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Department of Health and Human Services Definitions:

Adverse Event

An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g., subject becomes upset following completion of a depression questionnaire or subject experiences intestinal bleeding associated with aspirin therapy) that is directly or indirectly due to participation in a research study.

Assent

A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Child

A person who has not yet attained the age of consent to treatments or procedures involved in the research, under the applicable laws of the jurisdiction in which the research will be conducted. Children received additional protections under 45 CFR 46, Subpart D.

Department or Agency

The head of any federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

Guardian

An individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

Human Subject/Participant

A living individual about whom an investigator (where professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information.

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Interaction

Communication or interpersonal contact between investigator and human subject (e.g., a telephone interview).

Intervention

Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes (e.g., cognitive experiment).

Institution

Any public or private entity or agency (including federal, state, and other agencies).

IRB

An institutional review board established in accord with and for the purposes expressed in 45 CFR 46.

IRB Approval

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.

Legally Authorized Representative

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.

Minimal Risk

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.

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Parent

A child's biological or adoptive parent.

Permission

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

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. Prisoners receive additional protections under 45 CFR 46, Subpart D.

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 he or she can reasonably expect will not be made public (e.g., 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) in order for obtaining the information to constitute research involving human participants.

Research

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 purpose of the policy and procedures, whether or not they are supported or funded

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under program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Secretary

The Secretary of Health and Human Services and any other officer or employee of the DHHS to whom authority has been delegated.

Vulnerable Population

Includes children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, individuals who are unable to give informed consent due to a physical or mental condition, or individuals whose circumstances make them especially vulnerable to coercion.

Some studies may fall under the regulations promulgated by the FDA (21 CFR 50). These will generally be studies that involve the testing of an investigational medication or medical device. Refer to 21 CFR 50 for specific definitions regarding these studies. Some FDA definitions differ from the above DHHS definitions.

Liberty University Definitions:

In addition to definitions promulgated by federal agencies, the University policy uses the following definitions:

Generalizable Knowledge

Any information generated from data collected to describe, inform, generate or test hypothesis that will be shared with others in any public or semi-public venue other than closed meeting and/or the classroom setting. This may include dissemination of information through more

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traditional, formalized means such as journal publications or conference presentations. It also includes dissemination through things like local or state newsletters or posting on the Internet such that a wider audience could access the information freely.

Institutional Research

A study designed to obtain information to assist in the administration of the University.

Institutional research provides information for administrative planning, policy making, decision making, and includes examinations of institutional effectiveness. Institutional research is specifically defined as those data collection and interpretation efforts that: (a) will not be shared outside of the University environment; (b) will not be disseminated to other professionals or the public in any form; (c) presents no more than “minimal risk” (as defined by Federal regulations); (d) is not intended to produce “generalizable knowledge”; and (e) contains no identifiers in the data that might compromise an individual’s confidentiality. Institutional studies meeting this definition are not subject to the IRB policy and procedures.

IRB Alternate Committee Member

A member who substitutes for a regular IRB committee member of similar qualifications when the regular member is unavailable for proposal reviews.

IRB Committee Member

A current, active member of the IRB who often serves as a reviewer on Expedited and/or Full Review proposals. Committee members may consist of academicians with scientific training, clergy, medical doctors, persons without scientific training, students, former students, and consumers.

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Opt-out Parental Consent Procedure

A consent procedure whereby parents of minors sign and return a consent form if they DO NOT want their child to participate in a research study. This option is utilized when a large number of minors will be recruited, the study procedures involve no more than minimal risk, and the study topic is not included on the Protection of Pupil Rights Amendment (PPRA) [list](#). Permission from the district/school/organization through which students will be contacted is required for researchers to utilize the opt-out parental consent procedure.

Principal Investigator

The person who leads the project and is ultimately responsible for all aspects of it.

Research

Generally defined as systematic investigation—including research development, testing, and evaluation—designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)).

Student Class Project

A study in which a student investigator (individually or part of a group) gathers or analyzes information in a systematic manner, primarily for the learning experience (pedagogical purposes). It is not intended to contribute to generalizable knowledge and is not to be presented outside the class in which the research is being done or published/disseminated (including publication on the internet) in any way, presented, archived, or compiled with similar research for later publishing or presentation. Human subject research conducted for a senior project, master's thesis, seminar project, or dissertation does not fall under this definition and must be reviewed by the IRB.

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Systematic Investigation

Any activity that utilizes scientific methods (either quantitative or qualitative) in an orderly, iterative process of data gathering. These methods may be experimental, quasi-experimental, or pre-experimental in nature and may or may not involve random selection and/or random assignment. In general, they follow an orderly plan of the investigator's design or adoption.

Training

Refers to the process approved by the University, and required by federal regulations, to instruct investigators in the conduct of research involving human participants.