1 PURPOSE

1.1. This policy establishes definitions followed by the FAU Human Research Protection Program

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 (FDA Definition):ogu e2(w)-5.9n d un:Fderon)-6.3 (F)ot(at)-1.1 (-6.3 (F)(i)3.2 (vc)-8 (o)-12

_____

end date of the approval period.

2.13. Full Board Review: All review processes that require a fully 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 Subject (DHHS Definition): 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.

- 2.15.1. 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.
- 2.15.2. Interaction: Communication or interpersonal contact between investigator and subject.
- 2.15.3. 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)

2.16. Human Subject (FDA Definition): 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.

2.17. 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.

- 2.17.1. 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.
- 2.17.2. 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.

2.18. 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.

2.19. Interaction: Communication or interpersonal contact between the researcher and the subject.

2.20. Intervention: Physical procedures by which data are obtained and manipulations of the subject or the subject's environment that are performed for research purposes.

2.21. 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.

2.22. 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.

2.23. Non-Committee Review: