NOTE: Definitions are adapted from the International Council on Harmonisation; Good Clinical Practice: Consolidated Guideline (E6) Glossary; the FDA Code of Federal Regulations and applicable Guidance Documents; 45 CFR 46, HHS; and Institutional Policies and Procedures. Terms and definition that are applicable to the HIPAA Privacy Rule are from 45 CFR 164 (HHS).

Adverse Drug Reaction or Experience (ADR or ADE)	In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established, all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase "responses to a medicinal product" means that a causal relationship between a medicinal product and an AE is at least a reasonable possibility, i.e. the relationship cannot be ruled out. Regarding marketed medicinal products, an ADR is a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of diseases or for modification of physiological function (*see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting*).
Adverse Event (AE)	An AE in research can be any unfavorable or unintended event, including abnormal laboratory findings, symptom or disease, or death associated with the research or the use of a medical investigational test article. An AE in research may occur even in the absence of any error or protocol deviation and does not necessarily have to be caused by any identifiable aspect of the research.
ALCOAC criteria:	Key attributes for good documentation described by the FDA and adapted by the World Health Organization (WHO). Data should meet certain fundamental elements of quality. Whether they are recorded on paper or electronically, source data should be • **A**ttributable • **L**egible • **C**ontemporaneous • **O**riginal • **A**ccurate • **C**omplete
Applicable Regulatory Requirement(s)	Any law(s) and regulation(s) addressing the conduct of clinical studies of investigational products.

Archive File	A file in which the original and all subsequent revised versions of a standard operating procedure (SOP) or other document are maintained, so that the origination and revision history for an SOP or other document is available for review.
Assent	A child's affirmative agreement to participate in research. *Note: Failure to object should not be construed as assent.*
Audit	A systematic and independent examination of study-related activities and documents to determine whether the evaluated study-related activities were conducted and that the data were recorded, analyzed and accurately reported according to the protocol, Sponsor's SOPs, GCP and the applicable regulatory requirements.
Audit Certificate	A written statement, signed by an auditor, which documents that an audit was performed.
Audit Report	A written evaluation by the auditor of the results of the audit.
Audit Trail	The documentation ("paper trail") that allows reconstruction of the course of events.
Biologic Product	Any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product or analogous product applicable to the prevention, treatment or cure of diseases or injuries to humans. Biologic products include, but are not limited to, bacterial and viral vaccines, human blood and plasma and their derivatives and certain products produced by biotechnology, such as interferons and erythropoietins.
Biometrics	A method of verifying an individual's identity based on measurement of the individual's physical feature(s) or repeatable action(s) where those features and/or actions are both unique to that individual and measurable.
Blinding/Masking	A procedure in which one or more parties to the study are kept unaware of the treatment assignment(s). Single-blinding usually refers to the subject(s) being unaware and double-blinding usually refers to the subject(s), investigator(s), monitor and, in some cases, data analyst(s) being unaware of the treatment assignment(s).
Case Report Form (CRF)	A printed, optical or electronic document designed to record protocol-required data for each study subject and sent to the Sponsor for purposes of statistical analysis.

Certificate of Confidentiality	Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the Investigator and others who have access to research records to refuse to disclose identifying information on research subjects in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.
Certified Copy	A copy of original information that has been verified, as indicated by dated signature, as an exact copy having all of the same attributes and information as the original.
Clinical Research Coordinator (CRC)	Oversees and coordinates the daily activities of clinical research studies. He/She works closely with the clinical teams and investigators to ensure that all protocol required procedures and visits occur according to protocol specified guidelines. He/She typically manages participant enrollment including obtaining informed consent.
Clinical Research Nurse Coordinator (CRNC)	Carries out some of the same responsibilities as the Research Coordinator while fulfilling nursing tasks as required by the research study.
Clinical Trial	A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective.
Clinical Trial Report	A written description of a study of any therapeutic, prophylactic or diagnostic agent conducted in human subjects in which the clinical and statistical description, presentations and analyses are fully integrated into a single report.
Clinical Trial Agreement (CTA)	A legally binding agreement that manages the relationship between the sponsor that may be providing the study drug or device, the financial support and /or proprietary information and the institution that may be providing data and/or results, publication, input into further intellectual property.
Clinical Trials Office (CTO)	LSU Health Offices at the Health Sciences Center, Healthcare Network and Cancer Center serving as a central resource for initiating and conducting clinical trials for LSU Health investigators.
Closeout Visit	A final site visit by a monitor that must be conducted after a study has been completed, suspended or terminated for any reason.

