Definitions and Common Terms

**Adverse event:** An untoward or undesirable experience associated with the use of a medical product, such as a drug, device or biologic, in a patient or research subject.

**Advocate:** An individual who has the background and experience to act in, and agrees to act in, the best interest of the child for the duration of the child's participation in the clinical investigation.

**Agent:** For purposes of this document, an institution's employees or agents refers to individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. "Employees and agents" can include staff, students, contractors and volunteers, among others, regardless of whether the individual is receiving compensation. A student's affiliation with an academic institution makes them an agent of that institution; and thus the academic institution is engaged in the research regardless of where the research takes place.

**Allegation of noncompliance:** An unproven assertion of noncompliance.

**Alternate member:** Alternate Institutional Review Board (IRB) committee members may be designated, as needed, for regular voting members. The appointment of alternate members should be based on expertise similar to that of the regular voting member. An alternate member may vote only when the regular voting member is absent.

**Anonymous Data is:** any information about a living individual that was collected in a manner that identifiers were never associated with the information and that no one was ever able to identify from whom the information was collected. Subjects’ identities are unknown to the investigator, not requested, not recorded and not given. There is no possible way that the researcher, research team or anyone else could possibly link the data to the participant.

**Assent:** A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

**Assured institution:** An institution with a federalwide assurance (FWA) that has filed with the federal Office for Human Research Protections. Employees and agents of the institution holding an approved FWA are covered whenever they are involved in the conduct of the research covered by the FWA. Employees and agents are individuals performing institutionally designated activities and acting on behalf of the institution or exercising institutional authority or responsibility.

**Belmont Report:** Report by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research identifying the basic ethical principles underlying the conduct of research involving human subjects, that is, respect for persons, beneficence and justice. [http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html)

**Beneficence:** Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. Two general rules have been formulated as expressions of beneficent actions (Belmont Report, 1978): Do no harm, and Maximize possible benefits and minimize possible harms.

**Biologic product:** A biological product (biologic) is a medical product. Many biologics are made from a variety of natural sources, such as humans, animals or microorganisms. Like drugs, some biologics are intended to treat diseases and medical conditions. Other biologics are used to prevent or diagnose diseases. Examples of biological products include:

- Vaccines
- Blood and blood products for transfusion and or manufacturing into other products
- Allergenic extracts, which are used for both diagnosis and treatment, such as allergy shots
- Human cells and tissues used for transplantation, such as tendons, ligaments and bone
- Gene therapies
- Cellular therapies
- Tests to screen potential blood donors for infectious agents, such as HIV
- In general, the term “drugs” includes therapeutic biological products

**Certificate of Confidentiality:** Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect the privacy of research subjects by protecting investigators and institutions from being compelled to release information that could be used to identify subjects with a research project. Certificates of Confidentiality are issued to institutions or universities where the research is conducted. They allow the investigator and others who have access to
research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. [http://grants.nih.gov/grants/policy/coc/background.htm](http://grants.nih.gov/grants/policy/coc/background.htm)

**Children**: People 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 investigation**: The Food and Drug Administration (FDA) has defined clinical investigation to be synonymous with research. The FDA defines clinical investigation as 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.

**Coded Data**: Identifiers have been removed from the dataset but can readily be found through the use of a master list that is accessible to the investigator.

- The link that cross-references the subject’s identity with the code should be stored in a separate location from the data and should be locked. Consideration should be given by the Principal Investigator as to how many and which staff should have access to the link. Limiting the number of staff who have access to the link should be considered for more sensitive high-risk data.

**Confidential Data**: Confidential data is the protection of study participants’ data such that an individual participant’s data is protected and will not be disclosed except to another authorized person. Confidential data is not anonymous.

**Conflict of interest**: Any interest that could reasonably be expected to affect the objectivity of an IRB member with regard to a research project. A conflict of interest includes financial interests and may include nonfinancial interests, such as personal or ethical beliefs, or other factors.

**Consent document**: A structured, written description in lay terms of relevant research project information. The written consent document is not consent itself; it is the record of what has been communicated to a prospective subject. It is the document, based on a template provided by the IRB and approved by the IRB, to ensure that all regulatory elements are present and communicated to a potential subject. When signed by the potential subject, the consent document is a record of the receipt of research-related information by the subject. It also serves as reference material for the subject as the research project progresses. It is not legally binding, and the subject may choose to withdraw consent at any time (See Informed Consent).

**Consent Process**: The process designed by the research team to engage the participants in a discussion about what will take place in the study. This process starts at recruitment of participants and end when they are completely done with the study. When introducing the consent form, researchers must plan to talk about the consent form and its contents with the participants, their advocate, or their legal representation (See Informed Consent).

**Consultant**: A scientist or nonscientist from within or external to NCSU who has special expertise to act — at the request of the IRB — as an ad hoc reviewer of a research project application. These individuals have access to all documents relevant to the specific project under review, may participate in the deliberations and make recommendations on the project, but may not vote and are not counted toward quorum.

**Continuing noncompliance**: A pattern of repeated actions or omissions taken by an investigator that indicates a deficiency in the ability or willingness of an investigator to comply with federal regulations, NCSU IRB policy, or determinations or requirements of the NCSU IRB.

**Continuing review**: Periodic review of research activities at intervals appropriate to the degree of risk, but not less than once per year. The criteria for approval are defined by federal regulations.

**Cooperative research project**: Research projects that involve more than one institution as defined by federal regulations.

**Coordinating center**: An institution, department or center that agrees to be responsible for the conduct and administrative or coordinating functions of a multicenter research project.

**Co-principal investigator (co-PI)**: Investigator who plays a key role in scientific development and conduct of the study. The co-PI collaborates with the principal investigator who has overall responsibility for study conduct. Conditions of eligibility for the role of co-PI are the same as for a PI. Students, residents, fellows and research temporary professional personnel (appointees) are not eligible to be a PI or co-PI on IRB approved research.
Covered entity: HIPAA regulations apply to health plans, health care clearinghouses and health care providers who transmit health information. Any individual creating or accessing protected health information (PHI) for the delivery of health care at NCSU is within the covered entity.

Custom device: Custom device means a device that:

- Necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist;
- Is not generally available to, or generally used by, other physicians or dentists;
- Is not generally available in finished form for purchase or for dispensing upon prescription;
- Is not offered for commercial distribution through labeling or advertising; and
- Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice (such as a particular operating tool).

Data safety monitoring board (DSMB): A data safety monitoring board is an independent committee set up specifically to monitor data throughout the duration of a study to determine if continuation of the study is appropriate scientifically and ethically. Factors that suggest a DSMB is needed:

- A large study population and
- Multiple study sites. It is more difficult to recognize a pattern of increased or unusual problems or events when investigators treat small fractions of the population separately;
- Highly toxic therapies or dangerous procedures;
- High expected rates of morbidity or mortality in the study population;
- High chance of early termination of the study. DSMB membership is usually comprised of experts in the fields of medicine and science that are applicable to the study — statistical experts, lay representatives and others who can offer an unbiased assessment of the study progress.

Data safety monitoring plan (DSMP): A DSMP is a quality-assurance plan for a research study. A data and safety monitoring plan (DSMP) is meant to ensure that each clinical investigation has a system for appropriate oversight and monitoring of the conduct of the clinical investigation. The purpose of a DSMP is to ensure the safety of the participants, the validity of the data and the integrity of the study, and the appropriate termination of studies for which significant benefits or risk has been uncovered or when it appears that the investigation cannot be concluded successfully. A DSMP is commensurate with the risks involved with the research study. The DSMP may include a data and safety monitoring board (DSMB).

