# Policies and Procedures for the Protection of Human Research Subjects

| 101.A: Definitions | |
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Human Subjects Research includes all studies that meet both the definition of "research" and "human subjects" below.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Human subject means 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.

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.

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 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).

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.
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.

Roles

IRB means an institutional review board established in accord with and for the purposes expressed in this policy.

Principal Investigator (PI) is the individual responsible for overseeing all aspects of the study. ISU policy allows for only faculty or staff to act in the capacity of the PI for a research study.

Investigator/Research Team Member – An individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB. OHRP interprets an "investigator" to be any individual who is involved in conducting human subjects research studies. Such involvement would include: obtaining information about living individuals by intervening or interacting with them for research purposes; obtaining identifiable private information about living individuals for research purposes; obtaining the voluntary informed consent of individuals to be subjects in research; and studying, interpreting, or analyzing identifiable private information or data for research purposes.

Certification means the attestation by the PI that the PI will adhere to the federal regulations and ISU policies and procedures when conducting human subjects research.

Vulnerable Populations

Children are persons who have not attained the legal age to consent for participation in research, as determined under the applicable law of the jurisdiction in which the research will be conducted.

Prisoner is defined as an individual involuntarily confined in a pernal institution, including persons (1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities (e.g., for drug detoxification or treatment or alcoholism) under statues or commitment procedures providing such alternatives to criminal prosecution in a penal institution.

Cognitive Impairment means having either a psychiatric disorder or a developmental disorder that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative disease, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interest.

Informed Consent Process

Informed Consent is a person's (or the person's legally authorized representative) voluntary and legally effective agreement to participate in research; such consent can be obtained only under circumstances that provide the prospective subject or representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

Assent means a child's affirmative agreement to participate in research. Failure to object should not be construed as assent.

Permission is the agreement of parent(s) or guardian(s) to the participation of their child or ward in research.

Legally authorized representative means an individual or 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. If there is no applicable law addressing this issue, legally authorized representatives means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Confidential means that the subjects' names are known to the investigator.

Anonymous means that the subjects' names are not known to the investigator.

Risk is defined as the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research 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.

Deception is the withholding of complete information when consent is obtained.

Protocol Processing

IRB Approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

Approval period is the length of time (typically one year) during which an approved research protocol may be conducted.

Revisions Required means that a research protocol has been reviewed by the IRB, but revisions are required to be submitted and reviewed before approval may be granted.

Denial means that the IRB has determined that the risks to the human subjects outweigh the benefits to be gained by conducting the research.

Modification is a requested change to an approved protocol. Modifications must be approved by the IRB before implementation.

Continuation is a requested re-approval of an approved protocol.

Suspension is the immediate halt to all research activities that occurs when the IRB determines that harm has occurred and/or is likely to occur if the research is allowed to continue.

Termination of research activities occurs when the IRB withdraws approval of a study due to substantiated instances of harm, the potential for previously unrecognized harm, or, in some cases, confirmed circumstances of non-compliance.

Reporting

Adverse event occurs when a human subjects experiences a physical, psychological, social or other negative impact as a result of his/her participation in the research activity. Adverse events are reportable to the IRB.

Unanticipated Problem Involving Risks to Subjects or Others – OHRP considers unanticipated problems, in general, to include any incident, experience, or outcome that meets all of the following criteria:

1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

2. related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the

incident, experience, or outcome may have been caused by the procedures involved in the research); and

3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Noncompliance occurs whenever there is a failure to follow federal regulations, state laws or ISU policies and procedures, or when there have been deviations from the protocol approved by the reviewing IRB. Noncompliance may be serious, minor or continuing.