Coded	Direct personal identifiers have been removed (e.g., from data or specimens) and replaced with words, letters, figures, symbols, or a combination of these (not derived from or related to the personal information) for purposes of protecting the identity of the source(s), but the original identifiers are retained in such a way that they can still be traced back to the source(s). *Note: A code is sometimes also referred to as a "key," "link," or "map."*
Coercion	Persuasion (i.e., of an unwilling person) to do or agree to something by using obvious or implied force or threats.
Cohort	A group of subjects who share a common exposure or research experience. Examples are the treatment and control cohorts.
Common Rule	The colloquial name for 45 CFR 46, Subpart A, the basic Department of Health and Human Services (HHS) policy for protection of human research subjects. This regulation consolidates requirements for IRB review and informed consent to participate in human subject research. It applies to any HHS-funded research conducted on human subjects. FDA regulations (21 CFR Parts 50 and 56) closely mirror the Common Rule. Both sets of regulations apply when research is FDA-regulated and federally funded (wholly or partially).
Comparator	An investigational or marketed product (i.e., active control) or placebo, used as a reference in a clinical study.
Compassionate Use	Use of an investigational drug or biologic or unapproved medical device for a single subject (or small group of subjects) with a serious disease or condition, who does not meet the requirements for inclusion in a clinical investigation, and for whom no standard acceptable treatment is available. Prior FDA and IRB approval are required for compassionate use. *Note: The terms compassionate use and emergency use are not synonymous.*
Complaint	Any concern communicated by a person questioning any act or failure to act relating to an individual's rights to access to his or her protected health information (PHI), to maintain the privacy of his or her health information, to request restrictions on uses or disclosures of his or her PHI, to request confidential communications regarding his or her PHI, to request amendment of his or her PHI or to receive an accounting of disclosures of his or her PHI. (HIPAA)
Compliance	Adherence to all study-related requirements, GCP requirements and the applicable regulatory requirements.
Confidential Disclosure Agreement (CDA)/Non-Disclosure Agreement (NDA)	A document used when transferring confidential or proprietary information from one party to another for review only (no further use or dissemination), generally for the purpose of evaluating the potential for a future relationship between the parties.

Confidentiality (*Regulatory Perspective*)	The prevention of disclosure, other than to authorized individuals, of a subject's data or medical information. *Privacy concerns people, whereas confidentiality concerns data.*
Confidentiality (*Sponsor Perspective*)	The prevention of disclosure, other than to authorized individuals, of a Sponsor's proprietary information.
Conflict of Interest (COI)	Situation in which financial or other personal considerations may compromise — or have the appearance of compromising — an individual's professional judgment in conducting or reporting research. LSU Health considers someone to have a conflicting interest when the individual or the individual's spouse, domestic partner, children, and dependents have any of the following interests in the sponsor, product or service being tested, or competitor of the sponsor held by the individual or the individual's immediate family: • Involvement in the design, conduct, or reporting of the research. • Ownership interest, stock options, or other ownership interest of any value exclusive of interests in publicly-traded, diversified mutual funds. • Compensation of any amount in the past year or of any amount expected in the next year, excluding compensation for costs directly related to conducting research. • Proprietary interest including, but not limited to, a patent, trademark, copyright or licensing agreement. • Board or executive relationship, regardless of compensation. • Reimbursed or sponsored travel by an entity other than a federal, state, or local government agency, higher education institution or affiliated research institute, academic teaching hospital, or medical center. • Any other reason for which the individual believes that he or she cannot be independent
Contract	A written, dated and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters.
Contract Research Organization (CRO)	A person or an organization (commercial, academic or other) contracted by a Sponsor to perform one or more of that Sponsor's clinical study-related duties and functions.
Controlled Substance	A drug or other substance, or immediate precursor, included in schedule I, II, III, IV or V of part B of Title 21 of the United States Code, Food and Drugs, Chapter 13, Drug Abuse Prevention and Control, Subchapter i, Control and Enforcement, also cited as the "Controlled Substances Act."

