GLOSSARY OF DEFINITIONS

**Acting Board Chair** – An individual with relevant scientific/clinical background and expertise in research methods who is named by the Chair and/or the RSRB Director, to lead convened meetings and conduct specific administrative duties in the absence of the Chair. This individual must be an experienced board member in order to fulfill this role.

**Administrative review** - A review of a research protocol and supporting documents (e.g., safety review, scientific review, IRB minutes) to ensure the institution engaged in the research involving human subjects has met the requirements of all applicable regulations and policies. This review is NOT an IRB review.

**Adverse Event** – Any undesirable and unintended (although not necessarily unexpected) effect occurring as a result of interventions, interactions, or collection of identifiable private information in research. In medical research, any untoward physical or psychological occurrence in research, including abnormal laboratory finding or newly identified or worsening symptom(s) or disease(s) that occurs during the conduct of a research study.

**Allegation of Non-Compliance** – An unproven assertion of non-compliance.

**Alternate Board Member** – A member formally appointed and listed in the membership roster who may substitute for a primary member with whom the alternate has similar qualifications. Experienced members may be asked to continue as alternates when their terms expire or when their workload prevents them from carrying out their duties.

**Approval Date** – The date the IRB decision was made by the convened board, RSRB Chair, Vice Chair, or Experienced Member indicating all requirements of the approval criteria were met. It is also the first date that research can be performed (following notification from the RSRB), consistent with federal regulations, state and local laws, and University policy (i.e., other approvals/notices may be required before the research may proceed).

**Approval Period** – The duration of approval which begins on the day research is approved by the convened board or the RSRB Chair, Vice Chair, or Experienced member through and inclusive of the Expiration Date.
  - When continuing review is required, the approval period may not be longer than one year after that approval date.
  - When continuing review is not required, the approval period will continue until the date the study is closed (i.e., approval will not expire).

**Assent (minors)** – A child’s affirmative agreement to participate in research. Failure to object is not assent. Resistance to a research procedure in a non-verbal subject is an indication of dissent for that procedure.
**Assent (adults with decisional impairment)** – An affirmative agreement to participate in research given by a person with decisional impairment. Failure to object is not assent. Resistance to a research procedure in a non-verbal subject is an indication of dissent for that procedure.

**Authorization** – An individual’s written permission to allow the use or disclosure of specified protected health information for specified purposes, the contents of which comply with the required elements and statements under the HIPAA Privacy Rule.

**Biological Sample or Biospecimen** – Any material part or discharge of the human body known to contain DNA, such as tissue specimen, blood or urine.

**Board Chair/Vice Chair** – An individual with relevant scientific/clinical background and expertise in research methods who is appointed by the Institutional Official to lead convened meetings and conduct administrative duties required for a successful operation of the Board.

**Child** – A person who has not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted [45 CFR 46.402(a)]. In New York, the legal age for consent to treatments or procedures is 18. A child (sometimes referred to in this policy as a “minor”)

**Classified research involving human subjects** - Research involving human subjects where the protocol or other information required by the IRB for review and oversight, or required or provided by the research subjects, includes classified information.

**Clinical and Regulatory Systems (Systems)** – A division of the Office for Human Subject Protection (OHSP) that manages and maintains the OHSP applications and systems.

**Clinical Investigation** – Sometimes referred to as a clinical trial, is a study in which one or more human subjects are prospectively assigned to one of more interventions (inclusive of placebo or other control) to evaluate effects of the interventions(s) on biomedical or behavioral health-related outcomes.

- When the intervention is the use of a study drug; in which a drug is administered or dispensed to, or used, involving one or more human subjects (i.e., an experiment is any use of an approved or unapproved drug, except for the use of a marketed drug in the course of medical practice). A “marketed drug” is a drug that has been approved by the FDA and cleared for sale.
- When the intervention is the use of device, it is research involving one or more subjects to determine the safety or effectiveness of the device.

**Commerially Sponsored IND** – An IND submitted primarily by a company to conduct a clinical trial with the goal to obtain marketing approval for a new product.
Confidentiality – The process or method for ensuring that information collected from a subject is protected from inadvertent disclosure to persons/entities not authorized to have access to such information.

Conflict of Interest – A divergence between an individual’s private interests and his or her professional obligations to the University and its constituents (i.e., any situation or relationship that biases or has the potential to bias the conduct or outcome of the RSRB review).

Consent Capacity – An individual’s ability to understand the information relevant to making an informed, voluntary decision to participate in research.

Consent by Legally Authorized Representative (LAR) – The agreement given by a legally authorized representative to the participation in research of a person with decisional impairment.

