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Definition of Terms

Below are definitions for common IRB terms

Adverse event (AE): Any undesirable and unintended (although not necessarily unexpected) event experienced by a subject occurring as a result of interventions, interactions, or collection of identifiable private information in research. An adverse event can be internal or external as it relates to the location of the site.

Alteration of Informed Consent: An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent. For example, a study involving deception may not be able to fully state the true purpose (a required element) of the study in the consent. Therefore, the IRB must approve an alteration of the consent requirement.

Anonymous: Research in which all samples and data will be free of identifiers, including code numbers for which investigators have a link to individual identities. The data cannot be connected to the individual who provided it.

Archival Data: Data collected prior to the time of application to the IRB. These data may have been collected for either research or non-research purposes.

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.

Coded: Research in which (1) identifying information, such as name or social security number, has been replaced with a number, letter, symbol, or combination thereof (i.e., the code), *and* (2) a key to decipher the code exists (e.g., a master list), enabling linkage of the identifying information to the private data or specimens that are collected as part of the research.

Confidentiality: Confidentiality relates to how the research data is protected. Collecting the minimum necessary identifiable information is advised. Proper practices should be applied to collecting, maintaining, storing, and destroying identifiable information is collected: substituting codes for identifiers, removing identifiable information.

Deception: Intentionally misleading or providing untruthful information; any concealment or withholding of information from a participant; use of trickery or deceit.

De-identified: Research in which all samples and data will be stripped of identifiers, *including* code numbers for which investigators have a link to individual identities, after coming into the possession of the researcher. In this research, no master list of participants will exist, so there will be no link between samples/data and participants' identities.

Generalizable Knowledge: Generalizable knowledge can be applied to other people, times, situations, and places.

Human Subject: 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.

Interaction: Communication or interpersonal contact between investigator and subject.

Intervention: Procedure during the experiment in which a treatment or manipulation of the environment occurs to elicit a change in behavior or physiological functioning.

Identifiable Private Information: Private information or specimens are individually identifiable when they can be linked to the individual research participant by investigator(s) or others either directly or indirectly through coding mechanisms. Obtaining identifiable private information or specimens for research purposes falls under the definition of human subjects research.

Informed Consent: is typically a written document, whereby after a verbal discussion of the document with an opportunity for the subject to ask questions, the subject then signs it. At times it may be appropriate for an altered consent process to occur, such as a verbal process, online process, or obtaining a waiver of the requirement to obtain a written signature.

Legally Authorized Representative (LAR): 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. (45 CFR 46.102 (c)) (21 CFR 50.3 (1))

Minimal Risk: The probability (likelihood) and magnitude (degree or level) 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.

Non-compliance: Non-compliance is any departure from the IRB approved protocol procedures, forms, and other attachments and/or any failure to follow any applicable human research protection regulations and policies (including but not limited to HHS, FDA, and UMSL IRB).

Private Information: Private information includes information that can be identified with an individual and that is obtained in a context in which an individual can reasonably expect that no observation or recording is taking place, or information that has been recorded for specific purposes and which the individual can reasonably expect will not be made public (e.g., medical records).

Protocol deviation: Any deviations, whether intentional or unintentional, from the IRB-approved protocol that are implemented without prior to IRB approval. Examples include, but are not limited to accidental over-recruitment for a minimal risk study; a change implemented without prior UMSL IRB approval to eliminate apparent immediate hazards to research subjects; and posting of a recruitment flyer without prior UMSL IRB approval.

Publicly Available: Refers to public sources of data, such as new papers, data bases, libraries, and the internet. Data obtained from data banks, archives, or organizations that make data sets broadly accessible at a reasonable cost to the research community are also considered publicly available.

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

Risk: The probability that harm (including physical, psychological, social, legal, or economic) will occur as a result of participating in a research study.

Serious adverse event (SAE): Adverse events classified as serious include those resulting in death, life-threatening injury, hospitalization or prolongation of hospitalization, persistent or significant disability, or a congenital anomaly or birth defect. Events not meeting the above criteria but requiring intervention to prevent one of these outcomes are also considered serious adverse events.

Waiver of Informed Consent/Alteration of Informed Consent: An IRB may waive or alter some or all elements of consent, if the research meets the following requirements: 1) the research involves minimal risk to the participants; 2) the waiver will not adversely affect the rights or welfare of the participants; 3) the research could not practicably be carried out without the waiver; 4) When appropriate, the participants will be provided with additional pertinent information after participation; 5)if using identifiable private information or identifiable biospecimens, the research could not practicably be carried out using deidentified information or biospecimens.

Waiver of Documentation of Informed Consent: An IRB may waive the requirement for obtaining a signed consent document if: 1) The only record linking the participant and the research is the consent document and the principle risk of the research would be potential harm resulting from a breach of confidentiality, and each subject will be asked whether they want documentation linking themselves with the research, and their wishes govern the final decision; or 2) The research involves no more than minimal risk and involves no procedures for which consent is required outside of the research context; or 3)The subjects are members of a distinct community or cultural group in which signing forms is not the norm, the research is minimal risk and there is an alternative mechanism of documenting that informed consent was obtained.