Data Safety Monitoring Board/Committee (DSMB or DSMC)	A committee of clinical research experts, such as physicians and statisticians, and patient advocates who monitor the progress of a clinical trial and review safety and effectiveness data while the trial is ongoing. This committee is independent of the people, organizations, and institutions conducting the clinical trial. This committee can recommend that a trial be stopped early because of concerns about participant safety or because the main research question has been answered.
Data Safety Monitoring Plan	The plan for reviewing research data to ensure the safety of subjects and scientific validity of the research, including who will perform the monitoring, the type and frequency of review, and procedures for notifying appropriate entities (e.g., Investigators, sponsor, etc.) of the results. Note: Monitoring performed by a data and safety monitoring board is one type of data and safety monitoring plan.
Data Transfer and Use Agreement (DTUA or DUA)	A document used when transferring protected health information (PHI), including limited data sets, from one party to another.
De-Identified	All direct personal identifiers are permanently removed (e.g., from data or specimens), no code or key exists to link the materials to their original source(s), and the remaining information cannot reasonably be used by anyone to identify the source(s).
Device	Instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article (including a component part), or accessory that is recognized in the official National Formulary or United States Pharmacopoeia (or any supplement to these) and is: • Intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease in man or other animals, or • Intended to affect the structure or any function of the body of man or other animals, that does not achieve any of its primary intended purposes through chemical action within or on the body, and is not dependent upon being metabolized for the achievement of any of its primary intended purposes.
Diminished Decision Making Capacity	As it applies to informed consent, lacking the ability to provide valid informed consent to participate in research, (e.g., as a result of trauma, intellectual disability, certain mental illnesses, cognitive impairment, or dementia). *Note: Diminished decision-making capacity may be temporary, permanent, progressive, or fluctuating.*

Direct Access	Permission to examine, analyze, verify and reproduce any records and reports that are important to evaluation of a clinical study. Any party (e.g., domestic and foreign regulatory authorities, Sponsors, monitors and auditors) with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of subjects' identities and Sponsors' proprietary information.
Direct Entry	Recording data where an electronic record is the original capture of the data. Examples are the keying by an individual of original observations into the system, or automatic recording by the system of the output of a balance that measures subject's body weight. In these cases, the electronic document is the source document.
Disclosure	The external release, transfer, provision of access to or divulging in any other manner, of PHI by a CE. (HIPAA)
Documentation	All records, in any forms (including, but not limited to, written, electronic, magnetic and optical records; and scans, x-rays and electrocardiograms) that describe or record the methods, conduct and/or results of a study, the factors affecting a study and the actions taken.
Drug	Substance recognized in the United States Pharmacopoeia, Homeopathic Pharmacopoeia of the United States, or National Formulary (or any supplement to any of these), and is an article either intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or intended to affect the structure or any function of the body (other than food), or intended for use as a component of any substance described above.
Effective Date	The date on which an SOP or other document becomes available for use by personnel, after documented training.
Electronic Case Report Form (eCRF)	An auditable electronic record that is used in place of or in conjunction with the paper CRF defined above.
Electronic Medical Record (EMR)	An electronic (digital) collection of medical information about a person that is stored on a computer including information about a patient's health history, such as diagnoses, medicines, tests, allergies, immunizations, and treatment plans.
Electronic Patient Diary	An electronic record into which a subject participating in a clinical study directly enters observations or directly responds to an evaluation checklist.
Electronic Record	Any combination of text, graphics, data, audio, pictorial or other information representation in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system.

Electronic Signature	A computer data compilation of any symbol or series of symbols executed, adopted or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.
Eligibility	The determination that a potential subject satisfies or meets the enrollment criteria for inclusion into a clinical study. Subjects not meeting the criteria are ineligible to participate in the study.
Emergency Use	Use of an investigational drug or biologic or unapproved medical device for a human subject in a life-threatening situation for which no standard acceptable treatment is available and when there is not sufficient time to obtain IRB approval.
Engaged	An individual who intervenes or interacts with living individuals for research purposes, or obtains individually identifiable private information for research purposes.
Enrollment	The point at which a potential subject, who has met the enrollment criteria and any other study screening processes, has completed the informed consent process and is ready to actively participate in a study.
Enrollment Criteria	A set of specific criteria (demographic, physical, laboratory) that determine whether or not a potential subject can be enrolled into a clinical study. They may also be referred to as inclusion and exclusion criteria.
Essential Documents	All the documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.
Experiment	Any use of a drug (except for the use of a marketed drug) in the course of medical practice, or any evaluation of the safety and efficacy of a medical device.
Good Clinical Practice (GCP)	A standard established by the International Conference on Harmonization (ICH) for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical studies that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of study subjects are protected.
HIPAA Authorization	A detailed document that gives covered entities permission to use protected health information for specified purposes, which are generally other than treatment, payment or healthcare operations, or to disclose protected health information to a third party specified by the individual.
Humanitarian Device Exemption (HDE)	An application that permits the marketing of a Humanitarian Use Device

Humanitarian Use Device (HUD)	A device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect (or are manifested in) fewer than 8,000 individuals in the US per year
Human Subject	*As defined by DHHS*: A living individual about whom an investigator conducting research obtains (1) data through Intervention or Interaction with the individual, or (2) information that is both Private Information and Identifiable Information *As defined by FDA*: An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen an investigational medical device is used. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects
Impartial Witness	A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject to affirm the completeness of the consent process.
Informed Consent	The process by which a subject voluntarily confirms his or her willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form (ICF).
Informed Consent Form (ICF)	The form on which the process of conducting and achieving informed consent from potential study subjects is documented.
Initiation Visit	A meeting between the Sponsor representative(s) and investigator(s) (and other key personnel), at which the objectives and the methodology of the clinical study are defined, regulatory requirements are reviewed and appropriate training of the site's key personnel is conducted.
Inspection	The act by a regulatory authority of conducting an official review of documents, facilities, records and any other resources that are deemed by the authority to be related to the clinical study and that may be located at the site of the study, at a Sponsor's and/or CRO's facilities or at other establishments deemed appropriate by the regulatory authority.
Institutional Biosafety Committee (IBC)	A committee that reviews, approves and oversees clinical research studies in accordance with the responsibilities defined in the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

Institutional Review Board (IRB)	An independent body constituted of medical, scientific and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a research study by, among other things, reviewing, approving and providing continuing review of studies, of protocols and amendments and of the methods and material to be used in obtaining and documenting informed consent of the study subjects.
IRB of Record	The IRB that is responsible for the ethical review of Human Research on behalf of an institution/organization or individual investigator.
Interim Study Report	A report of intermediate results and their evaluation based on analyses performed during the course of a study.
International Committee of Medical Journal Editors (ICMJE)	A leading independent institution providing guidance for the report of biomedical research and health related topics in medical journals. ICMJE provides uniform requirements to help authors, editors, and others involved in peer review and biomedical publishing create and distribute accurate, clear, unbiased medical journal articles.
International Conference on Harmonization (ICH)	A tripartite group comprised of representatives from industry and regulatory agencies from the European Union, Japan and the United States that seeks to harmonize regulatory requirements for pharmaceutical products.
Investigational Device	A device (including a transitional device) that is the object of an investigation
Investigational Device Exemption (IDE)	An application that permits a device that would otherwise be required to comply with a performance standard (e.g., 510(k) submission) or to have pre-market approval by the FDA to be legally shipped for a clinical investigation.
Investigational Drug	A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical study, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
Investigational New Drug (IND)	Refers to the regulations in 21 CFR 312. An IND that is in effect means that 30 days have elapsed from the date that a complete IND application was submitted to the FDA and an appropriate IRB has reviewed and approved the Sponsor's clinical study, all the requirements under 21 CFR 312 are met and an investigational product can be distributed to investigators.

Investigational Product (IP)	A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use. Also, a device, including a transitional device that is the object of an investigation.
Investigator	A person who participates in the conduct of the clinical study at a study site. If a team of individuals at a site conducts a study, the investigator who is the responsible leader of the team may be called the principal investigator (PI).
Investigator's Brochure (IB)	A document that is provided by a clinical study Sponsor to investigators participating in that study. It is a compilation of the clinical and non-clinical data on the investigational product(s) relevant to the study of the investigational product(s) in human subjects.
Key Personnel	Any individual responsible for the design, conduct, or publication/ presentation of research results.
Label	According to the FDA, a display of written, printed or graphic matter upon the immediate container of any article.
Labeling	According to the FDA, all labels and other written, printed or graphic matter upon any article or any of its containers or wrappers, or accompanying such article.
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 procedures(s) involved in the research.
Life-Threatening Adverse Drug Experience	For FDA safety reporting purposes, any adverse drug experience that places the subject, in the view of the investigator, at immediate risk of death from the reaction as it occurred, i.e., it does not include a reaction that, had it occurred in a more severe form, might have caused death.
Material Transfer Agreement (MTA)	A contract that allows one party to perform research using the materials (e.g., data, specimens, etc.) of another party.
Minimal Risk	The probability and magnitude of harm or discomfort anticipated in the research that 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

Monitor	The person who periodically oversees the progress of a clinical study and ensures that it is conducted, recorded and reported in accordance with the protocol, SOPs, GCP and applicable regulatory requirement(s). The lead monitor is the monitor who assumes a supervisory role when more than one monitor participates in the monitoring of a clinical study.
Monitoring	The act of overseeing the progress of a clinical study and of ensuring that it is conducted, recorded and reported in accordance with the protocol, SOPs, GCP and applicable regulatory requirement(s).
Monitoring Report	A written report from the monitor to the Sponsor after each monitoring visit and/or other study-related communication according to the Sponsor's SOPs.
Multi-Center/Multi-Site Study	A study which uses the same protocol to conduct non-exempt human subjects research at more than one site, with each site completing all research activities outlined the protocol
Non-Clinical Laboratory Study	In vivo or in vitro experiments in which investigational products are studied prospectively in test systems under laboratory conditions to determine their safety. The term does not include studies utilizing human subjects or clinical studies or field trials in animals. The term does not include basic exploratory studies carried out to determine whether an investigational product has any potential utility or to determine physical or chemical characteristics of the investigational product. (See also GLP.)
Non-Significant Risk Device (NSR)	An investigational device that does not meet the definition of a significant risk device.
Notice of Privacy Practices (NPP)	This notice describes how subject's medical/dental information may be used and disclosed and how subject can get access to this information.
Office of Contracts Management (OCM)	LSUHSC office responsible for drafting, negotiating, and executing contracts with third parties involved in conducting clinical trials with LSUHSC investigators
Office of Innovation and Partnership (OIP)	LSUHSC office responsible for establishing and enabling the relationships necessary for certain aspects of research and collaboration to occur, including the negotiation of Material Transfer Agreements, Nondisclosure Agreements, and Inter-Institutional Agreements.

