: Any activity that involves Human Subjects as defined by either DHHS or the FDA.
2.16. **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) identifiable Private Information. For the purpose of this definition:

2.16.1. **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.

2.16.2. **Interaction:** Communication or interpersonal contact between investigator and subject.

2.16.3. **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).

2.17. **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. For research involving medical devices a human subject is also an individual on whose specimen an investigational device is used.

2.17.1. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.

2.18. **Immediate Family for purposes of Conflict of Interest:** Spouse and dependent children.

2.19. **Individual patient expanded access IND (also referred to as single patient IND):** Expanded access to an investigational drug for treatment use by a single patient submitted under a new IND, including for Emergency Use.

2.20. **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.

2.21. **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.

2.21.1. 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).

2.21.2. 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.

2.22. **Non-Full Board Review:** All review processes that do not require a convened IRB including non-human research determinations, non-engagement determinations, exemption determinations, and expedited review.

2.23. **Noncompliance:** Failure to follow the regulations or the requirements, determinations, or policies of the IRB.

2.24. **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.

2.25. **Pre-Reviewer:** Individual(s) who conducts pre-review of a submitted study.
2.26. **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.

2.27. **Research (as defined by DHHS):** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

   2.27.1. DOJ regulations state that implementation of Bureau of Prisons programmatic or operational initiatives made through pilot projects do not meet this definition.

2.28. **Research (as defined by FDA):** Any experiment that involves a test article and one or more human subjects, 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 Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug and Cosmetic 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.

   2.28.1. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. (21 CFR 50.3(c), 21 CFR 56.102(c))

2.29. **Serious Noncompliance:** Noncompliance that has, or has the potential to increase risk to research participants, compromise participants’ rights or welfare, or affect the integrity of the research/data or the human research protection program.

2.30. **Significant Risk Device:** An investigational device that:

   2.30.1. Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;

   2.30.2. 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;

   2.30.3. 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

   2.30.4. Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

2.31. **Suspension of IRB Approval:** Temporary withdrawal of IRB approval for some or all research procedures, including enrollment, short of Termination of IRB Approval.

2.32. **Termination of IRB Approval:** Withdrawal of IRB approval for all research procedures where the IRB does not anticipate re-opening the study.

2.33. **Unanticipated Problems Involving Risks to Subjects or Others:** Information that:

   2.33.1. Is unexpected (inconsistent with information previously reviewed by the IRB); and

   2.33.2. Indicates that subjects or others are at increased risk of harm because of the research study.

2.34. **Voluntary Suspension:** Voluntary interruption by the Principal Investigator (PI) or the PI Proxy of previously approved research enrollments and ongoing research activities, but is not considered a suspension or termination of IRB approval as defined above.

### 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. §1.01(13), Florida Statutes