Data use agreement: An agreement into which NCSU and the investigator enter with the intended recipient of a limited data set that establishes the ways in which the information in the limited data set may be used and how it will be protected.

Dead fetus: A fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles nor pulsation of the umbilical cord.

De-Identified Data: Identifiers have been removed from the dataset in a manner that any member of the research team is not able to identify the individual from whom such information was collected. De-identified data also pertains to health information that has been assigned and retains a code or other means of identification provided that:

- The code is not derived from or related to the information about the individual;
- The code could not be translated to identify the individual; and
- The covered entity does not use or disclose the code for other purposes or disclose the mechanism for re-identification.

Delivery: Complete separation of the fetus from the woman by expulsion or extraction or any other means.

Disclosure of Private Health information (PHI): The release, transfer, or provision of access to, or divulging in any manner of, information outside the covered entity.

Documentation: The act or an instance of furnishing or authenticating with documents. Documentation of informed consent includes use of a written consent form, approved by the IRB and signed and dated by the subject or the subject's legally authorized representative.
e-IRB: This is NC State’s online portal for submitting, reviewing, and approving all research proposals involving research with human subjects.

Emergency use: Use of a test article on 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)].

- Life-threatening includes both life-threatening and severely debilitating diseases or conditions where likelihood of death is high unless the course of the disease is interrupted, and diseases or conditions with potentially fatal outcomes, where the endpoint of clinical trial analysis is survival.
- The criteria for life-threatening do not require the condition to be immediately life-threatening or to immediately result in death. Rather, the subjects must be in a life-threatening situation requiring intervention before review at a convened IRB meeting is feasible.
- Severely debilitating: Diseases or conditions that cause major irreversible morbidity, such as blindness, loss of arm, leg, hand or foot, loss of hearing, paralysis, or stroke.

Encryption: The process of encoding messages or information in such a way that only authorized parties can read it. Encryption software executes an algorithm that is designed to encrypt computer data in such a way that it cannot be recovered without access to the key that de-codes it. Once you encrypt a file, you need to have a key to that encryption to access it again. You should never keep the encrypted file in the same place you keep the key or label the key/file in a way that links them together (information taken from Wikipedia).

Engagement of institutions in human subject research: An organization is considered engaged in human research when its employees or agents, for the purposes of the nonexempt research project, obtain:

- Data about the subjects of the research through intervention or interaction with them;
- Identifiable private information about the subjects of the research;
- The informed consent of human subjects for the research; or
- When the institution receives a direct federal award to conduct human subject research, even when all activities involving human subjects are carried out by a subcontractor (that is, employees or agents of another institution).

Enrollment: Occurs when an eligible, informed, prospective subject undergoes the initial informed consent process and voluntarily agrees to participate in a research project.

Exempt human subjects research: Studies determined by the IRB to meet the exempt criteria as defined by the federal regulations. These studies are no more than minimal risk studies. Exempt studies do not require periodic review by the IRB unless a change in the project is planned.

Expedited review. A review of research involving human subjects by the IRB chair or by one or more experienced reviewers designated by the chair from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110. These studies are no more than minimal risk studies

Expired study: When continuing review of the research does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. The study expires on the date specified on the approval letter and the consent document. No activities can occur after the expiration date.

Federalwide assurance (FWA): A formal, written, binding attestation in which an institution ensures to the Department of Health and Human Services (HHS) that it will comply with applicable regulations governing research with human subjects.


Fetus: The product of conception from implantation until delivery.

Final report: A report the principal investigator may elect to submit to the IRB to serve as a final record of any pertinent activity since the last continuing review report and to record research project completion.

Firewall: A firewall is a hardware or software application/device that restricts access to and from a computer or group of computers depending on which port or application is trying to be accessed. The "Windows Firewall" is a software program that allows you to control either by application which programs have access to the Internet or by port which ports can be open to incoming or outgoing data. https://oit.ncsu.edu/resnet/firewall
Food and Drug Administration (FDA): The regulatory authority in the United States that oversees the pharmaceutical and medical device industries. The FDA is responsible for ensuring that the drugs and medical devices marketed in the U.S. are safe and have a greater benefit than risk when used according to manufacturer's directions.