Phase I Study	The initial introduction of an investigational new drug/biologic into humans, Phase I studies are primarily designed to evaluate safety and usually include healthy subjects (depending on a number of factors, including expected toxicity and side effects, may be conducted using subjects with the disease or condition under study). Data from Phase I studies are used to determine the metabolism and pharmacologic actions of the drug/biologic in humans, the side effects associated with increasing doses and, if possible, to gain early evidence on effectiveness.
Phase II Study	Conducted subsequent to Phase I, Phase II studies are designed to evaluate the effectiveness of the drug/biologic for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug/biologic. Phase II studies are typically well-controlled, closely monitored and conducted in a relatively small number of patients, usually involving no more than several hundred subjects.
Phase III Study	Phase III studies are performed after preliminary evidence suggesting effectiveness of the drug/biologic has been obtained and are intended to gather additional information about the effectiveness and safety needed to evaluate the overall benefit-risk relationship of the drug/biologic and to provide an adequate basis for physician labeling. Phase III studies are expanded controlled and uncontrolled studies that usually include from several hundred to several thousand subjects.
Phase IV Study	Phase IV studies are conducted after marketing approval has been granted. Also known as post-marketing studies, they may be conducted as a condition of marketing approval or at a Sponsor's initiative. Since many more patients receive the drug/biologic once it is approved for use than received it during the formal clinical investigation phases, less common toxicities may be recognized. Populations not specifically targeted in the earlier phases of investigation may be included in Phase IV studies.
Planned Emergency Research	Research involving human subjects who are in need of emergency medical intervention (i.e., comparison of methods for providing cardiopulmonary resuscitation), but who cannot give informed consent because of their life-threatening medical conditions and who do not have an available legally authorized representative to provide consent.
Principal Investigator (PI)	Lead investigator of a team of research personnel who has the ultimate responsibility for the ethical conduct of the research.
Privacy	The right to protect a subject from intrusion and for the subject to control access to themselves. *Privacy concerns people, whereas confidentiality concerns data.*

Protected Health Information (PHI)	Individually identifiable health information that is (1) transmitted by electronic media; (2) maintained in electronic media; and, (3) transmitted or maintained in any other form or medium. For purposes of this definition, protected health information excludes individually identifiable health information in: (a) educational records covered by the Family Educational Rights and Privacy Act; (b) records maintained by an educational agency or institution, or by a person acting for such agency or institution, on a student who is eighteen years of age or older, or is attending an institution of postsecondary education, which are made or maintained by a physician, psychiatrist, psychologist, or other recognized professional or paraprofessional acting in his professional or paraprofessional capacity, or assisting in that capacity, and which are made, maintained, or used only in connection with the provision of treatment to the student, and are not available to anyone other than persons providing such treatment, except that such records can be personally reviewed by a physician or other appropriate professional of the student's choice; and (c) employment records held by a covered entity in its role as an employer.
Protocol	A document that describes the objective(s), design, methodology, statistical considerations and organization of a study. The protocol usually also gives the background and rationale for the study, but these could be provided in other protocol referenced documents.
Protocol Amendment	Any revision to a previously approved protocol for an investigation of an unapproved drug, biologic or medical device, or any change of investigator or sub-investigator that must be reported to regulatory authorities. Minor editorial or typographical changes or corrections are not considered protocol amendments.
Quality Assurance (QA)	All those planned and systematic actions that are established to ensure the study is performed and the data are generated, documented (recorded) and reported in compliance with GCP and the applicable regulatory requirement(s).
Quality Control (QC)	The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the study-related activities have been fulfilled.
Randomization	The process of assigning study subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.
Regulatory Authorities	Bodies having the power to regulate. In the ICH GCP Guidelines, regulatory authorities include those authorities that review submitted clinical data and those that conduct inspections, such as the FDA. In the European Union, these bodies are sometimes referred to as competent authorities.

