NOVA SOUTHEASTERN UNIVERSITY

Definitions and Acronyms

510(k)	A particular FDA Class For Medical Devices
AE	Adverse Event
CFR	Code of Federal Regulations
CMS	United States Center/College for Medicare and Medicaid Services
CRA	Clinical Research Associate
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRO	Contract Research Organization
DHHS	United States Department of Health and Human Services
DOT	United States Department of Transportation
DSMB	Data Safety Monitoring Board
FDA	United States Food and Drug Administration
FWA	Federal-Wide Assurance
GCP	International Council on Harmonization's *E6: Good Clinical Practices*
HDE	Humanitarian Device Exemption (FDA Class For Medical Devices)
HIPAA	Health Insurance Portability and Accountability Act of 1996
HUD	Humanitarian Use Device (FDA Class of Medical Devices)
IATA	International Air Transport Association
IB	Investigator's Brochure
IBC	Institutional Biosafety Committee
ICH	International Council on Harmonization
IDE	Investigational Device Exemption (FDA Class For Medical Devices)
IDMC	Independent Data Monitoring Committee
IND	Investigational New Drug (FDA Class For Drugs)
IRB	Institutional Review Board
IVRS	Interactive Voice Response System
NDA	New Drug Application (FDA Class For Drugs)
NIH	United States National Institutes of Health
NSR	Non-Significant Risk (FDA Risk Classification of Medical Device)

PHI	Protected Health Information as defined by the Health Insurance Portability and Accountability Act of 1996
PMA	Pre-Market Application (FDA Class For Medical Devices)
RDRC	Radioactive Drug Research Committee
SAE	Serious Adverse Event
SMO	Site Management Organization
SOP	Standard Operating Procedures
SPOOS	Significant Payments Of Other Sorts
SR	Significant Risk (FDA Risk Classification of Medical Device)
UAE	Unexpected Adverse Event

Adverse Event (AE)	Any untoward medical occurrence in a patient or clinical investigation subject administered a product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.
Assent	A child's affirmative agreement to participate in a clinical investigation. Mere failure to object may not, absent affirmative agreement, be construed as assent.
Beneficence	Doing no harm. Maximizing benefits while minimizing risks.
Case Report Form (CRF)	A printed, optical, or electronic document designed to record all of the protocol-required information to be reported to the sponsor on each trial subject.
Vice President Research and Technology Transfer	The highest ranked individual with direct responsibility for research operations. This is usually a corporate position.
Children	Persons who have not attained the legal age for consent to treatments or procedures involved in clinical investigations, under the applicable law of the jurisdiction in which the clinical investigation will be conducted.

Clinical Research Coordinator (CRC)	The person at the Center/College who manages the daily operations of a protocol and who is responsible to the Principal Investigator.
Contract Research Organization (CRO)	A person or organization that assumes, as an independent contractor with the sponsor, one or more of the obligations of a sponsor, e.g., design of a protocol, selection or monitoring of investigations, evaluation of reports, and preparation of materials to be submitted to the Food and Drug Administration
Data and Safety Monitoring Board (DSMB)	A committee of scientists, physicians, statisticians and others that collects and analyzes data during the course of a research study to monitor for adverse effects (events) and other trends (such as an indication that one treatment is significantly better than another, particularly when one arm of the study involves a placebo control) that would warrant modification or termination of the study or notification of subjects about new information that might affect their willingness to continue in the study. Also called Data Monitoring Committee.
Delegated Authority	The power given to an individual by the Principal Investigator as evidenced only in writing on the Delegation of Authority Log (or equivalent) and housed in the Investigator Binder
Diagnostic Specimen	Any human or animal material, including excreta, secreta, blood and its components, tissue, and tissue fluids being transported for diagnostic or investigational purposes, but excluding live infected humans or animals.
Double-Blind	The design of a study in which neither the investigator nor the subject knows which treatment the subject is receiving.
Expedited review	Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the convened IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.
Family Member	Any one of the following legally competent persons: Spouse; parents; children (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family

	relationship.
Federalwide Assurance (FWA)	An agreement or contract between the organization and OHRP, on behalf of the Secretary, DHHS, affirming that the organization will protect the welfare of research subjects in accordance with the regulations. The FWA replaces all other previous forms of assurance (i.e., MPA, SPA, etc.).
Guardian	An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care when general medical care includes participation in research.
Human Subject	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.
Inclusion/Exclusion Criteria	The characteristics that must be present (inclusion) or absent (exclusion) in order for a subject to qualify for a research protocol.
Independent Data Monitoring Committee (IDMC)	See Data Safety and Monitoring Committee
Infectious Substance	A material known to contain or suspected of containing a pathogen. A pathogen is a virus or micro-organism (including its viruses, plasmids, or other genetic elements, if any) or a proteinaceous infectious particle (prion) that has the potential to cause disease in humans or animals.
Institutional Biosafety Committee (IBC)	A committee based at the Center/College that reviews, approves and oversees recombinant DNA and/or gene transfer projects. This committee is not a replacement for, but a supplement to the IRB approval of a study.
Investigational New Drug (or Investigational Drug) (IND)	An investigational drug is a drug or biologic that is used in a clinical investigation. The FDA considers the term "Investigational New Drug" synonymous (21CFR 312.3). However, an investigational drug may be an approved drug that is being studied for an unapproved or approved use in a controlled, randomized or blinded clinical trial.
Institutional Review Board (IRB)	Any board, committee, or other group formally designated by an institution to review biomedical research involving humans as subjects, to approve the initiation of and conduct periodic review of such

