Definitions

Allegation of Noncompliance: An assertion of noncompliance that has yet to be proved or supported by evidence.

Adverse Event (AE): Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although, they can occur in the context of social and behavioral research.

Assent: A child's or other individual's affirmative agreement to participate in research where the child or individual is not eligible by age or impaired decision making ability to provide consent. Mere failure to object by the child or individual should not be construed as assent.

Authorization Agreement – Also called the Reliance Agreement, which documents respective authorities, roles, responsibilities, and communication between an organization providing the ethical review and a participating organization relying on a reviewing IRB.

Biological Product: a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings. (42 U.S.C. 262(i)) Biological products include, among other products, bacterial vaccines, allergenic extracts, gene therapy products, growth factors, cytokines, and monoclonal antibodies.

Case report/series - a detailed report of the diagnosis, treatment, and follow-up of an individual patient. Case reports may also contain some demographic information about the patient (for example, age, gender, ethnic origin).

Child: a person under eighteen years of age who has not been judicially emancipated under Civil Code Article 366, emancipated by marriage under Civil Code Article 367, or limitedly emancipated by authentic act per Civil Code Article 368.

HHS regulations at 45 CFR 46.402(a) define "children" as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."

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: Identifying information that would enable the investigator to readily ascertain the identity the individual to whom the specimens or data belong has been replaced with a letter, number, symbol, or combination thereof (the code), and a key to decipher the code exists that enables identification of the private information or specimens.

Compassionate use (expanded access) - the use of a new, unapproved drug or device to treat a seriously ill patient when no other treatments are available. The compassionate use provision provides a path to accessing investigational devices that have not received FDA approval or clearance for patients for whom the treating physician believes the device may provide a benefit in diagnosing, monitoring, or treating their disease or condition.

Conflict of interest:

> Investigator Conflict of Interest - circumstances which may bias or conflict with the integrity of human subject research. These circumstances may be personal or financial. Personal interests include not only the individual's own interests, but also those of which the individual has a familial or close personal relationship.
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> Institutional Review Board (IRB) Member Conflict of Interest - includes the interest of an IRB member (including alternates, consultants, and non-voting members) and his or her immediate family which may affect or have the appearance of affecting the review of human subjects research or the integrity of human subjects research.

Consent Form: The consent form is a formalization of the agreement to participate, and it is used to document the informed consent process.

Continuing Noncompliance: A pattern of noncompliance with repeated failure to adhere to the federal research regulations or institutional policies that may affect the rights or welfare of participants. The pattern of noncompliance is assessed by the number of incidents occurring during the course of implementation of a protocol, or across multiple protocols, conducted at Woman's, and if the same noncompliant action was repeated or many different noncompliant events occurred, especially after a remediation procedure such as training has been provided to the researcher or research staff.

Data and Safety Monitoring Plan (DSMP): the DSMP includes all aspects for ensuring the integrity of the data and for protecting the safety of current and future participants.

Data Use Agreement: an agreement that is required under the Privacy Rule and must be entered into *before* there is any use or disclosure of a limited data set (defined below) to an outside institution or party.

Dietary Supplement: defined by Dietary Supplement Health and Education Act of 1994 (DSHEA), as a product (other than tobacco) intended to supplement the diet that bears or contains one or more dietary ingredients. The dietary ingredients in these products can include vitamins, minerals, herbs and other botanicals, amino acids, other dietary substances intended to supplement the diet, and concentrates, metabolites, constituents, extracts, or combinations of the preceding types of ingredients. Dietary supplements are taken by mouth and can be found in many forms such as tablets, capsules, softgels, liquids, gelcaps, or powders.

Dispense: the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient. Dispense necessarily includes a transfer of possession of a drug or device to the patient or the patient's agent. (LA R.S. 37:1164). Louisiana law requires that dispensing may only be done by a licensed pharmacist or a physician who is registered with the board as a dispensing physician. (LA R.S. 37:1201).

Distribute or Distribution: means the delivery of a drug or device other than by administering or dispensing.

DSMB or DMC or DMB: Data Safety Monitoring Board, Data Monitoring Committee or Data Monitoring Board.

Drug: articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and articles (other than food) intended to affect the structure or any function of the body of man or other animals.

Emergency use: the use of an investigational drug or biological product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval [21 CFR 56.102(d)].

Engaged in research: An institution becomes "engaged" in human subject research [45CFR 46.102(d),(f)] when its employees or agents:

- intervene or interact with living individuals for research purposes; or
- obtain individually identifiable private information for research purposes

Expanded Access: a potential pathway for patients with a serious or life-threatening disease or condition to access an investigational medical device that has not been approved or cleared by the FDA for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available

Finding of Noncompliance: Noncompliance that is proven or supported by substantial evidence.

Generalizable knowledge: an activity that includes the following concepts:

- Knowledge contributes to a theoretical framework of an established body of knowledge
- Results are expected to be generalizable to a larger population beyond the site of data collection or population studied

- Results are intended to be replicated in other settings

Guardian: Any person designated by Court Order as the minor's legal guardian or as a person who can otherwise make medical decisions on behalf of the minor. The term 'guardianship' means the judicial placement of a child under the care of a person who will have the duty and authority of a guardian to make decisions in matters having a permanent effect on the life and development of the child, as set forth in article 719. 'Legal custody' means the right to have physical custody of the child and to determine where and with whom the child shall reside; to exercise the rights and duty to protect, train, and discipline the child; the authority to consent to major medical, psychiatric, and surgical treatment; and to provide the child with food, shelter, education, and ordinary medical care, all subject to any residual rights possessed by the child's parents.

HIPAA authorization: written consent obtained from a patient or health plan member that permits a covered entity or business associate to use or disclose PHI to an individual/entity for a purpose that would otherwise not be permitted by the HIPAA Privacy Rule.

Human Subject (DHSS definition): a living individual about whom an investigator (whether professional or student) conducting research (i) obtains information or biospecimens through intervention or interaction with the individuals, and uses, studies or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Human Subject (FDA definition): an individual who is or becomes a participant in research, either as a recipient of the test article or as a control and/or an individual on whose specimen a device is used. Under the FDA regulations and guidance, a human subject may include individuals whose de-identified tissue specimens are used in in vitro diagnostic medical device research. Private Information: Includes information about data or behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable in order to be considered information to constitute research involving no subjects. This may include identifiable private information obtained from a primary subject about a third party.

Humanitarian Use Device (HUD): a medical device intended to benefit patients in the treatment or diagnosis of diseases or conditions that affect or are manifested in fewer than 8,000 individuals in the United States per year.

Humanitarian Device Exemption (HDE): an exemption from FDA that indicates that the device is approved for marketing, but the approval is based on evidence of safety and probable benefit (rather than assurance of effectiveness).

Identifiable Sensitive Information: At HHS, information that has a degree of confidentiality such that its loss, misuse, unauthorized access, or modification could compromise the element of confidentiality and thereby adversely affect national health interests, the conduct of HHS programs, or the privacy of individuals entitled under The Privacy Act or the Health Insurance Portability and Accountability Act (HIPAA).

Identifiable private information: 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: a biospecimen for which the identity of the subject

may readily be ascertained by the investigator or associated with the biospecimen.

Identifier: one or more data elements that renders the subjects readily identifiable. This includes a code number or study ID number that can be used to link back to the individual.

Independent DMC: A committee composed of individuals with no connection or conflicts of interest related to the current study and organized to provide oversight of the emerging data and safety during the progress of a clinical trial. One of the primary purposes of the Independent DMC is to preserve the integrity of a randomized blinded trial.

Informed consent: a person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic,

therapeutic, or experimental procedure. The informed consent form must contain all required elements of 45CFR46.166, 21CFR50.20, and 21CFR50.25(a) and (b).

Interaction: may include direct communication between the subject and the investigator, as well as telephone or mail interaction.

Internal DMC: A committee composed of representatives of the study investigators and sponsors who are empowered to monitor the progress, safety, and integrity of a study.

Interventions: may include physical or medical procedures, as well as manipulations of the subject and his/her environment.

Investigational device: a device, including a transitional device, that is the object of an investigation.

Investigational device exemption (IDE): IDE refers to the regulations under 21 CFR 812. An approved IDE means that the IRB (and FDA for significant risk devices) has approved the sponsor's study application and all the requirements under 21 CFR 812 are met.

Legally Authorized Representative (LAR): 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 participating in the procedure(s) involved in the research (45CFR46.102(c)). Legally-authorized representatives will most likely be parents and other types of individual guardians.

Life-threatening: diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival.

Limited data set: a set of identifiable healthcare information that the HIPAA Privacy Rule permits covered entities to share with certain entities for research purposes, public health activities, and healthcare operations without obtaining prior authorization from patients, if certain conditions are met.

Major revisions: Major revisions are ones that materially affect an assessment of the risks and benefits of the study OR substantially change the specific aims or design of the study.

Medical Monitor: An individual assigned to monitor the progress, safety, and integrity of a study

Minor: a person who has not attained the age of eighteen years.

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.

Minor revisions: Minor revisions are ones that would not materially affect an assessment of the risks and benefits of the study and do not substantially change the specific aims or design of the study.