Regulatory Coordinator	Typically drafts or edits the protocol document and submits new protocols, amendments, continuing reviews and safety reports to the appropriate IRB for review. He/She is also responsible for maintaining data integrity, reviewing records, assisting with preparation of internal audits, resolving problems associated with noncompliance, tracking study activity, and ensuring that all clinical research proceeds in compliance with institutional and governmental policies and regulations.
Research	*As defined by DHHS*: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. *As defined by FDA*: Any experiment that involves a test article and one or more Human Subjects, and that meets any one of the following, • Must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice; • Must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR • Any activity the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.
Screening	A planned examination and/or interview process of a potential subject to assess his or her eligibility for enrollment in a clinical study.
Screening Failure	When a potential subject does not meet one or more criteria for inclusion in a clinical study.

Serious Adverse Event (SAE)	For FDA safety reporting purposes, an adverse event or suspected adverse reaction is considered “serious” if, in the view of either the investigator or Sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.
Short Form	A written document stating that the elements of informed consent required by regulation have been presented orally to the subject or the subject's legally authorized representative in a language understandable to the subject or the subject's legally authorized representative.
Significant Risk (SR) Device	An investigational device that is: • Intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; • For use in supporting or sustaining human life and represents a potential for serious risk to the health, safety, or welfare of a subject; • 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 • Otherwise presents a potential for serious risk to a subject.
Site Initiation Visit (SIV)	Visit that occurs after the study sponsor has already selected the site for participating in a clinical trial. This visit ensures that all required trial authorizations and documentation are in place and that the protocol and trial procedures are reviewed with the Investigator and the Investigator’s research team in accordance with the protocol, SOPs, GCP, and the applicable regulatory requirement prior to the start of enrollment.
Site Qualification Visit/Site Selection Visit/Pre-Site Visit	A meeting between the site and sponsor to assess if the site has the qualifications and facilities to execute all elements of the protocol. This visit occurs after the site has decided to participate in a trial and prior to receiving a site selection letter

Source Data	All information in original records and certified copies of original records of clinical findings, observations or other activities in a clinical study/trial necessary for the reconstruction and evaluation of the study. Source data are contained in source documents (original records or certified copies).
Source Documents	Original documents, data and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files and records kept at the pharmacy, the laboratories and medico-technical departments involved in the clinical study).
Specimen	Human biological material, including solid material (e.g., tissue, organs) body fluid (e.g., blood, urine, saliva, semen, cerebrospinal fluid), and cells.
Sponsor	An individual, company, institution or organization that takes responsibility for the initiation, management and/or financing of a clinical study.
Sponsor-Investigator	An individual who both initiates and conducts, alone or with others, a clinical study and under whose immediate direction the investigational product is administered to, dispensed to or used by a subject. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a Sponsor-investigator include both those of a Sponsor and those of an investigator.
Sponsored Projects Administration (SPA)	LSUHSC office responsible for oversight of grants and research contracts - from approving budget proposals before submission to financial reporting.
Standard Operating Procedure (SOP)	A document that specifies all the operational steps, acceptance criteria, personnel responsibilities and materials required to accomplish a task.
Statement of Investigator, FDA Form 1572	An agreement signed by the Investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic.
Sub-investigator (Sub-I)	An investigator who performs all or some of the PI functions, but does not accept primary responsibility for the research study
Subject	An individual who participates in a clinical study, either as a recipient of the investigational drug or medical device or as a control. The terms subject and participant are used synonymously.
Subject Identification Code	A unique identifier assigned by the investigator to each study subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports AEs and/or other study-related data.

Test Article	For AE reporting, a product given to a study subject, including the investigational product, a comparator or a placebo.
Unanticipated Adverse Device Effect	Any serious adverse effect on health or safety, or any life threatening problem or death caused by (or associated with) a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application; any other unanticipated, serious problem associated with a device that relates to the rights, safety, or welfare of subjects.
Unexpected Adverse Drug Experience (Reaction)	An adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product). *(See the ICH Guidance for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting)*
Vulnerable Subject	An individual whose willingness to volunteer in a clinical study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students; subordinate hospital and laboratory personnel; employees of the pharmaceutical company; members of the armed forces; and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent.

Approved by:

Jawed Alam

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