Full Board: Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

- have at least five members with varying backgrounds to promote complete and adequate review of the research activities commonly conducted by the institution;
- make every nondiscriminatory effort to ensure that the membership is not composed of entirely men or entirely women;
- include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas;
- include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution; and
- not allow any member to participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

Full Board Review: Studies reviewed by the full, convened IRB committee with a recorded vote and corresponding minutes to document the discussion.

GINA (Genetic Information Nondiscrimination Act of 2008): An Act of Congress in the United States designed to prohibit the use of genetic information in health insurance and employment. The Act prohibits group health plans and health insurers from denying coverage to a healthy individual or charging that person higher premiums based solely on a genetic predisposition to developing a disease in the future. The legislation also bars employers from using individuals' genetic information when making hiring, firing, job placement, or promotion decisions. http://www.eeoc.gov/laws/statutes/gina.cfm

GRAS (Generally Recognized as Safe): GRAS is an acronym for the phrase Generally Recognized As Safe. Any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive. http://www.fda.gov/food/ingredientspackaginglabeling/gras/

Greater than minimal risk: The research involves more than minimal risk to subjects.

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.

HIPAA Privacy Rule: The HIPAA Privacy Rule provides federal protections for individually identifiable health information held by covered entities and their business associates and gives patients an array of rights with respect to that information. At the same time, the Privacy Rule is balanced so that it permits the disclosure of health information needed for patient care and other important purposes. http://www.hhs.gov/ocr/privacy/hipaa/understanding/index.html

HIPAA authorization: A customized document or form that gives permission to use specified protected health information (PHI) for a specific purpose, or to disclose PHI to a third party specified by the investigator other than for treatment, payment or health care operations.

Human biospecimens: A quantity of tissue, blood, urine or other human-derived material. A single biopsy may generate several biospecimens, including multiple paraffin blocks or frozen biospecimens. The molecular makeup of such specimens reflects the physiologic or pathologic condition of the person from whom they derive; therefore, they provide sensitive and specific insight into the biologic state of the donor. A biospecimen can include subcellular structures (such
as DNA), cells, tissue (such as bone, muscle, connective tissue and skin), organs (such as liver, bladder, heart and kidney), blood, gametes, embryos, fetal tissue, and waste (such as urine and stool). Portions or aliquots of a biospecimen are referred to as samples. (Derived from National Cancer Institute Best Practices for Biospecimen Research.)

**Humanitarian use device exemption (HDE):** An FDA approval for a physician to use a humanitarian use device (HUD) in clinical treatment or as the subject of a clinical investigation.

**Humanitarian use device (HUD):** A device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the U.S. per year.

**Human research subject:** A living individual about whom an investigator conducting research obtains data through intervention or interaction with an individual or with his or her identifiable private information, or an individual who is or becomes a subject in research, either as a recipient of the test article or as a control.

**Human specimen research repository:** A collection of human specimens and associated data for research purposes, the physical structure where the collection is stored, and all relevant processes and procedures.

**Human subject as defined by Department of Defense:**

- Research involving a human being as an experimental subject. An activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction.
- Research involving human subjects. An activity that includes both a systematic investigation designed to develop or contribute to generalizable knowledge and involve a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.

**Human subject as defined by FDA.** An individual who is or becomes a subject 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 a medical device is used.

- 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 FDA regulation.

**Human subject as defined by HHS.** A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with an individual or with his or her identifiable private information or an individual who is or becomes a participant in research, either as a recipient of the test article or as a control.

