Glossary

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Revisions Table

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A. Lay Language for Informed Consent

Term	Definition
acute	new, recent, sudden
adverse effect	side effect
assay	lab test
benign	not malignant, usually without serious consequences
bolus	an amount given all at once
carcinogenic	capable of causing cancer
catheter	a tube for withdrawing or introducing fluids
chronic	continuing for a long time
clinical trial	an experiment with patients
controlled trial	a study in which the experimental procedures are compared to standard (accepted) treatments or procedures
culture	test for infection, or organisms that could cause infection
double blind	study in which neither the investigators nor the subjects know which intervention the subject is receiving
dysplasia	abnormal cells
edema	increased fluid
efficacy	effectiveness
extravasate	to leak outside of a blood vessel
hematoma	a bruise, a black and blue mark
heparin lock	needle placed in the arm with blood thinner to keep the blood from clotting
monitor	check on, keep track of, watch carefully
morbidity	undesired result or complication
mortality	death or death rate
necrosis	death of tissue
oncology	the study of tumors or cancer
percutaneous	through the skin
placebo	a substance of no medical value, an inactive substance
PRN	as needed
protocol	plan of study
random	by chance, like the flip of a coin
relapse	the return of a disease
retrospective	looking back over past experience

B. Frequently Used Terms

Adverse event – An undesirable and unintended, although not necessarily unexpected, result arising during the course of a research protocol.

Adverse Event Report – Report to appropriate institutional officials about adverse events.

Advertising – One mechanism or method used by researchers to recruit subjects for research studies.

Alternatives – Options that exist for a subject who is thinking about participating in research.

ARENA – Applied Research Ethics National Association: a membership organization for individuals interested in ethical issues relating to medicine and research.

Assent – Agreement by an individual not competent to give legally valid informed consent to participate in research (e.g., a child).

Assurance – A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with regulations governing the protection of human subjects in research. Assurance is the word used in the Federal Policy (Common Rule).

Authorized Institutional Official – See "Institutional Official."

Autonomy – See "Respect for Persons."

Belmont Report – A statement of basic ethical principles governing research involving human subjects issued in 1978 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

Beneficence – An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

Benefit – A valued or desired outcome; an advantage.

Certificate of Confidentiality – A Certificate of Confidentiality protects the compelled release of identifiable information about research subjects in any legal proceeding. These documents are issued by the DHHS and can be requested for all research, regardless of funding source [42 USC 241(d)].

Certification – The human subject regulations, in certain parts require the Institutional Review Board (IRB) to provide a "certification" to the government. For example, see the prisoner regulations at 45 CFR Part 46, Subpart C.

Chair – The person who leads the activities of the IRB.

Children – Persons who are minors as defined by law.

Clinical Investigation – Any experiment that involves a test article and one or more human subjects that is subject to Food and Drug Administration (FDA) requirements for research or marketing permits [21 CFR Part 50.3(c) and 56.102(c)].

Clinical Trial – A controlled study involving human subjects designed to contribute to generalizable knowledge about the safety and/or effectiveness of an intervention or treatment.

Co-Investigator- An individual involved with the PI in the scientific development or execution of a research project. A co-investigator typically devotes a specified percentage of time to the project and is considered senior personnel. The designation of a co-investigator does not affect the PI's roles and responsibilities. Another word used for co-investigator is sub-investigator.

Coercion – The act of inducing or pressuring an individual to consent to participate in research or to stay in research.

Cognitive Impairment – Some disorder that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished.

Common Rule – The short description of the Federal Policy for the Protection of Human Subjects in Research [56 FR 29003].

Compensation – Refers to payment or other benefits that will be given to subjects who volunteer to participate in research protocols.

Competence – The capacity to act on one's own behalf; the ability to understand information presented; to appreciate the consequences of acting or not acting on that information, and to make a choice.

Confidentiality – Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

Consent – Agreement to do something. Informed consent is agreement to do something based upon a complete understanding of that task.

Continuing Noncompliance- Noncompliance (serious or non-serious) that has been previously reported, or a pattern of ongoing activities that indicate a lack of understanding of human subjects protection requirements that may affect research participants or the validity of the research and suggest the potential for future noncompliance without intervention.

Control – Subject(s) used for comparison who are not given a treatment under study or who do not have a given condition, background, or risk factor that is the object of the study.

Continuing Review – The regulatory requirement that the Institutional Review Board (IRB) review research at intervals not greater than one year. The IRB may review research at more frequent intervals [45 CFR 46.109(e); 21 CFR 56.109(f)].

Data and Safety Monitoring Board (DSMB) – A group of people who monitor a clinical trial for adverse events and other trends. The Data and Safety Monitoring Board looks for any information that might warrant modification or termination of the trial or notification of subjects about new information that might affect their willingness to continue in the trial.

Deception – Intentionally misleading with respect to a research protocol.

Declaration of Helsinki – A code of ethics for clinical research approved by the World Medical Association. It has been widely adopted by medical associations worldwide and has been revised numerous times.

DHHS – Acronym for U.S. Department of Health and Human Services.

DSMB – Acronym for Data and Safety Monitoring Board.

Emancipated Minor – Defined by law, this refers to the legal status of a person who has not yet attained the age of legal competency but who is entitled to adult status for certain matters.

Embryo – Early stages of a developing organism, broadly used to refer to stages immediately following fertilization of an egg through implantation and very early pregnancy.

Expected Adverse Event (see also Unexpected Adverse Event) - is an adverse event that may be reasonably anticipated to occur as a result of the study procedures or study participation and should thus be described in the research proposal, the informed consent document and Investigator's Brochure (when applicable), or is part of the normal disease process or progression.

Exemptions – The Federal Policy for the Protection of Human Subjects contains six exemptions. Research falling under one of these exemptions is not required to undergo IRB review and the investigator is not required to abide by the requirements for obtaining information consent [See 45 CFR 46.101(b)]. FDA regulations contain an exemption from IRB review requirements for the emergency use of a test article [21 CFR 56.104(c)] and for certain taste and food quality evaluations and consumer acceptance studies [21 CFR 56.104(d)].

Expedited Review – Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire convened IRB. Federal regulations permit expedited review for: (1) certain kinds of research involving no more than minimal risk and that fall within a category listed on the November 9, 1998 Federal Register [63 FR 60364]; and, (2) for minor changes in previously approved research [45 CFR 46.110; 21 CFR 56.110].

Experiment – Generally, this refers to an intervention or interaction that is unproven and not yet scientifically validated.

External (off-site) Adverse Events – adverse events that occur in study participants for which THR is not the IRB of record.

FDA – Acronym for the Food and Drug Administration, a component of DHHS.

Federal Policy – Another short reference, along with the phrase "Common Rule," for the Federal Policy for the Protection of Human Subjects in Research [56 FR 28003].

Federal Register – The government's publication in which final and proposed rules or notices are published.

Fetus – The product of conception from the time of implantation until delivery. Refer to Subpart B of 45 CFR Part 46 for specific findings that are required for research involving fetuses.

FR – Acronym for Federal Register.

Full Board Review – Review of proposed research at a convened meeting of the IRB, at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in a nonscientific area [45 CFR 46.109; 21 CFR 56.108].

Generalizable Knowledge Defined - Knowledge that could be applied to populations outside of the patients served by the covered entity (i.e., THR hospital(s) or wholly owned entity(s)).

Grant – Financial support provided for a research study designed and proposed by the principal investigator.

Guardian – An individual who is authorized under applicable state or local law to give permission on behalf of another person to participate in research.

Helsinki Declaration – See "Declaration of Helsinki."

Human in Vitro Fertilization – Any fertilization involving human sperm and ova that occurs outside the human body.

Human Protections Administrator – An individual who has responsibility for day-to-day operation and implementation of the institution's program for protecting human subjects. The institutional title and duties of the Human Protections Administrator may vary widely from institution to institution. For example, an institutional compliance officer, head IRB administrator, or some other individual might fill this role, depending upon the nature of the institution. In any case, the Human Protections Administrator should have detailed knowledge of institutional protection mechanisms and be readily available for consultation with federal officials and institutional personnel. The IRB Chairperson should not serve as the Human Protections Administrator.

Human Subject – An individual who is the object of study in a research project. Under the Federal Policy (Common Rule), human subject means a living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information [45 CFR 46.102(f)]. Under FDA regulations, "human subject" means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient [21 CFR 50.3(g) and 56.102(e)]. An individual on whose specimen a device is used. For medical devices studies involving in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.

IDE – Acronym for Investigational Device Exemption.

IEC – Acronym for Independent Ethics Committee.

Internal (on-site) Adverse Events – adverse events that occur in study participants for which THR is the IRB of record.

Incapacity – Refers to a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.

Inclusion Criteria – The criteria that establish whether a person is eligible to participate in a clinical trial.

Incompetence – A legal term meaning inability to manage one's own affairs.

IND – Acronym for Investigational New Drug Application.

Independent Ethics Committee (IEC) – The equivalent of an IRB under the International Conference on Harmonisation Guidelines for Good Clinical Practice.

Informed Consent – A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure.

Intervention – includes 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].

Institution – Any public or private entity or agency (including federal, state, and other agencies) [45 CFR 46.102(b); and, 21 CFR 50.3(h) and 56.102(f)].

Institutional Review Board (IRB) – A review body established by regulation to protect the welfare of human subjects recruited to participate in research.

Institutional Official – The individual at an institution who is responsible for ensuring the effective administration and implementation of the institution's system for the protection of human subjects.

Investigational Device Exemption (IDE) – Exemptions from certain regulations found in the FDA, Medical Device Amendments that allow shipment of unapproved devices for use in clinical investigations [21 CFR 812.20].

Investigational New Drug Application (IND) – An application to conduct a clinical investigation involving a drug not yet determined by the Food and Drug Administration to be safe and effective for a particular use in the general population and not yet licensed for marketing [21 CFR 312.1].

Investigator – The individual who actually conducts a research investigation [21 CFR 50.3(d) and 56.102(h)].

IRB – Acronym for Institutional Review Board.

IRB Forum (formerly know as "McWIRB" – An IRB Listserve that is widely used and can be found at http://www.irbforum.org.

Justice – An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.

Legally Authorized Representative (LAR) – The person authorized by law to consent to something on behalf of another person. For research purposes, only select states permit a LAR to consent for research participation [45 CFR 46.102(c); 21 CFR 50.3(e)].

Member – A person who is listed on the roster of an IRB as a voting participant in IRB deliberations and actions.

Minimal Risk (Federal Policy, DHHS Subpart A, and FDA) – 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 [45 CFR 46.102(i); and, 21 CFR 50.3(k) and 56.102(j)].

Minimal Risk (DHHS Subpart C - 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 [45 CFR 46. 303(d)].

Monitoring – A mechanism for keeping track of any part of the research process: data analysis, recruitment of subjects, informed consent process, to ensure its compliance with Institutional Review Board dictates and the federal regulations.

National Bioethics Advisory Commission (NBAC) – A Presidentially appointed commission that issues reports and makes recommendations relating to the protection of human subjects in research.

NCI's (National Cancer Institute) definition for an Adverse event – an unexpected medical problem that happens during treatment with a drug or other therapy. Adverse events do not have to be caused by the drug or therapy, and they may be mild, moderate, or severe.

NIH – Acronym for National Institutes of Health.

Non-Affiliated Member – Member of an IRB who has no ties (and whose immediate family members have no ties) to the parent institution, its staff, or faculty. This individual is usually from the local community [45 CFR 46.107(d); and 21 CFR 56.107(d)].

Non-Scientist – Member of an IRB who does not have a scientific background, but may be affiliated with the institution [45 CFR 46.107(c); and, 21 CFR 56.107(c)]. At least one non-scientist member must be present at convened meetings to approve research [45 CFR 46.108(b); and, 21 CFR 46.108(c)].

Normal Volunteers – Volunteer subjects in a research study who do not have the condition under study. The 1993 Office for Protection from Research Risks (OPRR) Guidebook defines normal volunteers as follows: "Normal" may not mean normal in all respects. For example, patients with broken legs (if not on medication that will affect the results) may serve as normal volunteers in studies of metabolism, cognitive development, and the like. Similarly, patients with heart disease but without diabetes may be the "normals" in a study of diabetes complicated by heart disease [OPRR IRB Guidebook, 1993, G-9].

Notice of Proposed Rule-Making (NPRM) – Pursuant to the Administrative Procedure Act, the government must typically issue a notice of a proposed rule before it issues the final rule. This affords the public the opportunity to comment on contemplated government action.

Nuremberg Code – A code of research ethics developed during the trials of Nazi war criminals following World War II and widely recognized as a standard during the 1950s and 1960s for protecting human subjects.

Oral Consent – Typically refers to informed consent that is obtained from a subject without use of a written informed consent document.

Office for Human Research Protections (OHRP) – An office within the DHHS that was created in June of 2000. OHRP is responsible for the implementation of the DHHS regulations [45 CFR Part 46] governing the protection of human subjects in research.

Office for Protection from Research Risks (OPRR) – Until June 2000, this office was within the DHHS as part of the National Institutes of Health (NIH). OPRR was responsible for the implementation of the DHHS regulations [45 CFR Part 46] governing research involving human subjects. The Office for Human Research Protections supercedes OPRR.

Parental Permission – The agreement of one or both parents or a guardian to research involving a minor [45 CFR 46.402(c)].

Phase 1,2,3,4, Clinical Trials – Different stages of testing drugs in humans, from first application in humans (Phase 1) through limited and broad clinical tests (Phase 3), to postmarketing studies (Phase 4).

Phase 1 Clinical Trials – Phase 1 trials include the initial introduction of an investigational new drug into humans. These studies are typically conducted with healthy volunteers; however, where the drug is intended for use in patients with a particular disease, such patients may participate as subjects. Phase 1 trials are designed to determine the metabolic and pharmacological actions of the drug in humans, the side effects associated with increasing doses (to establish a safe dose range), and, if possible, to gain early evidence of effectiveness. They are typically closely monitored. The ultimate goal of Phase 1 trials is to obtain sufficient information about the drug's pharmacokinetics and pharmacological effects to permit the design of well-controlled, sufficiently valid Phase 2 studies. Other examples of Phase 1 studies include studies of drug metabolism, structure-activity relationships, and mechanisms of actions in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes. Typically, Phase 1 investigations involve anywhere from 20-80 subjects [21 CFR 312.21(a)].

Phase 2 Clinical Trials – Phase 2 trials include controlled clinical studies conducted to evaluate the drug's effectiveness for a particular indication in patients with the disease or condition under study, and to determine the common short-term side effects and risks associated with the drug. These studies are typically well-controlled, closely monitored, and conducted with a relatively small number of patients, usually involving no more than several hundred subjects [21 CFR 312.21(d)].

Phase 3 Clinical Trials – Phase 3 trials involve the administration of a new drug to a larger number of patients in different clinical settings to determine its safety, efficacy, and appropriate dosage. They are performed after preliminary evidence of effectiveness has been obtained, and are intended to gather necessary additional information about effectiveness and safety for evaluating the overall benefit-risk relationship of the drug, and to provide an adequate basis for physician labeling. In Phase 3 studies, the drug is used the way it would be administered when marketed. When these studies are completed and the sponsor believes that the drug is safe and effective under specific conditions, the sponsor applies to the FDA for approval to market the drug. Phase 3 trials usually involve several hundred to several thousand subjects [21 CFR 312.21(c)].

Phase 4 Clinical Trials – The FDA, when it gives market approval, may seek an agreement from the sponsor to conduct certain postmarketing studies to ascertain additional information about the drug's risks, benefits, and optimal use. These studies could include, but would not be limited to, studying different doses or schedules of administration than were used in Phase 2 studies, use of the drug in other patient populations or other stages of the disease, or use of the drug over a longer period of time [21 CFR 312.85].

Possibly related - There is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.

Public Health Service (PHS) – A division within the DHHS. PHS agencies include the National Institutes of Health, Centers for Disease Control, the Indian Health Service, and the Substance Abuse and Mental Health Services Administration.

Placebo – In biomedical research, a chemically inert substance given in the guise of medicine for its psychologically suggestive effect; used in controlled clinical trials to determine whether improvement and side effects may reflect imagination or anticipation rather than the actual power of a drug. In social and behavioral research, a condition that mimics the experimental context but does not include the experimental manipulation under study. As in biomedical research, the control condition is used to confirm that observed effects are the result of the experimental manipulation rather than the research context itself.

Pregnancy – The period of time from confirmation of implantation of a fertilized egg within the uterus until the fetus has entirely left the uterus (i.e., has been delivered). Implantation is confirmed through a presumptive sign of pregnancy such as missed menses or a positive pregnancy test [45 CFR 46.203(b)]. This confirmation may be in error, but, for research purposes, investigators must presume that a living fetus is present until evidence to the contrary is clear. Although fertilization occurs a week or more before implantation, the current inability to detect the fertilization event or the presence of a newly fertilized egg makes a definition of pregnancy based on implantation necessary.

Principal Investigator (PI) – An individual who has primary responsibility for the design, execution, and conduct of a research project. The PI bears direct responsibility for protecting every research subject.

Public Responsibility in Medicine and Research (PRIM&R) – A non-profit organization that organizes conferences, workshops, and other activities to further the protection of human subjects in research.

Prisoner – An individual involuntarily confined or detained in a penal institution, including persons: (1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities (e.g., for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution; or (4) incarcerated in a penal institution [45 CFR 46.303(c)].

Prisoner Representative – A member of an IRB who has appropriate background and experience to represent the interests and concerns of an individual who is involuntarily confined to an institution [45 CFR 46.304(b)].

Privacy – Concealment from others of information about oneself.

Protocol – The formal design or plan of an experiment or research activity. The protocol includes a description of the research design or methodology to be employed, the eligibility

requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Random Assignment – Assignment of subjects to different treatments, interventions, or conditions according to chance.

Recruitment – The process of enrolling human subjects in research protocols.

Research – Under the Federal Policy and the DHHS Subpart A, research is a systematic investigation designed to develop or contribute to generalizable knowledge [45 CFR 46.102(d)]. Under FDA regulations, "research" is synonymous with "clinical investigation" [21 CFR 56.102(c)].

Respect for Persons – A principle enunciated in the Belmont Report stating that (1) individuals should be treated as autonomous agents, and, (2) persons with diminished autonomy are entitled to protection.

Risk – The probability of harm or injury occurring as a result of participation in a research study.

Secretary – In the context of the federal regulations pertaining to the protection of human subjects in research, refers to the head of a federal agency [45 CFR 46.102(a)].

Serious adverse event - is described as any adverse event that:

(1) results in death;
(2) is life-threatening (places the subject at immediate risk of death from the event as it occurred);
(3) results in inpatient hospitalization or prolongation of existing hospitalization;
(4) results in a persistent or significant disability/incapacity;
(5) results in a congenital anomaly/birth defect; or
(6) based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).
(7) event(s) occurring in a gene therapy study and/or
(8) event(s) that changes in the risk/benefit ratio of the study or places the subject(s) or others at a greater risk of harm than previously known.