	research.
Investigational Product	An Investigational Drug or Device
Investigator's Brochure (IB)	A compilation of the clinical and nonclinical data on the investigational product(s) that is relevant to the study of the investigational product(s) in human subjects
Interactive Voice Response System (IVRS)	A telephone contact system that allows the user to key in requests and receive instructions or information.
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.
Life-threatening adverse event or life-threatening suspected adverse reaction	An adverse event or suspected adverse reaction is considered "life-threatening" if, in the view of either the investigator or sponsor, its occurrence places the patient or subject at immediate risk of death. It does not include an adverse event or suspected adverse reaction that, had it occurred in a more severe form, might have caused death.
Medical Monitor	The physician at the Sponsor who is responsible for the clinical investigation of a test product.
MedWatch	The FDA Medical Products Reporting Program is an initiative designed to educate health professionals about the critical importance of monitoring for and reporting adverse events and problems to FDA and/or the manufacturer and to ensure that new safety information is rapidly communicated to the medical community, thereby improving patient care. The purpose of the MedWatch program is to enhance the effectiveness of postmarketing surveillance of medical products as they are used in clinical practice and to rapidly identify significant health hazards associated with these products.
Minimal Risk	The degree of risk in which 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.
Monitor	When used as a noun, means an individual designated by a sponsor or contract research organization to oversee the progress of an investigation. The monitor

	may be an employee of a sponsor or a consultant to the sponsor, or an employee of or consultant to a contract research organization. Monitor, when used as a verb, means to oversee an investigation.
Open-Label	A study in which the subjects and the investigator are aware of the treatment the subject is receiving (i.e. not single-blinded or double-blinded).
Parent	A child's biological or adoptive parent
Placebo	An inactive substance designed to resemble the article being tested.
Principal Investigator	An individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.
Protocol	A plan that includes, at minimum, the objectives, rationale, design, methods and other conditions for conducting a research study.
Randomization	The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.
Research	A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
Research Coordinator	See Clinical Research Coordinator
Research Staff	Staff directly involved in research related activities. This is meant to include roles such as Principal Investigator, Sub-Investigator and Clinical Research Coordinator. Although other staff may interact with research subjects, for purposes of this manual the term "Research Staff" does not include support staff such as billing, dietary etc.
Serious Adverse Event (SAE)	Any untoward medical occurrence that: 1. Results in death, 2. Is life-threatening (places the patient or 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) 3. Requires inpatient hospitalization or prolongation of existing hospitalization,

	4. Results in persistent or significant disability/incapacity, or 5. Is a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience 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. (21CFR312.32(a))
Significant Payments Of Other Sorts (SPOOS)	Payments made by the sponsor of a covered study to the investigator or the institution to support activities of the investigator that have a monetary value of more than $25,000, exclusive of the costs of conducting the clinical study or other clinical studies, (e.g., a grant to fund ongoing research, compensation in the form of equipment or retainers for ongoing consultation or honoraria) during the time the clinical investigator is carrying out the study and for 1 year following the completion of the study
Center/College at NSU	The local institution which the research activity will actually be conducted. If research is conducted off campus it is still considered affiliated with NSU's Center/College
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, at the laboratories, and at medico-technical departments involved in the clinical trial).
Sponsor	An entity (person or organization) who initiates a clinical investigation, but who does not actually conduct the investigation, i.e., the test article is administered or dispensed to or used involving, a subject under the

	immediate direction of another individual. A person other than an individual (e.g., corporation or agency) that uses one or more of its own employees to conduct a clinical investigation it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.
Sponsor-Investigator	An individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, e.g., corporation or agency.
Subinvestigator	Any individual member of the clinical trial team designated and supervised by the investigator at a trial Center/College to perform critical trial related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).
Subject	See Human Subject
Suspected Adverse Event	Any adverse event for which there is a reasonable possibility that the drug caused the adverse event. For the purposes of IND safety reporting, "reasonable possibility" means there is evidence to suggest a causal relationship between the drug and the adverse event. Suspected adverse reaction implies a lesser degree of certainty about causality than adverse reaction, which means any adverse event caused by a drug.
Test Article	Any drug (including a 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 FDA or other federal regulations.
Unexpected Adverse Event (UAE)	Any adverse experience, the specificity or severity of which is not consistent with the current investigator brochure; or, if an investigator brochure is not required or available, the specificity or severity of which is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended. (21CFR312.32(a))
Vulnerable Subjects	Individuals whose willingness to volunteer in a clinical trial 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 industry, 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.
Ward	A child who is placed in the legal custody of the State or other agency, institution, or entity, consistent with applicable Federal, State, or local law.
Well-Being	The physical and mental integrity of the subjects participating in a research protocol.