- Intervention: Includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subjects' environment that are performed for research purposes.
- Interaction: Includes communication or interpersonal contact with a subject or his or her private identifiable information.
- Private information: Includes information about behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (such as a medical record). Private information must be individually identifiable in order to be considered information to constitute research involving human subjects. This may include identifiable private information obtained from a primary subject about a third party.

**Identifiable Data:** Any information about a living individual that is linked, associated with, or contains the name or any details of the individual that would allow someone to be able to directly or indirectly identify a subject from the information collected.

**Direct identifiers:** Identities of individual subjects are kept by the investigator. If subjects' identities are inseparable from data, then data is directly identifiable. Direct identifiers in research data or records include names; postal address information (other than town or city, state and zip code); telephone numbers, fax numbers, e-mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plant numbers; device identifiers and serial numbers; web universal resource locators (URLs); internet protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full face photographic images and any comparable images.
Indirect identifiers: Identities are kept separate from data, with information connecting them maintained by codes and a master list. Indirect identifiers in research data or records include all geographic identifiers smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent postal codes, except for the initial three digits of a ZIP code; all elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such age and elements may be aggregated into a single category of age 90 or older.

The 18 identifiers: Names, All geographical subdivisions smaller than a state, including street address, city, county, precinct, ZIP code and their equivalent geocodes, except for the initial three digits of a ZIP code, if according to the current, publicly available data from the U.S. Census Bureau. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older, Phone numbers, Fax numbers, Electronic mail addresses, Social Security numbers, Medical record numbers, Health plan beneficiary numbers, Account numbers, Certificate and license numbers, Vehicle identifiers and serial numbers, including license plate number, Device identifiers and serial numbers, Web Uniform Resource Locators (URLs), Internet Protocol (IP) address number, Biometric identifiers, including finger and voice prints, Full-face photographic images and any comparable images, Any other unique identifying number, characteristic or code (note this does not mean the unique code assigned by the investigator to code the data).

Informed consent: An ongoing process of communication between the subject and the investigator. Informed consent is a continual process by which a subject voluntarily confirms his or her willingness to participate in a research study, after having been informed and can demonstrate understanding of all aspects of the research 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.

Institutional official: The institutional official (IO) who is the signatory on the federalwide assurance (FWA) filed with OHRP to ensure compliance with regulations governing protection of human subjects. OHRP requires the institutional official to be a high-level official who has the authority to represent the institution named in the FWA.

Institutional review board (IRB): A specifically constituted review body established or designated by an entity to protect the rights and welfare of human subjects recruited to participate in biomedical or behavioral or social science research.

Interaction: Includes communication or interpersonal contact with a subject or his or her private identifiable information.

Intervention: Physical procedures by which data are gathered, such as venipuncture, and manipulations of the subject or the subject's environment that are performed for research purposes.

Investigational agent: A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial. This includes products with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, products used for an unapproved indication or products used to gain further information about an approved use.

Investigational device: Any health care product that does not achieve its primary intended purposes by chemical action or by being metabolized. A medical device that is the subject of a clinical study designed to evaluate the effectiveness and or safety of the device. Investigational use also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices.

Investigational device exemption (IDE): Application document submitted to the FDA proposing human clinical research to study an unapproved significant risk device, or a cleared or approved device for use other than its approved indication or intent. FDA grants permission so a device that otherwise would be required to comply with a performance standard or to have premarket approval can be shipped lawfully for the purpose of conducting investigations of that device. This FDA permission is evidenced by the assignment of an IDE number.

Investigational drugs or investigational biologics: New drugs or biologics that have not yet been approved by the FDA or approved drugs that have not yet been approved for a new use, and are in the process of being tested for safety and effectiveness.

Investigational new drug (IND): Application document submitted to the FDA proposing human clinical research to study an unapproved drug, or an approved product for a new indication or in a new patient population in a research study. New drugs that have not yet been approved by the FDA or approved drugs that have not yet been approved for a new use, and
are in the process of being tested for safety and effectiveness. This FDA permission is evidenced by the assignment of an IND number by the FDA or the granting of an IND exemption.