Consultant – An individual who may be requested to provide additional scientific and/or specialty expertise to the board as necessary. Consultants are not permissible as voting members.

Continuing Non-Compliance – Continuing Non-Compliance: Non-compliance that, in the judgment of the convened board, persists when there is:
- evaluation by the convened board,
- notice to the Investigator,
- prior submission of a corrective action plan(s), and
- lack of evidence of effective efforts towards resolution by the Investigator.

These events may or may not result in increased risk to subjects and may be due to a variety of factors. The non-compliance might imply that an Investigator is either unwilling or unable to develop and apply successful corrective measures.

Convened Board Review – Review of proposed human subject research by an Institutional Review Board that meets the membership requirements specified in federal regulations.

Corrective and Preventative Action (CAPA) – A plan identified by the Investigator to address any deficiency (finding) noted in the QI report, and is a straightforward, measurable solution to address the root cause and prevent the issue from occurring again in the future.

Covered Entity – A health plan, a health care clearinghouse, or a health care provider who transmits any health information in electronic form in connection with a standard transaction. See the University of Rochester Medical Center and Affiliates Notice of Privacy Practices for a list of all applicable facilities.

Data Monitoring Committee (DMC), Safety Monitoring Committee (SMC) or Data and Safety Monitoring Board (DSMB) – A formal committee of qualified individuals with relevant subject-matter expertise and who do not have any conflicts of interest (i.e., financial, intellectual, professional or regulatory) with the research established to review interim data to assess both safety and efficacy, and issue recommendations regarding the continuation, modification or termination of the study. Functions under a governing charter and membership may include health
professionals, laboratory scientists, statisticians, and ethicists, as well as, patient advocates. Depending upon the requirements of the study and the determination of the IRB, this committee/board can either be independent or include individuals involved in the conduct of the study.

**Data and safety monitoring** – The process for reviewing cumulative data throughout an ongoing study to ensure the safety of the study subjects and continued validity and scientific merit.

**Data and Safety Monitoring Plan (DSMP)** – A written plan outlining the appropriate oversight and monitoring of the conduct and progress of the study to ensure that important information that may affect the safety or welfare of subjects is collected, recognized and acted upon as quickly as possible, and to ensure the validity and integrity of the research data.

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

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

**DHHS** – Department of Health and Human Services (HHS)

**Dietary Supplement** – A product taken by mouth that is intended to supplement the diet and contains one or more dietary ingredients (e.g., vitamins, minerals, herbs, amino acids, extracts, combinations of preceding examples).

**Directory Information** – Information means information contained in an Education Record of a student that would not generally be considered harmful or an invasion of privacy if disclosed. It includes, but is not limited to, the student's name, address, telephone listing, electronic mail address, photograph, date and place of birth, major field of study, dates of attendance, grade level, enrollment status (e.g., undergraduate or graduate; full-time or part-time), participation in officially recognized activities and sports, weight and height of members of athletic teams, degrees, honors and awards received, and the most recent educational agency or institution attended.

**Disclosure of Data** - Disclosure occurs when individually identifiable health information is given to someone who is not an employee, student, volunteer or otherwise under the direction and control of the URMC and Affiliates covered entity. For example, showing source documentation to a representative of a clinical trial’s sponsor is a disclosure even if the representative does not physically remove any PHI from the research site.

**DoD Addendum** - An application to the Department of Defense attesting that the University of Rochester (DoD N-A-0039) will comply with all relevant federal regulations, DoD Instructions and Directives, and other relevant documents regarding the protection of human subjects in research.
**DoD Personnel** - DoD civilian employees and members of the military services.

**Drug** – Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and articles (other than food) intended to affect the structure or function of the body.

**Education Program** - Any program that is principally engaged in the provision of education, including, but not limited to, early childhood education, elementary and secondary education, postsecondary education, special education, job training, career and technical education, and adult education, and any program that is administered by an educational agency or institution.

**Education Records** - Records that are directly related to a student; and maintained by an educational agency or institution or by a party acting for the agency or institution. For more information on what is and is not included, please visit 20 U.S.C. § 1232g; (4) (A) and (B).

**Effective Date** - The date the RSRB decision takes effect. This is the first possible date research can be performed (following notification from the RSRB), consistent with federal regulations, state and local laws, and University policy (i.e., other approvals/notices may be required before the research may proceed).

- When the study is approved with no modifications, this date is the same as the approval date.
- When modifications are required to secure approval, the effective date is the date the modifications are reviewed and accepted.

**Eligible Student** - Any individual who is or has been in attendance at an educational agency or institution and regarding whom the agency or institution maintains education records, except as otherwise specifically provided in this part. If less than 18 years of age, notify parents and obtain consent or allow the parent to opt his/her child out of participating in certain school activities.

**Emergency Use** – The use of an unapproved test article in a human subject in a life-threatening situation in which no standard acceptable treatment is available, and in which there is not sufficient time to obtain IRB approval.

**Emergency Use IND** – A type of expanded access where the FDA issues authorization to ship and allow use of an investigational drug or biologic for the treatment of one patient or patients and there is not time for submission and review of a regular IND or for convened RSRB review.

**Employee or Agent** – An individual who: (1) acts on behalf of the institution; (2) exercises institutional authority or responsibility; or (3) performs institutionally designated activities, including but not limited to staff, students, contractors, and volunteers, regardless of whether the individual is receiving compensation.

**Event or Problem** – An incident, experience, or outcome that occurs during the conduct of a research study that may require reporting to the RSRB, Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), and/or the Sponsor.
**Expanded Access** – A mechanism within the FDA IND regulations for allowing use of investigational and approved drugs for patients with life-threatening or serious diseases or conditions when there is no comparable or satisfactory alternative therapy, for the primary purpose of diagnosing, monitoring, or treating a patient’s disease or condition. The use of an investigational device outside of a clinical trial for treatment of a patient.

**Expedited Review** – Process by which an RSRB Chair or an experienced RSRB member approves minimal risk research that falls into one or more types of research categories designated by the Office for Human Research Protections.

**Experienced Board Member** – A member, as determined by the Chair, who has demonstrated during a period of active participation, a broad understanding and competency with human subject protection ethics, board operations, and regulatory requirements, including expedited and limited IRB review procedures.

**Expiration Date or Last Date of Approval Period** – The last date on which the research protocol is RSRB approved and research activities can be performed. An expiration date may not be more than one year from the date the approval period begins.

**External Event** – An event occurring in a research study conducted by non-UR employees or agents. The study may be approved by the RSRB or an external Reviewing IRB.

**External Research Personnel** – Individuals not acting as an employee or agent of the UR as defined by Policy 102 University of Rochester’s Human Research Protection Program.

**Family Educational Rights and Privacy Act (FERPA)** - is a Federal law administered by the U.S. Department of Education; 34 CFR Part 99. FERPA applies to all educational agencies and institutions that receive federal funding.

**Family Members** – Members of the immediate family, specifically dependents, spouses and domestic partners.

**Fetus** – The product of conception from implantation until delivery.

**FWA** – Federalwide Assurance; certifies with the Department of Health and Human Services that the UR will comply with the HHS regulations for the protection of human research subjects.

**Greater Than Minimal Risk** – The probability and magnitude of harm or discomfort anticipated in the research are greater than those ordinarily encountered in everyday life or during the performance of routine physical or psychological examinations or tests.

**Genetic Predisposition** – The presence of a variation in the composition of the genes of an individual or an individual’s family member that is scientifically or medically identifiable, and that is determined to be associated with an increased statistical risk of being expressed as either a
physical or mental disease or disorder in the individual or having offspring with a genetically influenced disease, but which has not resulted in any symptoms of such disease or disorder.

**Genetic Test** – Any laboratory test of human DNA, chromosomes, genes or gene products to diagnose the presence of a genetic variation linked to a predisposition to a genetic disease or disorder in the individual or the individual’s offspring.

- Examples are tests for breast cancer, prostate cancer, Huntington disease, sickle cell anemia, etc…
- The RSRB does not consider genetic testing to include studies of gene expression.

**Group C Treatment IND** – Under agreement between FDA and the National Cancer Institute (NCI), a mechanism for distribution of an investigational agent to oncologists for treatment of cancer under protocols outside the controlled clinical trial. Group C drugs are distributed only by the National Institutes of Health (NIH) under NCI protocols.

**Guardian** – An individual who is appointed by a court as the legal guardian of a child.

**Health Information** – Any information including genetic information, whether oral or recorded in any form or medium, that:

- Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and
- Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

**HRPP** – Human Research Protection Program

**Humanitarian Device Exemption (HDE)** – An application approved by the FDA for use of a HUD which is exempt from the effectiveness requirements of section 514 and 515 of the Food, Drug, and Cosmetic Act.

**Humanitarian Use Device (HUD)** – A medical device intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4,000 people in the United States per year.

**Human Gene Transfer** - The deliberate transfer into human research subjects of either:

- Recombinant nucleic acid molecules, or DNA or RNA derived from recombinant nucleic acid molecules, or
- Synthetic nucleic acid molecules, or DNA or RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria:
  o Contain more than 100 nucleotides;
  o Possess biological properties that enable integration into the genome (e.g., cis elements involved in integration);
  o Have the potential to replicate in a cell;
Human Subject (HHS) – A living individual about whom an investigator (whether professional or student) conducting research obtains:

- Obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; OR
- Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Human Subject (FDA) – An individual who is or becomes a participant (“subject”) 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. For research involving medical devices, a human subject is also an individual on whose specimen an investigational device is used.

Human Subject Research – any activity that either:

- Meets the HHS definition of research and involves human subjects as defined in the HHS regulations; OR
- Meets the FDA definition of research and involves human subjects as defined in FDA regulations

Identifiable Biospecimen – A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Identifiable Private Information – Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Immediately Life Threatening Disease or Condition – Stage of disease in which there is the reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment, inclusive of sight-threatening or limb-threatening conditions, as well as other situations involving risk of irreversible morbidity, or the patient is in the stage of disease that requires intervention before review at a convened meeting of the IRB is feasible.

Implant – A device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more.

Independence – Individuals external to the study organizers, Investigators, and those related to the study who perform the data and safety monitoring. Aside from being paid for their duties, it is expected that these individuals have no ongoing financial relationship with a study’s sponsor and are not involved in the conduct of the study in any role other than that of an SM, DMC, SMC, or DSMB member. Further guidance within the FDA Guidance for Clinical Trial Sponsors Establishment and Operation of Clinical Trial Data Monitoring Committees.

Individually Identifiable Health Information – Information that is a subset of health information, including demographic information collected from an individual, and:
- Is created or received by a health care provider, health plan, employer, or health care clearinghouse; AND
- Relates to the past, present, or future physical or mental health or condition of an individual; 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,
- That identifies the individual; OR,
- With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

**Informed Consent** – An ongoing process of information exchange that takes place between the potential subject and the Investigator, which begins at the time the potential subject initially learns about the research and continues throughout the course of the study.

**Institutional Conflict of Interest** – A situation where the financial interests of the University might directly or significantly affect institutional processes for the conduct, direction, review or oversight of research. This may apply through the institution having a financial interest or through an institutional leader having a financial interest.

**Institutional Official (IO)** – The individual who has the authority (as delegated by the President of the University of Rochester) to oversee the implementation and maintenance of the Human Research Protection Program.

**Institutional Leader** – An individual who has significant administrative authority and responsibility over issues involving research (i.e., the type of authority normally exercised by an officer, dean, department chair, division chief in a clinical department, or center director).

**Institutional Review Board (IRB)** – The committee formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, research involving human subjects. The IRB at the University of Rochester is the Research Subjects Review Board (RSRB).

**Interaction** – Includes *communication or interpersonal contact* between the investigator/research team and the subject.

**Internal Event** – An event occurring in a research study conducted by employees or agents of the University of Rochester (UR). The study may be approved by the RSRB or an external Review IRB.

**Internal Research Personnel** – An employee or agent of the UR as defined by Policy 102 University of Rochester’s Human Research Protection Program.

**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.
Investigational Device – A medical device, including a transitional device*, that is the object of a clinical study designed to evaluate the effectiveness and/or the safety of the device.

*Transitional device is one that was previously regulated as a new drug before 5/28/1976

Investigational Device Exemption (IDE) – An application submitted to the FDA for an investigational device to be used in a research study in order to collect safety and effectiveness data required to support requests to legally market a device.

Investigational Drug – A new drug or biological drug that is used in a clinical investigation. Also includes a biological product this is used in vitro for diagnostic purposes. Examples of types of studies where an investigational drug is used includes:

- A drug in any of the clinical stages of evaluation (i.e., Phase 1, 2, 3), which has not been approved by the FDA for general use or cleared for sale in interstate commerce.
- A marketed drug involved in a post-marketing surveillance (i.e., Phase 4) study.
- A marketed drug proposed for a new use.
- A marketed drug to be used in new dosage form or method of administration.
- A marketed drug that contains a new component.
- A new combination of two or more marketed drugs.
- A combination of marketed drugs in new proportions.

Investigational New Drug Application (IND) – A request for FDA authorization to administer an investigational drug to humans. If required, such authorization must be secured before RSRB approval of the research study, and prior to interstate shipment and administration of the investigational drug.

Investigator – Any individual who is responsible for the administration, design, conduct, or reporting of sponsored research, internally funded research that involves human subjects, or proposals for such funding. This term also includes study coordinators, and may also include other individuals as determined by the Dean.

Investigator Initiated Research – Pertains to the individual(s) who wrote the protocol. For FDA-regulated research this individual is called a “sponsor-investigator”.

Legally Authorized Representative (LAR) – An individual authorized to consent on behalf of a prospective subject. Federal regulations (45 CFR 46.116 and 21 CFR 50.20) defer to state law for persons authorized to provide such consent. Per New York State law, another individual is legally authorized to consent on behalf of a prospective adult subject for the subject’s participation in research under the following categories:

- A health care agent and proxy (authorized under New York Public Health Law, Article 29-C);
- A guardian appointed under the Mental Hygiene Law, Article 81;
- An individual appointed by the prospective subject under an Advance Directive for Medical Research Participation (research proxy);
- In certain instances, a family member or close friend according to Article 29-CC (Family Health Care Decision Act); or, other relevant law.

*Medical Device* – An instrument, apparatus, implement, machine, or other similar or related article which is intended for diagnostic purposes, or in the cure, mitigation, treatment, or prevention of disease, or which does not achieve its primary intended purposes by chemical action or by being metabolized.

*Minimal Risk* – The probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

*Minimal Risk (for Prisoner Research)* - 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 (non-incarcerated) persons.

*Minor Modification* – Changes to the research that, in the judgment of the RSRB, do not substantially alter the research aims or methodology, nature of subject participation, level of risk, proposed benefits, or subject population; such that the increase of risk is no more than minimal. Examples include, but are not limited to, addition of research locations or participating sites (for multi-site research), administrative changes to protocol or protocol related documents.

*Neonate* – A new born who is between the stage of delivery and determination of viability.

*Non-Compliance* – Failure to follow the federal, state, or local regulations or laws governing the protection of human subjects in research, institutional policies related to human subject research, or the requirements or determinations of the RSRB/IRB of record with respect to the conduct of the research as approved.

*Non-Invasive* – As applied to a diagnostic device or procedure, is one that does not by design or intention:

- Penetrate or pierce the skin, mucous membranes of the body, the ocular cavity, or the urethra, OR
- Enter the ear beyond the external auditory canal, the nose beyond the nares, the mouth beyond the pharynx, the anal canal beyond the rectum, or the vagina beyond the opening of the cervix.

*Non-Significant Risk Device* – An investigational device that does not present a potential for serious risk to the health, safety, or welfare of the subject.

- Examples include: most daily wear contact lenses, lens solutions, heel cups, antibacterial surgical garments, incontinence devices, oral training splints, and ultrasonic tooth cleaners.

*Nonviable Neonate* – A neonate after delivery that, although living, is not viable.
Office for Human Subject Protection (OHSP) – The department at the UR delegated the authority by the IO for daily administration of the Human Research Protection Program and oversight of human subject research.

Open Label IND – A mechanism for carrying out a study to obtain additional safety data once the controlled study has ended to provide continued treatment so subjects may receive the benefits of the investigational drug until marketing approval is obtained.

Other Modification – Changes to the research submission that do not fall under an expedited review category, or as a minor modification to the research.
- Examples include, change of study team members except for the Principal Investigator, documents requiring re-formatting only, administrative corrections to the application that do not change the research, corrections to approval dates.

Parent – A child’s biological or adoptive parent.

Personally Identifiable Information (PII) – The term includes but is not limited to a student’s name; the name of the student’s parent or other family members; the address of the student or student’s family; a personal identifier, such as the student’s social security number, student number or biometric record; other indirect identifiers, such as the student’s date of birth, place of birth, and mother’s maiden name; other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstance, to identify the student with reasonable certainty; or information request by a person who the educational agency or institution reasonably believes knows the identity of the student to whom the education record relates.

Persons with Decisional Impairment – Adults who are 18 years of age and older who lack full consent capacity due to a temporary, permanent, progressive, or fluctuating inability to understand or process sufficient information about the study to reach a valid, self-directed, voluntary decision about participation.

Phase 1 Clinical Trial – The initial introduction of an investigational new drug into humans. These studies are closely monitored and are usually conducted in healthy human volunteers and are designed to determine the metabolic and pharmacological actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. These studies also evaluate drug metabolism, structure-activity relationships, and the mechanism of action in humans. Assessment of safety and adverse events is the primary objective.

Phase 2 Clinical Trial – Early controlled clinical studies conducted to obtain preliminary data on the effectiveness of the drug for a particular indication(s) in patients with the disease or condition. This phase also helps determine the common short-term side effects and risks associated with the drug, and may be conducted to determine optimal drug dosing.
**Phase 3 Clinical Trial** – Intended to gather the additional information about effectiveness and safety needed to evaluate the overall risk-benefit relationship of the drug. These studies also provide an adequate basis for providing information to the general population about the drug and for development of information for physician labeling.

**Phase 4 Clinical Trial** – Post-marketing studies of an FDA-approved drug in order to gain more information (e.g., to further study the incidence of a specific adverse reaction or the long-term effects of the drug on morbidity and mortality). Studies may include, for example, evaluation of different dosages or schedules of administration, use of the drug in other stages of the disease, use of the drug over a longer period of time, or, if approved for use in adults, use of the drug in a pediatric population.

**Pregnancy** – The period of time from confirmation of implantation of a fertilized egg within the uterus until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

**Principal Investigator** – An individual who meets the qualifications and requirements outlined in the University of Rochester “Principal Investigator Eligibility Policy” (regardless of funding source) and who has the full and final responsibility for the conduct of the approved research.

**Prisoner** – Includes any individual who is:
- Involuntarily confined or detained (i.e., ability to leave institution is restricted) in a penal institution (e.g., prison, jail, juvenile offender facility);
- Detained in other facilities by virtue of statues or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, or is;
- Detained pending arraignment, trial or sentencing.

**Prisoner of War (POW)** - A detained person as defined in Articles 4 and 5 of the Geneva Convention Relative to the Treatment of Prisoners of War of August 12, 1949. In particular, one who, while engaged in combat under orders of his government, is captured by the armed forces of the enemy.

**Prisoner Representative** – A member formally appointed and listed in the membership roster who has the appropriate background, experience and working knowledge to provide an understanding and appreciation of prison conditions from the prisoner's perspective.

**Privacy** – Having the control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

**Private Information** – 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 that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., medical, employment and educational records).
**Protection of Pupil Rights Amendment (PPRA)** - A Federal law administered by the U.S. Department of Education; 34 CFR Part 98. PPRA applies to programs and activities of an educational agency or other recipient of funds under any program funded by the U.S. Department of Education. PPRA also applies to any research funded by the U.S. Department of Education. In summary, under PPRA parents and students must be notified of any event where students will disclose personal information or complete a survey/evaluation concerning eight specific areas; parents must have the opportunity to opt their child out of participating and may inspect the instrument being administered to the student prior to its administration.

**Protected Health Information (PHI)** – Includes but is not limited to any information that is created or received by a health care provider that relates to:
- The past, present, or future physical or mental health or condition of an individual; or
- Provision of health care to an individual; or,
- The past, present, or future payment for the provision of health care to an individual.

**Protected Information Surveys** - The Protection of Pupil Rights Amendment (PPRA), 20 U.S.C. § 1232h, identifies eight specific protected areas (“protected information surveys”):
- Political affiliations or beliefs of the student or student’s parent;
- Mental or psychological problems of the student or student’s family;
- Sex behavior or attitudes;
- Illegal, anti-social, self-incriminating, or demeaning behavior;
- Critical appraisals of others with whom respondents have close family relationships;
- Legally recognized privileged relationships, such as with lawyers, doctors, or ministers;
- Religious practices, affiliations, or beliefs of the student or parents; or
- Income, other than as required by law to determine program eligibility.

**Quality Improvement (QI)** – A division of the Office for Human Subject Protection responsible for reviewing research conducted by the University of Rochester to monitor activities are conducted in accordance with IRB requirements, the approved protocol, applicable Federal regulations, University of Rochester policies, and good clinical practice (GCP) standards. The effort to assess and take measures to improve the level of performance of a program, process, or institution.

**Quality Improvement Review** – A comprehensive, systematic, and independent assessment of study-related activities and documents to evaluate compliance with ethical principles, IRB approved protocols, applicable federal and state regulations, UR policies and guidelines and OHSP policies and guidelines, when applicable.

**Quality Improvement Reviewers** – OHSP staff who conduct QI reviews and consultations.

**Quality Improvement Review Types** - The types of QI reviews established by the QI program as defined below:
 **Routine**: A comprehensive on-site QI review to provide a regulatory assessment of study compliance. Routine reviews include a selected sample of human subject research conducted across the University. The selection of studies is a risk-based determination and may be made on such factors as risk of the study, enrollment of vulnerable populations, and degree of external oversight.

 **Directed**: A comprehensive or targeted (i.e. the consent process) on-site QI review requested by the RSRB or an External IRB AdHoc committee to provide an assessment of study compliance. The review may be focused on one aspect of the research or may be a more broad review of study conduct.

 **Site-Requested**: A comprehensive or targeted QI review requested by an Investigator. These reviews are conducted within the limitations of available resources.

**Quality Management Plan (QMP) Consultation** – A comprehensive, on-site consultation to provide resources that guide, integrate, and enhance continuous quality improvement for a research site, research program, or department/division. The reviewer focuses on aiding the study team to set-up, implement, evaluate, and/or prioritize areas of potential risk to target within their quality management plan.

**QI Review Final Report** – A written report incorporating a brief description of the study and the results of the QI Review, including detailed findings, Investigator Response and Corrective and Preventative Action plan to each finding, and the review rating.

**QI Review Finding** – A noted deficiency during a QI review.

**QI Review Findings Index** – A central database of review findings maintained by the Director of Quality Improvement.

**QI Review Rating** – A summary rating applied to each routine, for-cause, or site-requested QI review, based upon the quantity and severity of the review findings. The review rating is dependent upon whether or not subjects have been consented in the study and whether or not consent is required.

**Quality Improvement Study Start Up or Quality Management Plan Consultation Summary** - A written report incorporating a brief description of the study and a summary of all discussion points from the in-person discussion. The summary is meant to guide the continued actions of the study team as they progress through the conduct of the approved study.

**Quality Improvement RSRB Audits** – An internal audit conducted by the reviewer for each review or consultation. Audit content is determined in collaboration with the Ad Hoc RSRB Audit Committee [comprised of the Associate Vice President for Human Subject Protection, the RSRB Executive Director, the Quality Improvement Director, and RSRB Senior Specialist] and is applied consistently to each study. Audit results are discussed bi-annually with the Ad Hoc RSRB Audit Committee.
Recombinant Nucleic Acid – Molecules that are constructed by joining nucleic acid molecules and can replicate in a living cell.

Recruitment Materials – Material potential subjects will see or hear that is used as part of the recruitment process, including web sites, flyers, posters, newspaper ads, television or radio ads, brochures, doctor-to-patient or Investigator-to-subject letters, social media ads (e.g., Facebook, Twitter), or any other material used as a recruitment method.

Recruitment Methods – The means used to identify potential research subjects, or to draw potential research subject’s attention to research, including but not limited to identification through records and recruitment materials.

Reliance or IRB Authorization Agreement – A formal, written document that provides a mechanism for an institution engaged in research to delegate IRB review to another IRB, such as an independent IRB or another institution’s IRB, and document respective authorities, roles, responsibilities, and communication between the Reviewing and Relying IRBs. The agreement may apply to a single study or to certain categories of studies. Institutions may use different descriptive terms, e.g., reliance agreement, cooperative agreement, IRB authorization agreement (IAA), or memorandum of understanding (MOU).

Relying IRB – The Institutional Review Board (IRB) that delegates the responsibility of IRB review and approval to another IRB.

Research involving a human being as an experimental subject - an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction.

Research Monitor - An individual with expertise commiserate with the research protocol and the nature of the risk, whose role is to protect the safety and well-being of human subjects. The Research Monitor may be a member of the RSRB, another individual designated by the RSRB, or a member of the data and safety monitoring board. The Research Monitor shall be independent of the research team.

Research Proxy – An individual designated by the subject to make decisions regarding the subject’s participation in research. The research proxy may be named under the following circumstances:

- The prospective subject/subject has full consent capacity and the named individual will make decisions at a time in the future when the subject lacks full consent capacity; OR,
- The prospective subject/subject has decisional impairment and lacks full consent capacity, but retains sufficient capacity to choose a research proxy to act as his/her representative to give consent to initial or continued study participation.

Related to the Research – There is some aspect of the study (e.g., research procedure, existence of a laptop database) that is directly related to or associated with the event (e.g., physical
harm/adverse event, breach of confidentiality). “Directly” means possibly, probably, or definitely related to the study drug, the device, a study procedure or participation in the study.

Research (HHS) – A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. A “systematic investigation” generally means that there is a study plan/protocol that is followed. Contributing to “generalizable knowledge” means that there is or will be a report, publication, poster, communication, etc. that provides the results and conclusions of the research to other people/clinicians/researchers outside the department/institution.

Research (FDA) – Any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the FDA under these sections of the Food, Drug and Cosmetics Act, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. For research involving drugs, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice.

Research Education and Training (Education) – A division of the Office for Human Subject Protection responsible for education and training of the research community at the University of Rochester.

Research Risk – The probability of harm or injury occurring as a result of participation in a research study. The type of the risk/s (physical, psychological, social, legal, or economic) as well as probability and magnitude are variables that determine the overall risk exposure.

Research Subjects Review Board (RSRB) – A system of institutional review boards established by the University President and the Board of Trustees.

Research Subjects Review Board (RSRB) Office – The OHSP division that operates the institutional review boards for the University of Rochester.

Reviewing IRB (IRB of Record) – The Institutional Review Board (IRB) designated to review and approve human subject research as per 45 CFR 46.111 and in accordance with the Reliance Agreement.

