

Human Subjects Protection Program
Glossary

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310 AOB (MC 672)
1737 West Polk Street
Chicago, IL 60612-7227
Phone: 312 996-4995 Fax: 312 413-0238
www.research.uic.edu/protocolreview/irb

- **1572 Form:** Department of Health and Human Services Public Health Service Food and Drug Administration "Statement of Investigator" (TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART (312) NOTE(1): No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).
- **Adverse Event (AE) for [JBVAMC Research]:** Any untoward occurrence (physicals, psychological, social, or economic) in a human subject participating in research. An AE in research can be any unfavorable or unintended event including abnormal laboratory finding, symptom, disease, or death associated with the research or the use of as 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.
- **Advertising:** Material intended to be seen or heard by potential participants, including email solicitations.
- **Agent:** An individual employed by, or acting as a consultant to, the University of Illinois, Chicago who is authorized to act on its behalf.
- **Alternate [Committee Member]:** An alternate IRB member has the same voting authority, similar professional training and expertise, and IRB responsibilities as their IRB counterpart. This individual is an alternate in terms of scheduling (i.e., the IRB Member and Alternate attend every other IRB meeting, can substitute for one another if there is an unexpected absence or an absence during a particular protocol review due to Conflict of Interest). The alternate and IRB member counterpart cannot both vote at a fully convened IRB meeting.
- **Amendment:** Any change to an IRB-approved study protocol regardless of the level of review it receives initially.
- **Anonymous Data:** Information that was previously recorded or collected without any of the 18 identifiers as defined by HIPAA, and no code is assigned which would allow data to be traced to an individual.
- **Approved:** An approval is granted if the research activity meets the criteria for approval as defined in 45 CFR 46.111 as applicable and no changes to the research application are recommended (DHHS, FDA, and VA, as applicable).
- **Assent:** An individual's affirmative agreement to participate in research obtained in conjunction with permission from the individual's parents or guardian, or consent from the individual's legally authorized representative. Mere failure to object should not, absent affirmative agreement, be construed as assent.
- **Assurance:** A contract or agreement that establishes standards for human participants research as approved by the Office for Human Research Protections (OHRP).

- **Audit**: A systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), good clinical practice (GCP) and the applicable regulatory requirements.
- **Authorization**: A customized document, usually as a part of the informed consent document, that gives covered entities within University of Illinois, Chicago permission to use specified protected health information (PHI) for a specific purpose, or to disclose PHI to a third party specified by the individual other than for treatment, payment or healthcare operations.
- **Biologic**: A biological product or trivalent organic arsenical. A biological product that is used *in vitro* for diagnostic purposes.
- **Biological Product**: Any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment, or cure of diseases or injuries of human beings.
- **Business Associate**: A person or organization that performs a function or activity involving the use or disclosure of protected health information on behalf of the University of Illinois, Chicago. This includes, for example: data analysis, processing or administration; web site hosting; utilization review; quality assurance; billing; collections; benefit management; practice management; legal services; actuarial services; accounting and auditing; consulting; management and administrative services; accreditation; transcription services, billing services, coding services, financial services; or any other service in which the person or organization obtains PHI from or for covered entities. Individuals who are part of the University of Illinois, Chicago workforce are not considered business associates.
- **Cancer Center Protocol Review Committee (CC-PRC)**: The CC-PRC reviews each cancer-related protocol at the time of initial review and continuing review, and reviews amendments that involve revisions to the protocol or Investigator's brochure.
- **Capacity to Consent to Research**: The capacity to consent to research is the ability to give informed consent for participation in research. When research involves health care procedures, having capacity to consent not a means that a person is able to make an informed decision about the provision, withholding, or withdrawal of a specific treatment or course of treatment. A person is not able to make an informed decision if the person is unable to understand the nature, extent, or probable consequences of the proposed treatment or course of treatment, is unable to make a rational evaluation of the burdens, risks, and benefits of the treatment or course of treatment, or is unable to communicate a decision by speech or other means. A person may be able to make decisions about medical care, but lack capacity to consent to research. The fact that a guardian has been appointed for a person does not mean that the person is unable to make decisions about medical care, or lacks capacity to consent to research.
- **Case Histories**: These include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including progress notes of the physician, the individual's hospital chart(s), and the nurses' notes.
- **Certificate of Confidentiality**: A document issued by the National Institutes of Health that provides additional protection of data from legal subpoena in any civil, criminal,

administrative, legislative, or other proceeding, whether at the federal, state, or local level. The Certificate provides protection against compelled disclosure of identifying information or other identifying characteristics of a research participant enrolled in biomedical, behavioral, clinical, and other forms of sensitive research information that if disclosed could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. A project need not be federally funded to be awarded a Certificate of Confidentiality.

- **Certification:** The official notification to the supporting Department or Agency that a research project or activity involving human participants has been reviewed and approved by an IRB in accordance with an approved assurance.
- **CFR:** Code of Federal Regulations
- **Child/Children:** A person under the age of 18 may be requested to consent to participate in research only if that person has been determined to be a Mature Minor with respect to the research proposed. Refer to Emancipated Minor, Mature Minor, and Minor/LAC for further information about minors' abilities to consent to medical treatment and research, and the evaluation required to determine separately capacity to consent to medical care and capacity to consent to research.)
- **Clinical Investigation/Study/Trial:** (1) Any experiment in which an Investigational Agent is administered or dispensed to, or used involving, one or more human participants. (2) Any use of an Investigational Agent except for the use of a marketed drug biologic or device in the course of medical practice (clinical care). (3) Any investigation in human participants intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an Investigational Agent, and/or to identify any adverse reactions to an Investigational Agent, and/or to study absorption, distribution, metabolism, and excretion of an investigational product with the object of ascertaining its safety and/or efficacy. The terms *research*, *clinical research*, *clinical study*, *study*, *clinical trial*, *trial*, and *clinical investigation* are used as synonyms throughout policies and procedures, SOPs, and tip sheets in the library.
- **Clinical Research Center:** The UIC CRC offers services to investigators such as nursing support, laboratory testing, bionutrition services, education, biostatistical support, informatics support, and administrative support. Investigators may use one or more of the various services or may conduct research in the CRC unit with the aid of the CRC staff.
- **Coded Data:** Health information that has been stripped of all 18 identifiers as defined by HIPAA, but a code was assigned so that the information could be linked back to an individual.
- **Collaborative IRB Training Initiative (CITI):** An internet-based set of educational modules on the protection of human participants in research. It is sponsored by a consortium of IRB professionals and researchers from universities and medical schools across the country and is administered by the University of Miami.
- **Compassionate Use:** Commonly used to describe some of the ways of making unapproved, FDA-regulated products available to patients. There is no FDA regulation or policy defining a "compassionate use." In general, the FDA describes these uses of drugs as "treatment uses," because their intent is to provide treatment of patients, not primarily to evaluate the safety and effectiveness of the drugs, the primary and usual purpose of studies under an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE). FDA refers to compassionate use

requests for individual patients as a "Single patient IND" study or an IDE protocol deviation. Wider use usually takes place under a "Treatment IND" (see definition below), a "treatment protocol" under an existing commercial IND, or under a Humanitarian Device Exemption (HDE). The use of an investigational device in an individual patient with a serious, but not life-threatening condition, in a manner inconsistent with the approved investigational plan, or by a physician who is not part of the clinical study. The IDE Sponsor must submit an IDE supplement to the FDA requesting approval for a protocol deviation, including a description of the patient's condition, the circumstances necessitating treatment, a discussion of why alternative therapies are unsatisfactory and the probable risk of the device is no greater than the probable risk from the disease or condition, and the patient protection measures that will be followed. *Prior FDA approval is required before compassionate use occurs.*

- **Compensation:** Anything of value, including cash, equity, options, grants, fees, stipends, honoraria, royalties, licensing revenue, loans, gifts, personal expense accounts or allowances, given directly to an Investigator or an Investigator's Family Member from non-University sources; promise of future employment of an Investigator or Family Member; or promise of other future compensation of an Investigator or Family Member. For purposes of SOP ONLY, this also includes IRB Members, the Executive Director of the HRPO, and the HRPO staff.
- **Compensation in Research:** Payment or medical care provided to participants injured in research. This does not refer to payment (remuneration) for participation in research.
- **Competent Individual:** A person at least 18 years of age, or an Emancipated Minor or Minor/LAC, who has not been determined to be incapable of making an informed decision about health care. A competent individual may consent to medical treatment (subject to the limitation of the Minor/LAC's authority; see the definition of Minor/LAC below). A competent individual may have capacity to consent to research, but a separate determination of capacity should be made, especially in the case of an Emancipated Minor, Minor/LAC, or a cognitively impaired person.
- **Confidentiality:** The investigator's agreement as to how a subject's identifiable private information will be handled, managed, and disseminated.
- **Continuing non-compliance:** A pattern of repeated actions or omissions taken by an Investigator or study personnel that indicates a lack of ability or willingness to comply with federal regulations, UIC IRB policies and procedures, or the determinations of the UIC IRB.
- **Continuing Review:** Periodic review of research activities necessary to determine whether the risk/benefit analysis has changed, whether there are unanticipated findings involving risks to participants or others, and whether any new information regarding the risks and benefits should be provided to participants.
- **Continuous Quality Improvement (CQI):** A methodology employed by the Human Research Protections Office, when needed, to improve existing processes by identifying the root cause of a problem, developing and implementing an action plan, and evaluating the outcome to assure problem resolution.
- **Cooperative Agreement:** A joint agreement, approved by OHRP, in which multiple institutions agree to participate in a research project while relying on the review of one primary IRB's review and approval in order to avoid duplication of effort. The

primary IRB responsibilities may be rotated among the participating institutions.

- **Cooperative Research**: Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human participants and for complying with this policy. With the approval of the department or Agency head, an institution participating in a cooperative project may enter in to a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.
- **Cooperative Research Project**: A project which involves more than one institution.
- **Coordinating Center**: An institution, department, or center, which agrees to be responsible for the conduct, administrative, or coordinating functions of a multi-center research project. The Institution's Principal Investigator is responsible for operations and data analysis for the study but does not enroll participants in the study. Participants are enrolled at participating sites that provide the coordinating center with data only.
- **Covered Entity**: A health plan, a health care clearinghouse, or a health care provider who transmits health information and is therefore subject to the HIPAA regulations. For the purpose of this policy, the UIC Schools of Medicine and Dentistry are a covered entity. University of Illinois Medical Center (UMMC), and University Physician's Incorporated (UPI) are covered entities that are affiliated with the SOM/Dentistry covered entity. PHI can be shared amongst these covered entities without being considered a disclosure.
- **Data and Safety Monitoring**: A plan to oversee the implementation of a study protocol for compliance monitoring.
- **Data and Safety Monitoring Board (DSMB)**: A formally appointed independent group consisting of at least three members assigned to conduct interim monitoring of accumulating data from research activities to assure the continuing safety of research participants, relevance of the study question, appropriateness of the study, and integrity of the accumulating data. Membership should include expertise in the relevant field of study, statistics, and research study design.
- **Data and Safety Monitoring Committee (DSMC)**: Another term for DSMB.
- **Data and Safety Monitoring Plan (DSMP)**: A DSMP describes how the Investigator plans to oversee the research participant's safety and welfare and how adverse events will be characterized and reported. The intensity and frequency of monitoring should be tailored to fit the expected risk level, complexity, and size of the particular study.
- **Data Use Agreement**: An agreement between a covered entity and the recipient of the PHI. This agreement establishes who is permitted to use or receive the limited data set; and provides that the limited data set recipient will:
 - Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;
 - Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;
 - Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;
 - Ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to

- the limited data set recipient with respect to such information; and
- Not identify the information or contact the individuals.
- **Date of Approval**: The approval date is the first date of approval for the protocol.
- **Date of Expiration**: The expiration date is the last date that the research is approved. Federal regulations do not allow for any period extending the conduct of research beyond the last date that the protocol is approved (no greater than 364 days). For example, if the approval stamp states, "UIC IRB Approval Starts from January 1, 2009 to December 31, 2009," the informed consent form and research protocol is no longer valid as of midnight December 31, 2009.
- **Deidentified Biological Specimens**: Materials derived from human participants, such as blood, urine, tissue, organs, hair, nail clippings, mouth swabs or any other materials that are either collected specifically for research purposes or as residual specimens from diagnostic, therapeutic or surgical procedures.
- **De-Identified Health Information**: Health information that has been stripped of all 18 identifiers as defined by HIPAA, so that the information could not be traced back to an individual.
- **Deferred**: Deferred means the research does not meet the criteria for approval (DHHS, FDA, and VA as applicable), lacks sufficient information to conduct an adequate review, or the IRB panel recommends revisions to the IRB Application, Protocol, informed consent document(s), or other pertinent documents rendering it unable to assess the risk/benefit analysis without the completed revisions.
- **Departmental Review**: The UIC HSPP requires Departmental Review for all protocols that are submitted for convened review, unless the protocol qualifies for review by the Cancer Center Protocol Review Committee (CC-PRC) or Clinical Research Center review by the Scientific Advisory Committee review (SAC).
- **Department of Health and Human Services (DHHS)**: The United States government's agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.
- **Designated Record Set**: A group of records maintained by a covered entity that includes medical and billing records about an individual for the purpose of treatment, payment, or provision of health care. Research records that are not contained in the participant's medical record are not likely to be a part of the designated record set.
- **Deviation**: Any difference in study conduct from the criteria or procedures prescribed in the approved protocol, which may or may not affect the participants' rights, safety, welfare, and/or the integrity of the study and resultant data. Deviations may result from the action of the participant, investigator, or staff.
- **Disapproved**: A study is disapproved if it is found to be unethical, without scientific or scholarly merit and/or does not meet the criteria for approval (DHHS, FDA, and VA as applicable, see appropriate SOP). Written notification from the IRB of a decision to disapprove a protocol is accompanied by the IRB panel's reasons for the decision and an invitation for reply by the Investigator by submitting a new protocol.
- **Disclosure of PHI**: The release, transfer, or provision of access to, or divulging in any manner of information outside UIC or other covered components of the UIC covered entity.
- **Dispense**: Only a licensed pharmacist, physician, dentist or podiatrist may dispense

a drug.

- **Dissent**: An individual's negative expressions, verbal and/or non-verbal, indicating objection to participation in the research or research activities.
- **Distribution of a Drug**: A drug is distributed when it is provided to a patient in a pre-labeled container with patient-specific identification and does not require any manipulation (i.e., counting, packaging, transfer to another container, mixing, preparing, compounding). Distribution of drugs must be carried out upon the order of an authorized prescriber.
- **DSMB**: Data & Safety Monitoring Board.
- **Emergency Research**: Research conducted in participants who are in a life-threatening or emergency situation, where available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
- **Emergency Use**: The use of an investigational drug, agent, biologic, or device with a human participant in an immediate serious life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB and/or FDA approval.
- **Emergency Use IND**: The need for an investigational drug may arise in an emergency situation that does not allow time for submission of an IND in the usual manner. In such cases, FDA may authorize shipment of the drug for a specified use [21 CFR 312.36]. Such authorization is usually conditioned upon the sponsor filing an appropriate application as soon as practicable. *Prospective IRB review is required unless the conditions for exemption are met* [21 CFR 56.104(c) and 56.102(d)]. *Informed consent is required unless the conditions for exception are met* [21 CFR 50.23].
- **Emergency Use of an Investigational Device**: An emergency situation in which there is a need to use an investigational device in a manner inconsistent with the approved investigational plan, or by a physician who is not part of the clinical study. Deviations from the investigational plan are permitted when necessary to protect a human participant 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. *Prior FDA approval for shipment or emergency use of the device is not required*, but the use should be reported to the FDA within five (5) days from the time the IDE Sponsor learns of the use.
- **Emergency Use of an Unapproved Medical Device**: Emergency use of an unapproved device occurs when:
 - The treating physician is not an investigator under the IDE; *and* each of the following conditions exist to justify the emergency use:
 - The patient is in a life-threatening condition that needs immediate treatment;
 - No generally acceptable alternative for treating the patient is available; and
 - Because of the immediate need to use the device, *there is no time to use existing procedures to get FDA approval for the use*. The treating physician must have substantial reason to believe that the patient will benefit from the use of the device.

- **Equity:** This term includes, but is not limited to, preferred and common stock, stock options, warrants, bonds and notes, interests in LLCs or partnerships, and other forms of ownership. For purposes of this policy, investments in mutual funds or other investments in which an independent party has primary decision-making control regarding stock or shares held are not included in the definition of equity.
- **Essential Documents:** Those documents that individually and collectively permit evaluation of both the conduct of a clinical trial or investigator initiated research and the quality of the data that are produced.
- **Executive Director, Human Research Protections Program:** This individual provides guidance, leadership, and expertise to the Institutional Official in matters related to human research ethics and subject safety by: 1) ensuring compliance with all federal, state, and local laws pertaining to the use of human research participants, 2) developing HRPP strategic and financial plans, 3) managing relationships between internal clients and subject matter experts and external oversight agencies, consultants, sponsors, and other professionals in circumstances involving human participants.
- **Exempt Review:** Studies determined by the IRB to meet the exempt criteria as defined by the Federal regulations. Exempt studies do not require periodic review by the IRB unless a change in the project is planned.
- **Expedited Review:** Studies determined by the IRB to meet the expedited criteria as defined by the Federal regulations.
- **Expiration:** 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 and all research activities must stop until the protocol is renewed.
- **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.
- **FDAAA:** The Food and Drug Administration Amendments Act (FDAAA) of 2007 (US Public Law 110-85) expanded the scope of registration of clinical trials at ClinicalTrials.gov, increased the amount of information that must be provided at the time of registration, required the inclusion of trials results, and imposed penalties for non-compliance.
- **Facilitated Review:** Facilitated review is defined as a review to streamline the review process by accepting the NCI CIRB's responsibility to ensure that a comprehensive review of the research protocol was completed. The UIC IRB, by relying on the NCI CIRB's review, is able to focus the review on the informed consent/parental permission/HIPAA Authorization document(s) and child assent(s).

Facilitated review differs from expedited review in that the NCI CIRB makes the initial determinations related to 45 CFR 46, 21 CFR 50, and the regulations related to Subpart D. The initial review of the research protocol and consent/parental permission/HIPAA authorization document(s) will be initially approved by the NCI CIRB, the IRB of record. The UIC IRB either accepts or rejects the NCI CIRB's review of the research protocol and focuses on the review of the informed consent/parental permission/HIPAA Authorization document(s) and child assent(s).

UIC is responsible for making determinations related to the local institution regarding the assent document.

- **Family Member:** Spouse, parent, child, or sibling of an Investigator or IRB Member.
- **Family Member for FDA Regulated Research Consultation:** A Family Member for FDA Regulated Research Consultation means 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.
- **Fetus:** The product of conception from implantation until delivery.
- **Finder's Fee:** Compensation of any type (cash, office or medical supplies, educational stipends, gift certificates, priority in authorship listings, travel reimbursement, or anything else of value) to an individual made in exchange for referral or recruitment of a participant to a research study. Such payments, generally, are made to residents, physicians, nurses, or others in a position to identify potential participants that might qualify for enrollment into a study. The fee is paid only for participants who are actually enrolled into the study.
- **Food and Drug Administration (FDA):** The FDA is the federal oversight agency responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.
- **FDA:** [US] Food and Drug Administration
- **For Cause Audit:** These audits are conducted by the HRPP Compliance Team to assess the Investigator's compliance with federal regulations, state and local laws, and Human Research Protections Program and UIC IRB policies and procedures. These audits of IRB approved research studies are in response to identified concern(s). Concerns may be identified by an IRB panel, an external source (e.g. OHRP, FDA or Sponsor), or an internal source (e.g. participant, family member, or Institutional personnel).
- **Full Board Review:** Studies reviewed by the full, convened IRB panel with a recorded vote and corresponding minutes to document the discussion.
- **Full time:** (1) Those faculty whose entire professional compensation is determined by the School and UIC in accordance with the Medical Service Plan or by agreements with School affiliates; and (2) those faculty designated as full-time in their faculty appointment letters or faculty contracts, even though they receive all or part of their compensation from the U.S. Department of Veterans Affairs or other affiliates of the School.
- **Greater than Minimal Risk:** Does not meet the definition of minimal risk.
- **Guardian:**
- **Guardian of the Person:**
- **HIPAA:** Health Insurance Portability and Accountability Act
- **HPA:** Human Protections Administrator.
- **HRPP:** Human Research Protections Program
- **Human Immunodeficiency Virus (HIV):** Any of the lentiviruses and especially HIV-1

that infect and destroy helper T-cells of the immune system causing the marked reduction in their numbers that is diagnostic of AIDS.

- **Human Subject:** “Human Subject” as defined by DHHS regulations means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. [45 CFR 46.102(f)]
 - **Intervention:** This term as defined by DHHS regulations means both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. [45 CFR 46.102(f)].
 - **Interaction:** This term as defined by DHHS regulations means communication or interpersonal contact between investigator and subject. [45 CFR 46.102(f)].
 - **Private information:** This term as defined by DHHS regulations means information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). [45 CFR 46.102(f)].
 - **Identifiable information:** This term as defined by DHHS means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).
 - **For FDA regulated research,** a human participant is an individual who is or becomes a participant in research, either as a recipient of the test article as a control, or if a device is used on their specimen sample. A participant may be either a healthy individual or a patient.
 - **For VA Research,** a human subject is a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or through identifiable private information (38 CFR 16.102(f)). The definition provided in the Common Rule includes investigators, technicians, and others assisting investigators, when they serve in a “subject” role by being observed, manipulated, or sampled. As required by 38 CFR 16.102(f) an intervention includes all physical procedures by which data are gathered and all physical, psychological, or environmental manipulations that are performed for research purposes.
- **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 United States per year.
- **Humanitarian Use Device Exemption (HDE):** A Federal Drug Administration (FDA) approval for a physician to use a HUD in clinical treatment or as the subject of a clinical investigation.
- **Immediate Family:** This term means spouse and dependent children.
- **Imminent Threat of an AE in Research [for JBVAMC]:** Any situation in which an AE in research has not yet occurred but is likely to occur as determined by an IRB, research, or clinical team member without preventive measures.
- **IND:** Investigational New Drug application. An IND is a request for authorization from the FDA to administer an investigational drug or biologic to humans. Such

authorization must be secured prior to interstate shipment and administration of any new drug or biological product that is not the subject of an approved drug application or product license.

- **Independent Safety Monitor (ISM)**: An individual assigned to conduct interim monitoring of accumulating data from research activities to assure the continuing safety of research participants, relevance of the study question, appropriateness of the study, and integrity of the accumulating data. The individual should have expertise in the relevant medical, ethical, safety and scientific issues. The ISM should be an independent person not affiliated with the protocol. The ISM should not have a conflict of interest as to the research activities.
- **Individually Identifiable Health Information**: Any information collected from an individual (including demographics) that is created or received by a health care provider, health plan, employer, and/or health care clearinghouse that relates to the past, present or future physical or mental health or condition of an individual, or the provision of health care to an individual or the past, present or future payment for the provision of health care to an individual and identifies the individual and/or to which there is reasonable basis to believe that the information can be used to identify the individual, such as social security number even if the name is not included.
- **Industry-Sponsored**: When a commercial entity contributes to the design or conduct of the study (as evidenced by a sponsor's protocol, sponsor's identification number and/or the executed clinical trial agreement); coordinates the study as a multi-center trial; reimburses UIC or a UIC Investigator for costs associated with conducting the trial; or will have access to, or publish or present the data gained from conducting the trial.
- **Informed Consent**: An individual's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. The consent process begins when a potential research participant is initially contacted.
- **Institutional Biosafety Committee (IBC)**: A Committee required by Institutions receiving funding from the National Institutes of Health (NIH) for research involving recombinant DNA molecules. The IBC provides oversight of Human Gene Transfer, the deliberate transfer of DNA, transfer of DNA or RNA derived from recombinant DNA into human research participants. It is further charged with reviewing and approving research conducted with microorganisms pathogenic to humans, plants, or animals. The IBC also provides guidance on the proper acquisition, handling, transfer, and disposal of potentially hazardous or regulated biological materials.
- **Institutional Official**: The individual authorized to act for the institution and, on behalf of the institution, obligates the institution to the terms of the assurance.
- **Institutional Review Board (IRB)**: A specifically constituted review body established or designated by an institution to protect the rights and welfare of human participants recruited to participate in biomedical or behavioral/social science research.
- **International Research**: Research in the United States that is conducted in whole or in part in a state other than Illinois, in the District of Columbia, or in a U.S. Territory.
- **Investigational Agent**: (1) A new drug/agent or biologic that is used in a clinical investigation. (2) A biological product that is used *in vitro* for diagnostic purposes. (3) A drug or biologic that is lawfully marketed in the U.S. may still be considered investigational if the clinical investigation of the product involves a well-controlled

study in support of a new indication for use, or a significant change in the labeling, advertising, route of administration, dosage level, patient population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with use of the product.

- **Investigational Biologic**: Any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries which has not been released by the FDA for general use or cleared for sale in interstate commerce. Biological products are made from living organisms derived from living material--human, plant, animal, or microorganism.
- **Investigational Device**: Any healthcare 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**: A FDA approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have pre-market approval to be shipped lawfully for the purpose of conducting investigations of that device. The investigator or sponsor must obtain either a "significant risk" (SR) Investigational Device Exemption (IDE) from the FDA, or a "non-significant risk" (NSR) IDE from the IRB. The IDE permits use of the device in a clinical investigation to evaluate the safety and/or efficacy of the investigational medical device. Clinical studies of SR investigational devices must comply with the FDA's investigational device exemption (IDE) regulations and be conducted only with IRB approval.
- **Investigational Drugs/Investigational Biologics (Test Articles)**: A new drug or biologic that is used in a clinical investigation. The term investigational biologic also includes a biological product that is used *in vitro* for diagnostic purposes. Investigational drugs or biologics may include:
 - Products that are not generally recognized as being safe and effective for any use under the conditions prescribed, recommended, or suggested by the FDA; or
 - Products already approved by the FDA as safe and effective for specific indications that are being studied for new indications (or doses, strengths, or frequency).
- **Investigational New Drug (IND)**: Current Federal law requires that a drug be the subject of an approved marketing application before it is transported or distributed across state lines. Because a sponsor will usually ship the investigational drug to clinical investigators in many states, it must seek an exemption from that legal requirement. The IND is the means through which the sponsor technically obtains this exemption from the FDA. The FDA approval is evidenced by the assignment of an IND number by the FDA or by the granting of an IND Exemption. There are three IND types:
 - An Investigator IND is submitted by a physician who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug, or an approved product for a new indication or in a new patient population.
 - Emergency Use IND allows the FDA to authorize use of an experimental drug in

- an emergency situation that does not allow time for submission of an IND in accordance with 21CFR , Sec. 312.23 or Sec. 312.34. It is also used for patients who do not meet the criteria of an existing study protocol, or if an approved study protocol does not exist.
- Treatment IND s submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and the FDA review takes place.
 - **Investigational New Drug Exemption (IDE)**: Regulations in 21 C.F.R. § 312.2(b)(1) provide for the exemption of some studies for some drugs from IND regulations if the study meets the following five criteria:
 - The study is not intended to support FDA approval of a new indication or a significant change in the product labeling.
 - The study is not intended to support a significant change in the advertising for the product.
 - The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that *significantly increases the risks* (or decreases the acceptability of the risks) associated with the use of the drug product.
 - The study is conducted in compliance with institutional review board (IRB) and informed consent regulations set forth in parts 56 and 50 (21 CFR parts 56 and 50).
 - The study is conducted in compliance with § 312.7 (promotion and charging for investigational drugs).
 - **Investigational Use**: A substance in any clinical stage of evaluation which has not been released by the FDA for general use or cleared for sale in interstate commerce. An investigational drug may also be defined by one of the following:
 - A drug in any of the clinical stages of evaluation (Phase I, II, and III) which has not been released by the FDA for general use or cleared for sale in interstate commerce.
 - Any commercially available drug proposed for a new use.
 - A new dosage form or method of administration
 - A commercially available drug which contains a new component such as an excipient, coating.
 - A new combination of two or more commercially available drugs.
 - A combination of commercially available drugs in new proportions.
 - **IRB Authorization Agreement (IRB AA)**: A written agreement which is the primary method by which the UIC IRB serves as the IRB of Record for a site, which is not a legal entity of UIC.
 - **IRB Member**: An individual serving as an IRB Member including Chairs, Vice Chairs and alternates; also, for purposes of SOP ONLY, the Executive Director of the HRPO and HRPO staff.
 - **IRB of Record**: An IRB is considered the IRB of record when it assumes IRB responsibilities for another institution and is designated to do so through an approved Assurance with OHRP. A Memorandum of Understanding or an Institutional Authorization Agreement is required, designating the relationship, for UIC to serve as the IRB of Record.
 - **Limited Data Set**: Protected health information that excludes direct identifiers of the

individual or of relatives, employers, or household members of the individual, with the exception of city, state, ZIP Code, elements of dates, and other numbers, characteristics, or codes not listed as direct identifiers.

- **Local Research Context**: Knowledge of the institution and community environment in which human participants research will be conducted. Where the research involves greater than minimal risk to participants, the mechanism of obtaining local research context is dependent upon the nature and complexity of the research.
- **Major Modification**: Any modification that does not meet the definition of a minor modification.
- **Medical Device**: A product labeled, promoted or used in a manner that meets the following definition: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
 - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, or
 - 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 any of 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 any of its primary intended purposes.

* Note that a Medical Device may also be regulated as an Electronic Radiation Emitting Product.
- **Memorandum of Understanding (MOU)**: A formal agreement between University of Illinois, Chicago and another institution that identifies the University of Illinois, Chicago Institutional Review Board as the IRB of record for that institution and defines the responsibilities for both the UIC IRB and the other institution.
- **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. An example of minimal risk is the risk of drawing a small amount of blood from a healthy individual for research purposes (because the risk of doing so is no greater than the risk of doing so as part of a routine physical examination).
- **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 examinations of healthy persons.
- **Minimum Necessary Standard**: The least information reasonably necessary to accomplish the intended purpose of the use, disclosure, or request of PHI.
- **Minor Modification**: A proposed change in research related activities that does not materially affect an assessment of the risks and benefits of the study **AND** does not substantially change the specific aims or design of the study (i.e. clerical revisions of the consent form, change in research personnel) **AND** no procedure has been added to the protocol that would have required review as greater than minimal risk during prior reviews.
- **Neonate**: A newborn.

- **Non-compliance:** Failure to comply with applicable Federal Regulations, UIC IRB and Human Research Protections Program policies and procedures, UIC policy, or the requirements or determinations of the UIC IRB. For VA research this also includes non-compliance with the requirements of VA regulations or directives.
- **Non-Human Participant:**
 - Research that does not involve the process of obtaining specimens or data through intervention or interaction with individual participants or identifiable private information may qualify for a “non-human participant” determination.
 - Specimens/data that are received by the Investigator as de-identified (stripped of all identifiers) with no code or link that would allow an Investigator to establish identity would qualify as a “non human participant.” For example, a publicly available, unidentifiable, non-linked cell line may qualify as a “non-human participant.” Research utilizing de-identified specimens/data must be submitted to the UIC IRB and the IRB will determine which studies qualify as a “non-human participant.” If there is a link, the research may possibly qualify for an expedited review.
 - A cadaver is not considered to be a human participant. Therefore, research on specimens/data obtained from a cadaver would qualify as a “non-human participant.” Research involving cadavers may be submitted to the HRPO for a determination of “non-human participant research” if such documentation is needed.
- **Non-Human Subjects Research:** Activities that do not meet the DHHS or FDA definitions of human subjects research.
- **Non-Research:**
 - Non-Research is an activity that does not involve a **systematic** approach involving a predetermined method for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. Examples of activities that would not normally be considered systematic investigations include, but are not limited to:
 - Training activities (e.g., human participants being trained to perform a certain technique or therapy such as art therapy, psychoanalysis, oral history techniques); and
 - Classroom exercises involving human participants or human participant data where the objective of the activity is to teach proficiency in performing certain tasks or using specific tools or methods.
 - Research that does not contribute to generalizable knowledge may be results (or conclusions) of an activity that are not intended to be extended beyond a single individual or an internal program (e.g., publications or presentations). Examples of activities that are typically not generalizable include:
 - Biographies and service or course evaluations, unless they can be generalized to other individuals;
 - Services, courses, or concepts where it is not the intention to share them beyond the UIC community; and
 - Classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices.

- Quality Assurance activities designed to continuously improve the quality or performance of a department or program where it is not the intention to share them beyond the UIC community.
- Thesis or dissertation projects conducted to meet the requirements of a graduate degree are usually considered generalizable and, therefore, require IRB review and approval.
- **Non-Scientist Member**: A member of the IRB whose primary concerns are in nonscientific areas and who have had little or no scientific or medical training or expertise. Examples of individuals who would not be eligible as a non-scientist are nurses, pharmacists and other biomedical health professionals.
- **Non-significant 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.
- **Not Less Than Once Per Year**: All research proposals, with the exception of exempt proposals, must receive IRB continuing review at a minimum of once every year, per Federal regulations. There are no exceptions or grace periods allowed.
- **Office for Human Research Protections (OHRP)**: The office under the Department of Health and Human Services responsible for implementing DHHS regulations (45 CFR 46) governing biomedical and behavioral/social science research involving human participants.
- **Office for the Protection of Human Subjects**: The OPRS is the primary coordinating office for the UIC human subjects protection program.
- **Ombudsman**: A neutral third party that advocates for the participant or their family or legally authorized representative. Also known as a subject advocate.
- **Parent**: A child's natural or adopted parent.
- **Participant Advocate or Advocacy Group**: An individual or group of individuals that seek to safeguard the rights and welfare of research participants.
- **Participating Site**: The site Principal Investigator is not the lead principal investigator. The site contributes data to the study, but does not have overall responsibility for the conduct and analysis of the study.
- **Performance Site**: A site where research is performed.
- **Performance Site(s) Engaged in Research**: A performance site becomes "engaged" in human participants' research when its employees or agents 1) intervene or interact with living individuals for research purposes, or 2) obtain individually identifiable private information for research purposes. Further, a performance site is considered to be "engaged" in human participants' research when it receives a direct Federal award to support the research.
- **Performance Sites Not Engaged in Research**: A performance site is "not engaged" in human subjects research if its employees or agents do not 1) intervene or interact with living individuals for research purposes, or 2) obtain individually identifiable private information for research purposes. If a University of Illinois, Chicago Investigator or his/her staff, including site personnel contracted by University of Illinois, Chicago, performs all research related activities as well as screening, recruiting, or consenting at the performance site, the performance site would be considered "not engaged" in research, unless the non-UIC performance site releases

identifiable private information to UIC researchers without first obtaining participants' permission.

- **Permission:** The agreement of parent(s) or guardian(s) of children to the participation of their child or ward in research.
- **Person Engaged in Research:**
 - Person who intervenes with living individuals by performing invasive or noninvasive procedures for research purposes (e.g., drawing blood; collecting other biological samples; dispensing drugs; administering other treatments; employing medical technologies; utilizing physical sensors; utilizing other measurement procedures).
 - Person who intervenes with living individuals by manipulating the environment for research purposes (e.g., controlling environmental light, sound, or temperature; presenting sensory stimuli; orchestrating environmental events or social interactions; making voice, digital, or image recordings).
 - Person who interacts with living individuals for research purposes (e.g., engaging in protocol-dictated communication or interpersonal contact; conducting research interviews; obtaining informed consent).
 - Person who releases, obtains, receives, or possesses private information that is individually identifiable (either directly or indirectly through coding systems) for research purposes (e.g., obtaining private information from medical records and/or research records in an individually identifiable form).
- **PHI:** Protected Health Information, including individually identifiable health, financial and other personal information.
- **Pregnancy:** Encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the 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.
- **Primary Campus Entity:** School, department, or interdepartmental program under whose auspices the project will be carried out.
- **Principal Investigator:** Individuals that perform or participate in a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. **OR** Individuals who actually conduct 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. Individuals which meet either of these definitions constitute individuals performing 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).
- **Principal Site:** The Institution's Principal Investigator is the lead principal investigator for a multi-site research study and has overall responsibility for the study. Some of the research participants are enrolled in the study under the auspices of the

Institution and other participants are enrolled in the study under the auspices of other participating institutions.

- **Privacy**: Privacy refers to persons and to their interest in controlling the access of others to themselves.
- **Prospective**: Research utilizing human participants' specimens/data that will be collected after the research is approved by the IRB.
- **Protected Health Information (PHI)**: Individually identifiable health information that is or has been collected or maintained by a covered entity, including information that is collected for research purposes only, and can be linked back to the individual participant.
- **Protocol Exception**: A deviation approved by the IRB prior to implementation.
- **Quality Assurance**: Interval auditing targeted to specific aspects of a protocol to determine adherence. QA review is conducted on a portion of the study activities such as 5, 10, or 15% of all records.
- **Quality Control**: Real-time observation for protocol adherence- Review 100% data points.
- **Quality Improvement Plan**: A plan or a system, including structure and defined responsibilities, which provides a framework for all quality activities, including quality assurance, quality control, and the reporting of these activities.
- **Radiation Exposure**: The quantity used to indicate the amount of ionization in air produced by x- or gamma-ray radiation while conducting radiological procedures.
- **Radiation Safety Committee (RSC)**: A sub-committee, under the University of Illinois Chicago Risk Management Committee, which is responsible for the review and approval of research studies involving human participants and radiation exposure.
- **Radiological Procedure**: Any procedure involving radiation (e.g., X-ray) or a radiopharmaceutical.
- **Recruitment**: Seeking individuals to enroll or participate in a research project.
- **Related to the research procedures**: An event is "related to the research procedures" if in the opinion of the principal investigator, it was more likely than not to be caused by the research procedures or if it is more likely than not that the event affects the rights and welfare of current participants.
- **Repository**: A storage site or mechanism by which identifiable human tissue, blood, genetic material or data are stored or archived for research by multiple Investigators or multiple research projects.
- **Research involving human subjects**: This term means any activity that either:
 - Meets the DHHS definition of "research" and involves "human subjects" as defined by DHHS; or
 - Meets the FDA definition of "research" and involves "human subjects" as defined by FDA.
 - This term as defined by DHHS regulations means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. [45 CFR 46.102(d)].
 - This term as defined by FDA regulations means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or need not

meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug, and Cosmetic Act, but 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. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations. [21 CFR 50.3(c), 21 CFR 56.102(c)]

- “Experiments that 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” means any use of a drug other than the use of an approved drug in the course of medical practice. [21 CFR 312.3(b)]
 - “Experiments that 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” means any activity that evaluates the safety or effectiveness of a device. [21 CFR 812.2(a)]
 - “Any activity in which results are being submitted to or held for inspection by FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research. [21 CFR 50.3(c), 21 CFR 56.102(c)]”
- **Research Misconduct**: Any fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
 - **Research Payments**: Cash and non-cash payments for reimbursement of time and expenses associated with participation in research activities.
 - **Research Related Injuries**: Injuries directly resulting from interventions that study participants would not have been exposed to had they not volunteered to participate in the study. [NOTE: Research Related Injuries do NOT include normal progression of the participants disease, or conditions not directly resulting from interventions that the participants would not have incurred had they not volunteered to participate in the study].
 - **Retrospective**: Research utilizing human participants’ specimens/data that were previously collected (e.g., on the shelf) before the research was approved by the IRB.
 - **RiSC**: is a computer-based electronic system used for tracking research protocol submissions and correspondence to investigators from UIC OPRS.
 - **Routine Audit**: Audits are conducted to provide a comprehensive examination of research participant eligibility, the informed consent process, administration/use of the investigational product, examination of protocol and regulatory adherence, documentation of medical oversight and reporting of unanticipated problems involving risk to participants or others. These audits of IRB approved research studies are conducted on an as needed basis, at the request of the investigator/research staff, and as deemed necessary by the Human Research Protections Office, Institutional Administration, IRB Executive Committee, or by one of the IRB Panels.
 - **Secretary**: The Secretary of U.S. Department of Health and Human Services or another officer or employee of the Department of Health and Human Services to whom appropriate authority has been delegated by the Secretary.

- **Sensitive Information**: Includes, but is not limited to, information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products; information pertaining to illegal conduct; information, that if released, might be damaging to an individual's financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination; information pertaining to an individual's psychological well-being or mental health; and genetic information. Information in other categories, not listed here, might also be considered sensitive because of specific cultural or other factors.
- **Serious non-compliance**: An action or omission taken by an investigator or study personnel that any other reasonable investigator would have foreseen as compromising the rights or welfare of the participant.
- **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 1) is intended as an implant; 2) is used in supporting or sustaining human life; or otherwise prevents impairment of human health; 3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or 4) otherwise presents a potential for serious risk to the health, safety, or welfare of a participant.
- **Source Data**: All information in original records and certified copies of original records of clinical findings, observations, or other activities in a study necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents.
- **Source Documents**: The original documents, data, and records (for example, hospital records, clinical and office charts, laboratory notes, participants' diaries or evaluation checklists, pharmacy dispensing records, x-rays, participant files, and records kept at the pharmacy and laboratories). Source documentation serves to substantiate the integrity of trial data, confirm observations that are recorded, and confirm the existence of study participants.
- **Sponsor**: A person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual; a pharmaceutical, biotechnology, or medical device company; a governmental agency; academic institution; private organization; or other organization.
- **Sponsor-Imposed Suspension**: A sponsor-imposed suspension is when the IRB receives written notification from the Investigator that the sponsor has stopped the research study or portions of the research. This will be acknowledged by the IRB, the IRB Chair, or his/her Designee when the appropriate level of review determines the suspension is appropriate. Submit notice through the prompt reporting form.
- **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., it does not include a corporation or agency. The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.
- **Study Personnel**: Study personnel include all individuals working on a research project in collaboration with, or under the supervision of an Investigator.
- **Suspension**: A suspension means a determination from the IRB to temporarily

withdraw approval of all or some specific research activities or permanently withdraw approval of some specific research activities, indicating that the specified activities must stop immediately. The appropriate party may impose additional criteria for suspension, if needed, to protect the participants from potential harm per the UIC HSPP policy *Administrative Hold, Suspension, or Termination of IRB Approval*.