**IRB authorization agreement:** A formal, written agreement in which the reviewing IRB agrees to serve as the IRB of record for a relying institution, including an academic institution. Agreements are generally used to cover a single research study, categories of research studies or research studies within a research program.

**IRB of record:** A reviewing IRB that assumes IRB responsibilities for another institution and is designated to do so through an approved federalwide assurance on file with the federal Office for Human Research Protections.

**Label:** The FDA-approved label is the official description of a drug or biologic product that includes indication (what the product is used for); who should take it; adverse events (side effects); instructions for uses in pregnancy, children and other populations; and safety information for the patient. Labels are often found inside product packaging.

**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.

**Limited data set:** A limited data set allows retention of specific elements of identifying private information: geographic subdivisions, town, city, state, ZIP code, dates, age. Limited data sets are not considered to be de-identified information.

**Local research context:** Knowledge of the institution and community environment in which human subjects research will be conducted.

**Material transfer agreement (MTA):** A contract that governs the transfer of tangible research materials between two organizations when the recipient intends to use the materials for his or her own research purposes.

**Medical device:** A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory that is:

- Listed in the [online FDA database](https://www.fda.gov).
- 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, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes [21 U.S.C. 321(h)].

**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.

**Minimal risk for prisoners:** The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives or in the routine medical, dental or psychological examination of healthy persons. The regulations further state that the IRB must find that the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers [45 CFR 46.305(a)(3)]. If Subpart C does not apply, the IRB may use an equivalent definition of minimal risk for prisoners. [45 CFR 46.303(d)]

**Modification or Revision:** Any change to an IRB-approved study protocol regardless of the level of review it receives initially.

**Neonate:** A newborn zero to 28 days old.

**Nonaffiliated member:** Any IRB member who is not currently affiliated with NCSU and whose immediate family members are not affiliated with NCSU. Examples of NCSU affiliation include employment, participation as a student in a NCSU academic program or receipt of post-employment benefits, such as health and wellness or a pension.

**Noncompliance:** Failure to comply with federal regulations, NCSU policies and or requirements or determinations of the Institutional Review Board, or provisions of the approved research study.

**Nonsignificant risk (NSR) device study:** A study of a device that does not meet the definition for a significant risk device and does not present a potential for serious risk to the health, safety or welfare of participants.
Non-unanticipated problem involving risk to subjects or others (Non-UIRPTSO): A reportable event that does not meet the NCSU IRB’s definition of a UIRPTSO. See Unanticipated problem involving risk to subjects or others (UIRPTSO).

Nonviable neonate: A neonate after delivery that, although living, is not viable.

Notification: Process of notifying research subjects of changes in the research by letter or phone.

Office for Human Research Protections (OHRP): The office under the Department of Health and Human Services responsible for implementing HHS regulations (45 CFR 46) governing biomedical and behavioral and or social science research involving human subjects.

Oral (verbal) consent: A spoken presentation of the elements of informed consent to the prospective subject or their legally authorized representative. The presentation may be based on information contained within an oral consent script or the written consent document. Oral consent is often associated with waiving the documentation of consent. Oral consent is usually recorded in the research project files.

Password Protected: All data collection and storage devices must be password protected with a strong password. A strong password is at least 8 characters long, uses at least 3 out of 4 character groups: UPPERCASE, lowercase, numeric and special characters and does not contain an easily-guessable string.

Permission: The agreement of parents or guardians to the participation of their child or ward in research.

Pregnancy: Encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as a missed menses, until the results of a pregnancy test are negative or until delivery.

Preparatory to research: Any action taken in assessing the research question or hypothesis, such as accessing medical records, querying of databases for any type of individually identifiable health information, or any activity where PHI is accessed to prepare a research protocol.

Principal investigator (PI): Adheres to federal regulations, state and local laws, institutional policies, IRB policies and procedures regarding the safety and protection of human subjects, and good clinical practice (GCP) guidelines. The principal investigator ensures adherence by:

- Supervising the research process.
- Taking responsibility for ensuring that key study personnel are properly trained, qualified, and have appropriate facilities and resources to conduct the research.
- Ensuring adherence to the study protocol.
- Monitoring the informed consent process.
- Communicating regularly and effectively with the research staff.
- Taking responsibility for protecting the safety and welfare of research subjects.

Prisoner: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial or sentencing. If Subpart C does not apply, the IRB may use an equivalent definition of prisoners. [45 CFR 46.303(c)]

Prisoner of war: Any person captured, detained, held or otherwise under the control of Department of Defense personnel (military and civilian, or contractor employee) except DOD personnel held for law enforcement purposes (DOD directive 3216.2, section 4.42).

Privacy versus confidentiality: Privacy is about people and their choice to share personal information. It is a right in health care and research. Confidentiality is about data. It is the investigator’s obligation to protect subjects’ information.

Private information: Information about behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information that has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public, such as a medical record. Private information must be individually identifiable in order to be considered information to constitute research involving human subjects. This may include identifiable private information obtained from a primary subject about a third party.
**Protected health information (PHI):** Individually identifiable health information transmitted by electronic media, maintained in electronic media or maintained in any other form.

**Protocol violation:** Problems that violate the terms of a study but do not meet the criteria for an UPIRTSO. See Unanticipated problem involving risk to subjects or others (UPIRTSO).

**Reconsenting:** Process of notifying research subjects of changes in the research, including documentation of the subject's continued informed consent through signature on a revised written consent form.

**Recruitment:** A component of the consent process, is the process of distributing or presenting information that describes the research project and eligibility criteria so that a prospective subject may consider enrollment.

**Relying organization:** An organization, including an academic institution, with whom NCSU has either entered into an IRB Authorization Agreement or an agreement entered into as part of a cooperative research project.

**Reportables event:** A process (with an associated IRB form) used by an investigator to report any problem or event or other act or omission to the IRB that in their opinion is a UPIRTSO.

**Research activities:** Research activity includes all contact with the research subject (such as enrolling subjects, intervention or interaction), data collection and data analysis.

**Research (as defined by DOD):** An activity that includes both a systematic investigation designed to develop or contribute to generalizable knowledge and involves a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information, or activities covered by section 32 CFR 219.101 (including exempt research involving human subjects) and DOD Instruction 3216.02.

**Research (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 FDA under section 505(j) 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
- Any activity 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

**Research (as defined by HHS):** A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

**Research involving a human being as an experimental subject (as defined by DOD):** An activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving a human being as an experimental subject is a subset of research involving human subjects. This definition relates only to the application of section 980 of Title 10 USC; it does not affect the application of 32 CFR 219. This definition does not include activities that are not considered research involving human subjects, activities that meet the exemption criteria at section 32 CFR 219.101(b), and research involving the collection or study of existing data, documents, records, or specimens from living individuals. Section 980 of Title 10 USC imposes limitations on waiving informed consent when using DOD appropriated funds. Section 980 of Title 10 USC is applicable only to DOD funded research involving a human being as an experimental subject. Section 980 of Title 10 USC is not applicable to exempt research involving human subjects.

**Research involving human subjects (as defined by DOD):** An activity that includes both a systematic investigation designed to develop or contribute to generalizable knowledge and involves a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information, or activities covered by section 32 CFR 219.101 (including exempt research involving human subjects) and DOD Instruction 3216.02.

**Screen failures:** Subjects who consented to participate in research but who were disqualified during screening procedures.
Short-form consent document: A written consent document stating that the elements of consent have been presented orally. A witness to the oral presentation is required.