Multi-site research (cooperative research): When the same protocol is being conducted at multiple locations (NIH definition) and/or when a single project involves more than one institution (45CFR46 definition).

Newborn: a child who is not more than thirty days old, as determined within a reasonable degree of medical certainty by an examining physician.

Noncompliance: A violation of any federal, state, or local regulation that governs human research, any institutional policy on human subjects research, or any deviation from the protocol approved by the IRB or stipulations imposed by the IRB as a condition of approval.

Noncompliance that may affect subject safety, increase risks to subjects, affect the integrity of the data, violate the rights and welfare of subjects, or affect the subject's willingness to participate in research.

Noninvasive: 21CFR812.3, Noninvasive, when applied to a diagnostic device or procedure, means one that does not by design or intention: (1) Penetrate or pierce the skin or mucous membranes of the body, the ocular cavity, or the urethra, or (2) enter the ear beyond the external auditory canal, the nose beyond the nares, the mouth beyond the pharynx, the anal canal beyond the rectum, or the vagina beyond the cervical os. For purposes of this part, blood sampling that involves simple venipuncture is considered noninvasive, and the use of surplus samples of body fluids or tissues that are left over from samples taken for noninvestigational purposes is also considered noninvasive.

Organizational Conflict of Interest: any relationship, interest, activity, commitment, or obligation that may adversely affect or be in conflict with the services Woman's performs as a federal awardee.

Parent: any living person who is presumed to be a parent under the Civil Code or a biological or adoptive mother or father of a child.

Private information: includes gathering of information for specific purposes (including medical records) or observation of a subject without his or her knowledge.

Protected Health Information (PHI): Protected health information includes all individually identifiable health information, including demographic data, medical histories, test results, insurance information, and other information used to identify a patient or provide healthcare services or healthcare coverage. PHI relates to information created or received in the past, present, or future. 'Protected' means the information is protected under the HIPAA Privacy Rule.

Relying Institution: the institution that has assigned an external Institutional Review Board (IRB) to serve as the Reviewing IRB under an IRB Authorization Agreement. Note the use of relying *institution* and not relying *IRB*, as the reliance agreement is between institutions.

Research: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45CFR46.102(d))

FDA definition - *"**clinical investigation**"* to be synonymous with *"research"*. *"Clinical investigation"* means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

Reviewing IRB (single IRB of record): The IRB that will provide review for all or most sites participating in a multi-site study.

Serious Adverse Event (SAE): Any adverse event that meets any of the following conditions: (1) results in death; (2) is life-threatening (places the subject at immediate risk of death from the event as it occurred); (3) requires inpatient hospitalization or prolongation of existing hospitalization; (hospitalization for a protocol-specified activity or for an elective, pre-planned procedure is not considered an SAE.) (4) results in persistent or significant disability/incapacity; (5) results in a congenital anomaly or a birth defect; or (6) based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention. Serious adverse events should be reported to the IRB and will be reported to the Vice President of Research.

Serious Noncompliance: Noncompliance which, in the judgment of the convened IRB, significantly increases risk to participants, significantly decreases potential benefits, or compromises the integrity of the Human Research Protection Program (HRPP).

Severely debilitating: diseases or conditions that cause major irreversible morbidity. Examples of severely debilitating conditions include blindness, loss of arm, leg, hand, or foot, loss of hearing, paralysis, or stroke.

Significant risk device: Significant risk device is an investigational device that: (1) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; (2) is for use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject; (3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or (4) otherwise presents a potential for serious risk to a subject.

Suspension: temporary cessation of IRB approval of research activities

Systematic Investigation: a study designed to answer research questions, be methodologically driven and collect data in an organized and consistent way, analyze data with quantitative or qualitative analysis, and draw conclusions from results

Termination: permanent cessation of IRB approval of research activities

Test article: any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the act or under sections 351 or 354-360F of the Public Health Service Act

Treatment Investigational Device Exemption (IDE): An approved IDE specifies the maximum number of clinical sites and the maximum number of human subjects that may be enrolled in the study. During the course of the clinical trial, if the data suggest that the device is effective, then the trial may be expanded under a new IDE to include additional patients with life-threatening or serious diseases.

Tutor: one other than a parent who has qualified for the office and has been confirmed or appointed by a court.

Unanticipated Problem or Unanticipated Problems Involving Risks to Subjects or Others: 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 a subject's participation 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) related to the research than was previously known or recognized.

Ward: Any child who has been adjudged dependent by a court and who is under the control of a under the control of a public official, agency, or tutor.

Witness: A third party present during the oral presentation of the consent form and the consent interview.