Suspended research projects still have IRB approval and require continuing review. For example, the IRB may stop the enrollment of new subjects, although may allow the continuation of currently enrolled subjects, if appropriate. The convened IRB would review the investigator's response, if any.

- **Tabled**: A study is tabled if it is unable to be reviewed at the meeting due to lack of time, lack of quorum, lack of IRB panel expertise, and/or other extenuating circumstances.
- **Termination**: A termination means determination from the IRB to permanently withdraw approval of all research activities, indicating that the specified activities must stop immediately due to significant concerns. A convened IRB must review the PIs response, if any. The only exception for immediately halting research is for the continuation of follow-up activities necessary to protect the participants' safety. (AP: to cite the corresponding policy and procedure). Terminated research projects no longer have IRB approval and do not require continuing review. The UIC HSPP policy *Administrative Hold, Suspension, or Termination of IRB Approval* must be followed.
- **Test Article**: Any drug, biological product, or medical device for human use in a clinical investigation. It also applies to a biological product that is used *in vitro* for diagnostic purposes.
- **Treatment IDE**: The treatment IDE is a mechanism to facilitate the availability of investigational devices to desperately ill patients as early in the development process as possible (before general marketing begins) and to obtain additional data on the device's safety and effectiveness. Treatment use of an investigational device will be considered when:
 - The device is intended to treat a serious or immediately life-threatening disease or condition;
 - There is no comparable or satisfactory alternative device, drug or other therapy available to treat or diagnose the disease or condition in the intended patient population;
 - The device is under investigation in a controlled clinical trial for the same use under an approved IDE, or all clinical trials have been completed; and
 - The sponsor of the controlled clinical trial is pursuing marketing approval/clearance of the investigational device with due diligence.
- * *Treatment IDE studies require prospective IRB review and informed consent.* A sponsor may apply for a waiver of local IRB review under a treatment IDE if it can be shown to be in the best interest of the patients, and if a satisfactory alternate mechanism for assuring the protection of human subjects is available (e.g., review by a central IRB). Such a waiver does *not* apply to the informed consent requirement. An IRB may still opt to review a study even if FDA has granted a waiver.
- **Treatment IND**: The treatment IND is a mechanism to facilitate the availability of investigational drugs and biologics to desperately ill patients as early in the

development process as possible (before general marketing begins) and to obtain additional data on the drug or biologic's safety and effectiveness. Treatment use of an investigational drug or biologic will be considered when:

- The drug/biologic is intended to treat a serious or immediately life-threatening disease or condition;
- There is no comparable or satisfactory alternative device, drug or other therapy available to treat or diagnose the disease or condition in the intended patient population;
- The drug/biologic is under investigation in a controlled clinical trial for the same use under an approved IND, or all clinical trials have been completed; and
- The sponsor of the controlled clinical trial is pursuing marketing approval/clearance of the investigational drug/biologic with due diligence.

* *Treatment IND studies require prospective IRB review and informed consent.* A sponsor may apply for a waiver of local IRB review under a treatment IND if it can be shown to be in the best interest of the patients, and if a satisfactory alternate mechanism for assuring the protection of human participants is available, e.g., review by a central IRB. Such a waiver does *not* apply to the informed consent requirement. An IRB may still opt to review a study even if FDA has granted a waiver.

- **Trial Site**: The location where the research is conducted.
- **Unanticipated**: An event is “unanticipated” when it was unforeseeable at the time of its occurrence. The word unanticipated, is not a synonym for unexpected. A research protocol can monitor for an unexpected event, but cannot monitor for an unforeseen event. All unanticipated events are unexpected, but not vice versa.
- **Unexpected**: An event is “unexpected” when its specificity and severity are not accurately reflected in the informed consent document, Investigators Brochure, or Package Insert.
- **Unexpected Death [for JBVAMC]**: The death of a research subject in which a high risk of death is not projected as indicated by the written protocol, informed consent form, or sponsor brochure. This definition does not include deaths associated with a terminal condition unless the research intervention clearly hastened the subject's death.
- **Use of PHI**: Querying, viewing, and/or extracting any protected health information for research purposes within a covered entity.
- **VA**: Veterans Administration
- **JBVAMC**: Veteran's Affairs Illinois Health Care System
- **Veteran's Affairs (VA) VA-sponsored Tissue Bank**: A tissue repository located at a VA facility or an approved off-site location that operates in accordance with established VA policies. The repository stores human biological specimens collected under VA-approved research protocols and are under VA ownership and VA control.
- **Veterans Affairs Approved Tissue Bank**: A tissue bank located at a non-VA facility that has the appropriate approval from the Office of Research & Development (ORD). The bank must meet all the safeguards for a VA sponsored tissue bank. Non-VA sites that may not be acceptable tissue banks are non-academic, for-profit institutions such as pharmaceutical companies.
- **Violation**: A deviation that affects the participant's rights, safety, welfare, and/or the

integrity of the resultant data.

- **Voluntary Suspension by The Investigator**: A decision by an investigator to voluntarily suspend or terminate some or all research activities being conducted under an IRB approved research protocol, which may be pending further review or investigation by the IRB or other entity within the institution, even if prompted by a verbal or written recommendation from the IRB Chair or another institutional official, *is not considered a suspension or termination of IRB approval.*
- **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.
- **Whistle-blower**: An individual who reports sensitive information to the UIC IRB regarding potential non-compliance issues or research activities that have potentially placed participants or others at increased risk in relationship to the conduct of the research.