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): Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to 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 submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

2.4. Clinical Trial (NIH Definition): 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 those interventions on health-related biomedical or behavioral outcomes.

2.5. Conflicting Interests: An IRB member or consultant has a conflicting interest if any of the following are true for the individual or an immediate family member:

- 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 of review of the research or submission related to the research;
- 2.5.4. Proprietary interests related to the research, including copyrights, patents, or trademarks;
- 2.5.5. Any other reason for which the IRB member or consultant believes they 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 non-compliant issue.

2.7. Designated Reviewer: An Experienced IRB Member designated by the IRB Chair to conduct Non-Committee Review.

2.8. 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.

2.9. 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.

2.10. 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.

2.11. 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.

2.12. 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 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: All review processes that do not require a convened IRB including non-human research determinations, non-engagement determinations, exemption determinations, and expedited review.

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

2.25. 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.

2.26. Private Information: Information about a 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.

2.27. 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.

2.28. Protocol Violation: Unapproved changes in the research study design and/or procedures that are within the investigator's control and not in accordance with the IRB-approved protocol that may affect the participant's rights, safety or well-being, or the completeness, accuracy and reliability of the study data.

2.29. Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

2.30. 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.

2.31. Significant Risk Device: An investigational device that:

- 2.31.1. Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- 2.31.2. 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;
- 2.31.3. 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
- 2.31.4. Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

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

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

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

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

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

3 REFERENCES

45 CFR §46.102, §46.202, §46.303, §46.402
21 CFR §50, §56.102, §312.3, §812.3
§1.01(13), Florida Statutes