Safety Monitor (SM) – A qualified professional with relevant subject-matter expertise whose primary responsibility is to provide periodic safety monitoring throughout the conduct of the study. Unless independence is required, the SM may be an individual responsible for conducting the study.

Scientific Reviewer – The individual(s) designated by the leadership of the Principal Investigator’s Center, Department, or School, or other delegated entity as allowed in this policy, who conducts the scientific review.
**Serious Adverse Event** – An adverse event that is fatal or life threatening, permanently disabling, requires or prolongs hospitalization, or results in significant disability, congenital anomaly, or birth defect. Also, an adverse event that causes a prolonged or permanent harm that is psychological, social, legal, or financial.

**Serious Disease or Condition** – A disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible, provided it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.

**Serious Non-Compliance** – Non-compliance that results in an increased risk to subjects or others, adversely affects the rights, welfare and safety of the research subjects, or adversely affects the scientific integrity of the study. Non-compliance may also be deemed serious when it involves fraud and/or scientific misconduct, even in research posing minimal risk to subjects.

**Significant Risk Device** – An investigational device that presents a potential for serious risk to the health, safety, or welfare of a subject, and 1) is intended as an implant, 2) is to be used in supporting or sustaining human life, or 3) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health.

- Examples include: catheters (other than urological), ventilators, cardiopulmonary resuscitation (CPR) devices, temporomandibular joint disorder (TMJ) prostheses, stents, lithotripters, sutures and absorbable bandages/materials, electroconvulsive therapy (ECT) devices, extended wear contact lenses, pacemakers, contraceptive devices, most laser systems, and most hemodialysis systems.

**Sponsor** – An entity who takes responsibility for and initiates a clinical investigation regardless of financial support, and may be an individual, company, governmental agency, academic institution, private organization, or other organization. This entity does not actually conduct the clinical investigation, unless the entity is a Sponsor-Investigator.

**Sponsor-Investigator** – An individual who initiates and conducts a clinical investigation, and has the direct oversight of the administration, dispensing and/or use of the test item (e.g., holds the IND/IDE).

**Student Record** - Any information recorded in any way, including, but not limited to, handwriting, print, computer media, video or audio tape, film, microfilm, and microfiche.

**Study Start Up (SSU) Consultation** – A comprehensive, in-person consultation, after IRB approval and before enrollment begins, to evaluate study documentation (e.g. regulatory file, data collection forms, plans for protocol adherence) to assist the study team in their ability to achieve compliance with applicable regulations, policies, and guidelines. The reviewer collaborates with
the study team to understand study-specific regulations, policies, and guidelines, providing tools and resources.

**Synthetic Nucleic Acid** – Nucleic acid molecules that are chemically (or by other means) synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules.

**Test Article** – Any drug, biologic, or medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Food, Drug and Cosmetics Act or under sections 351 or 354-360F of the Public Health Service Act.

**Treatment IND** – A type of expanded access where an IND is obtained as a mechanism for providing patients not in a clinical investigation with investigational drugs. A treatment IND may be granted once sufficient data have been presented to show the drug may be effective and does not have unreasonable risks.

**Treatment Use** – Use of an investigational device for treatment or diagnostic purposes.

**Unaffiliated Institution** – An entity or organization that is external to the University of Rochester (e.g., another academic institution, another medical center or hospital, advocacy group).

**Unaffiliated Investigator** – A researcher who is not an employee or agent of the University of Rochester (e.g., private practice practitioner, faculty or staff at another academic institution or medical center).

**Unanticipated (Unexpected)** – An experience that was not expected or previously observed, or is not consistent in nature, severity, or frequency with existing risk information, such as in the investigator’s brochure, device manual, research protocol, consent form, or other available information (e.g., IND application for an investigational drug or IDE application for an investigational device). Interchangeable with “unexpected”. An event/problem occurring in one or more subjects in a research project that is not consistent with the expected natural progression of any underlying disease, disorder, or condition of the subject experiencing the event/problem.

**Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO)** – Any incident, experience, or outcome that meets all of the following criteria:

- unexpected (in terms of nature, severity, or frequency) given the research procedures and subject population being studied; and
- related to a subject’s participation in the research; and
- suggests that the research places subjects, research staff, family members or other individuals not directly participating in the research at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or expected.
**Use of Data** - Use involves the sharing, employment, application, use, examination or analysis of such information within URMC and Affiliates. For example, a clinical trial coordinator in the School of Medicine and Dentistry analyzing a research subject’s individually identifiable health information is using PHI.

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

**Written or In Writing** – Writing on a tangible medium (e.g., paper) or in an electronic format.