UCF COLLEGE OF BUSINESS

IRB Definitions

These definitions are just a few taken from the UCF Institutional Review Board document: **HRP 001: Definitions.**

Administrative Review:

Any of the following:

- 3.1.1 Determination of whether an activity is Human Research.
- 3.1.2 Determination of whether Human Research is exempt from regulation.
- 3.1.3 Reviews of non-exempt research using the expedited procedure.

Clinical Trial: A biomedical or behavioral research study of human subjects designed to answer specific questions about diagnostic procedures or therapeutic interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new diagnostic procedures or therapeutic interventions are safe, efficacious, and effective.

Designated Reviewer: The IRB chair or an Experienced IRB Member designated by the IRB chair to conduct Non-Committee Reviews.

Human Research: Any activity that either:

- 3.10.1 is Research as Defined by DHHS and involves Human Subjects as Defined by DHHS; or
- 3.10.2 is Research as Defined by FDA and involves Human Subjects as Defined by FDA.

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) information that is both Private Information and Identifiable Information.

For the purpose of this definition:

- 3.11.1 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.
- 3.11.2 Interaction: Communication or interpersonal contact between investigator and subject.
- 3.11.3 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).
- 3.11.4 Identifiable Information: Information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

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. A human subject includes an individual on whose specimen a medical device is used. Immediate Family: Spouse and dependent children.

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.

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