1. POLICY

All Purdue University faculty, students, and staff involved in activities that fall under the federal definitions of Human Subjects Research are required to comply with federal and state laws as well as University policies and procedures for the protection of human research subjects.

This guideline serves to clarify types of activities that are determined to be Human Subjects Research in order to assist investigators in the Institutional Review Board (IRB) process at Purdue University.

2. DEFINITIONS

Health and Human Services Definitions

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

2.2 *Human Subject.* A living individual about whom an investigator (whether professional or student) conducting research:

2.2.1 Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

2.2.2 Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

(a) *Intervention* includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

(b) *Interaction* includes communication or interpersonal contact between investigator and subject.

(c) *Private information* includes 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

(d) *Identifiable Private Information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

(e) An *Identifiable Biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

2.3 *Clinical Trial*. 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.

Food and Drug Administration Definitions

2.4 *Research*. Clinical investigation activities that include:

2.4.1 Use of a drug other than the use of a FDA approved drug in the course of medical practice (21 CFR 312.3(b)).

2.4.2 Use of a medical device other than the use of a FDA approved medical device in the course of medical practice (Food, Drug and Cosmetic Act 530(g)(3)(a)(i)).

2.4.3 Gathering data that will be submitted to or held for inspection by FDA in support of a FDA marketing permit for a food, certain dietary supplements, an infant formula, a food or color additive, a drug, biologic or medical device for human use, or an electronic product. (21 CFR 50.1(a))

2.5 *Human Subject*. An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. (21 CFR 56.102(e)).

3. GUIDELINES

The Human Research Protection Program has developed the following guidelines to assist Investigators in determining which activities are subject to IRB review.

3.1 Any activity that qualifies as Research (as defined above) and includes one or more Human Subjects (as defined above) must be reviewed and approved (or declared exempt) by the IRB prior to the commencement of the study.

3.2 Human Subject Research activities must be reviewed by the IRB irrespective of funding.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46

21 CFR 50

21 CFR 56

5. REFERENCES TO OTHER APPLICABLE SOPs

301 Exemption Determinations

302 Initial Review

303 Expedited Review