Adverse Event

An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g., A subject becomes upset following the completion of a depression questionnaire, or a 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. The child must actively show his or her willingness to engage in research rather than just complying with directions to participate and not resisting in any way.

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 and takes administrative action to ensure the policy set for in 45 CFR 46 is applied to research involving human subjects.

Guardian

An individual authorized under applicable state or local law to consent on behalf of a child to general medical care. A child's guardian may also provide legally effective informed consent for participation in research.

Human Subject/Participant

A living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information or biospecimens and uses, studies, and analyzes said information.

Interaction

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

Intervention

Includes both physical procedures by which information or biospecimen 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 department or agency (including federal, state, and other agencies).

IRB

An institutional review board was established in accordance with and for the purposes expressed in 45 CFR 46. An IRB has the authority to approve, require modifications (to secure approval), or disapprove research.

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. If there is no applicable law addressing this issue, a legally authorized representative means, in the non-research context, an individual recognized by institutional policy as acceptable for providing consent on behalf of a prospective subject for the individual's participation 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.

Parent

A child's biological or adoptive parent.

Permission

The agreement of parent(s) or guardian(s) 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 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. "This excludes individuals who reside in settings related to corrections, including residential treatment programs to which persons have been consigned by

administrative or court order, halfway houses, and persons who are in public health custody" (Office for Human Research Protections (OHRP), 2021).

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 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) 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 purposes of the policy and procedures, whether they are supported or funded under a program that 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 are different from the above DHHS definitions.

Liberty University Definitions:

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

Generalizable Knowledge

The extent to which information generated from research can be applied to individuals other than the participants.

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, and 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.

Opt-Out Parental Consent Procedure

A 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 study qualifies for a waiver of consent. The district/school/organization through which students will be contacted may require researchers to utilize the opt-out parental consent procedure even if a study qualifies for a waiver of consent.

Principal Investigator

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

Research

Generally defined as a 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 as part of a group) gathers or analyzes information systematically, 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.

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.