Significant risk (SR) device study: A study of a device that presents a potential for serious risk to the health, safety or welfare of a participant and:

- Is intended as an implant;
- Is used in supporting or sustaining human life, or otherwise prevents impairment of human health;
- Is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or
- Otherwise presents a potential for serious risk to the health, safety or welfare of a participant.

Sponsor-investigator: An individual who both initiates and conducts an investigation, and under whose immediate direction:

- The investigational drug is administered or dispensed, and or
- The investigational device is administered, dispensed or used. The term does not include any person other than an individual.

Study expiration: If IRB approval of a specific study expires before continuing review and approval occur, investigators must stop all research activities involving human subjects related to that study except where they judge that it is in the best interests of already enrolled subjects to continue to participate. When investigators make this judgment, they must promptly notify the IRB. When the IRB reviews the investigator's decision, it may decide whether it is in the best interests of already-enrolled subjects to continue to participate in the research by considering the best interests of subjects either one at a time or as a group. If an IRB determines that it is not in the best interests of already-enrolled subjects to continue to participate, investigators must stop all human subjects research activities, including intervening or interacting with subjects, or obtaining or analyzing identifiable private information about human subjects. Investigators may resume the human subjects research activity once continuing review and approval by the IRB has occurred.

Suspension for cause: An action initiated by the IRB to stop temporarily some or all research procedures pending future action by the IRB or by the investigator or his or her personnel. Examples of a suspension for cause might include:

- Inappropriate involvement of human subjects in research
- Violation of the rights or welfare of human subjects or others
- Serious or continuing noncompliance with federal regulations or IRB policies
- New information regarding increased risk to human subjects or others

Termination for cause: An action initiated by the IRB to stop permanently some or all research procedures.

Test article: Any investigational drug, biologic product, such as blood or a vaccine, or medical device for human use.

Treatment investigational device exemption (IDE): A mechanism through the FDA for providing eligible participants with investigational devices for the treatment of a serious or life-threatening illness for which there are no satisfactory alternatives.

Treatment investigational new drug (IND): A mechanism through the FDA for providing eligible participants with investigational drugs for the treatment of a serious or life-threatening illness for which there are no satisfactory alternatives.

Unanticipated problem involving risk to subjects or others (UPIRTSO): Any unanticipated problem or adverse event that meets these three criteria:

- Serious. Serious problems or events that result in significant harm (which may be physical, psychological, financial, social, economic or legal) or increased risk for the subject or others (including individuals who are not research subjects). These include:
  - Death;
  - Life-threatening adverse experience;
  - Hospitalization, whether inpatient, new or prolonged;
  - Disability and or incapacity, whether persistent or significant;
  - Birth defect or anomaly;
- Breach of confidentiality; and
- Other problems, events or new information (such as publications, DSMB reports, interim findings, product-labeling change) that in the opinion of the local investigator may adversely affect the rights, safety or welfare of the subjects or others, or substantially compromise the research data.

- Unanticipated. Unexpected problems or events are those that are not already described as potential risks in the protocol consent document, not listed in the investigator's brochure or not part of an underlying disease. A problem or event is unanticipated when it was unforeseeable at the time of its occurrence. A problem or event is unanticipated when it occurs at an increased frequency or at an increased severity than expected.
- Related. A problem or event is related if it is possibly related to the research procedures.

**Viable:** As it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

**Waiver of Consent:** It is recognized that there is valuable research that would be difficult, or impossible, to conduct if consent were required; and that subjects can still be adequately protected in the absence of full consent. Accordingly, the regulations also allow for waiver or alteration of some or all of the elements, as noted in 45 CFR 46.116(d). (1) the research involves no more than minimal risk to subjects (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) the research could not practicably be carried out without the waiver or alteration; and (4) whenever appropriate, the subjects will be provided with additional pertinent information after they have participated in the study.

**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.

**Withdrawals:** Subjects who signed the consent form, but later withdrew from the study, either before or after receiving a study drug, device or intervention. This does not include screen failures.