

GLOSSARY

Human Subject: "Human Subject" means a living individual about whom an investigator... conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information... private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)... (45 CFE 46.102[f]) (c.f. FDA 56.102[e]).

Research: "Research" means a systematic investigation designed to develop or contribute to generalizable knowledge (45 CFR 46.102[e]) (c.f. FDA 56.102[c]).

Research Development and Related Activities: "Research development and related activities" include all formal investigative efforts by faculty, students and staff that are designed to develop or contribute to generalized knowledge. Research development and related activities include those whose results are intended or used for publication, distribution, or use outside a specific instructional setting. Research and related activities may range from use of normal to abnormal subjects involving physiological, psychological, or social phenomena. The activities or procedures utilized may be invasive or non-invasive, modifications of diet, daily routine or service delivery, alternation of environment, observations, administration of questionnaires or tests, study or examination of human organs, tissues, fluids and other materials, or personal data from which the subjects could be identified.

Human Subject Involvement/Manipulation: "Human subject" means 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. "Intervention" includes both 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. "Interaction" includes communication or interpersonal contact between investigator and subject.

"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 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). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Minimal Risk: This term is considered to be the probability and magnitude of physical, psychological or social harm that is normally encountered in daily life or in routine medical or psychological examination. In any assessment of degree of risk, the age of the subject must be considered. The University Human Subjects Research Review Committee is charged with determining the degree of physical, psychological, or social risk, if any, in each case. Physical, psychological, and social risks include the following:

Physical Risks: Physical risks are those present when a substance is injected or ingested into a subject's body or special diets administered or some other physical intervention is performed on the subject's body, or the subject's body is in any way unduly stressed. A physical risk may involve unusual physical activity or strong aversive stimulations. Physical stimuli such as noise, electric shock, heat and/or humidity, cold and/or wind, electric magnetic or gravitational fields, ionizing or non-ionizing radiation may involve physical risks. Engaging a subject in a social situation which could involve violence may also create a physical risk.

Psychological Risks: Psychological risks are those present when there is possibility that a subject will undergo a significant degree of psychological damage or discomfort directly or indirectly as a consequence of participating in an experiment or project. Sensory deprivation, sleep deprivation, use of hypnosis, deception, or mental stresses are among a few of the examples of psychological risks.

Social Risks: Social risks exist when there is a possibility that the research may cause the subject to experience a loss of personal reputation, employment status or income, or material possessions, or be put in legal jeopardy, or experience personal indignity.