Serious Non-compliance is defined by the THR to be failure to comply with laws or regulations, THR policies, or the requirements or determinations of the IRB when that failure actually or potentially increases risk to subjects adversely affects the rights, welfare and safety of the research subjects or adversely affects the scientific integrity of the study. Willful violation of policies, state and local laws, and/or federal regulations may also constitute serious noncompliance. A single instance of non-compliance may be determined by the IRB to be serious non-compliance.

Site Visit – Typically refers to a visit from a federal office to ensure the entity is complying with federal regulations.

Sponsor – Typically refers to the entity that initiates a clinical investigation but does not actually conduct the investigation [21 CFR 50.3(e) and 56.102(j)].

Sponsor-Investigator – An individual who both initiates and actually conducts a clinical investigation [21 CFR 50.3(f) and 56.102(k)].
Study Coordinator- Responsible for management and facilitation of the research project under the direction of the PI.

Study Personnel – Individuals who are directly involved in conducting research with human participants, or are directly involved with handling identifiable private information related to those participants in the course of a research project, regardless of the source of research funding. Students who are directly involved in either aspect of research involving humans are considered key personnel. All key personnel are required to obtain human subject protection training, all other required research training per THR research training policy and submit a conflict of interest report.

eIRB Study Staff Role - Assists investigator in carrying out study protocol

Subjects – See "Human Subject."

Subpart A – The DHHS codification of the Federal Policy for the Protection of Human Subjects in Research is found in Subpart A of 45 CFR Part 46.

Subpart B – Subpart B of the DHHS regulations [45 CFR Part 46] contains additional protections for pregnant women and fetuses that are involved in research, and references human in vitro fertilization research.

Subpart C – Subpart C of the DHHS regulations [45 CFR Part 46] contains additional protections for prisoners who are involved in research.

Subpart D – Subpart D of the DHHS regulations [45 CFR Part 46] contains additional protections for children who are involved in research.

Surveys – Studies designed to obtain information from human subjects through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.

Suspension – Typically used in the context of a federal agency taking action against an institution. For example, the Office for Human Research Protections can suspend an Assurance, preventing the institution from continuing to conduct studies supported with federal funds.

Systematic Investigation Defined - The systematic gathering and analysis of information.

Test Article – Any drug, biological product for human use, medical device for human use, human food additive, color additive, electronic product subject to FDA regulations under 42 USC 262, 263b-263N [21 CFR 50.3(j) and 56.102(e)].

Tuskegee – Often used erroneously to refer to the U.S. Public Health Service Syphilis Study in Tuskegee, Alabama.

Undue Influence – This refers to a prohibition in the Common Rule that investigators not use unfair measures or influence to enroll persons in research [45 CFR 46.116].

Unaffiliated Member – See "Non-affiliated member."

Unanticipated Adverse Device Effect - Unanticipated adverse device effect means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects (21 CFR 812.3(s)).

Unanticipated Problems Involving Risks to Subjects or Others – This is a regulatory phrase which requires reporting of this event to the IRB and to the government [45 CFR 46.103(d)(5); 21 CFR 56.108(b)].

Unexpected Adverse Event (see also Expected Adverse Event) – An adverse event is defined as being unexpected if the event exceeds the nature, severity, or frequency described in the current THR application including the protocol, consent form and investigator brochure (when applicable). An unexpected AE also includes any AE that meets any of the following criteria:
-Results in subject withdrawal from study participation,
-Due to an overdose of study medication, or
-Due to a deviation from the THR approved study protocol

Voluntary – Free of coercion, duress, or undue influence.

Vulnerable population – This is a regulatory phrase which refers to a group of people who have some condition or situation that makes them more susceptible to coercion or undue influence [45 CFR 46.107(a)].

Waiver of Informed Consent – An action taken by the IRB permitting the investigator to pursue research involving human subjects without obtaining informed consent [45 CFR 46.116(d)].