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 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** – For initial review, the interval that begins on the day research is approved by the convened RSRB or the RSRB Chair, and may not be longer than one year after that effective date. For continuing review, a fixed date for expiration of the annual RSRB approval will be used.

**Assent** – A child’s affirmative agreement to participate in research. An affirmative agreement to participate in research given by a person with decisional impairment.

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

**Board 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.

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 – Any experiment 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.

Commercially 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 set of conditions in which an Investigator has a secondary interest (e.g. personal or financial gain) that may bias their judgment concerning their primary research interest (e.g., subject welfare, integrity of research). A financial conflict of interest exists when the University reasonably determines that a financial interest or a significant financial interest could directly and significantly affect the design, conduct or reporting of University research.

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 – A pattern of non-compliance that continues despite identification by the RSRB, notice to the Investigator, or prior submission of a corrective action plan. This pattern may or may not result in increased risk to subjects. Although it may be due to a variety of factors, continuing non-compliance implies 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.

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).

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.

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.

**Expeditied 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 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 review procedures and is so designated by the Chair.

**Expiration Date** – 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 at a non-UR and Affiliates institution engaged in the research, over which another (non-UR) IRB has jurisdiction.

**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 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.

**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 (e.g., tests for breast cancer, prostate cancer, Huntington disease, sickle cell anemia).
**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 Subject (HHS)** – A living individual about whom an investigator (whether professional or student) conducting research obtains:
- Data through intervention or interaction with the individual, or
- Identifiable private information

**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

**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 this 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.
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 – Process for seeking and obtaining agreement of the subject to participate in research and the subject’s ability to provide an informed and voluntary decision to participate in research.

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 RSRB approved research study, occurring in a study for which the UR RSRB acts as the IRB of record, or occurring in a study conducted at URMC and Affiliates approved by an IRB acting as IRB of record under an agreement with the UR (e.g., Western 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.

**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. For research involving prisoners, the definition is modified by a restriction to the daily lives of ‘healthy persons’.

**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 Changes** – 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 more than minimal, or there is the addition of procedures in research categories that do not qualify for expedited review.

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, 1) Penetrate or pierce the skin or mucous membranes of the body, the ocular cavity, or the urethra, or 2) 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.

Parent – A child’s biological or adoptive parent.

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).

**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.

**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 to compare research records to approved documents, regulatory standards and policies, and recommends corrective and preventative actions.

**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.

- **For-Cause (Directed)**: A comprehensive or targeted on-site QI review requested by the RSRB. These reviews are conducted on studies identified by the RSRB to provide an assessment of study compliance. The review may be focused on one aspect of the research (i.e. the consent process) 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.

**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.

**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 Institutional Review Board (IRB) review to another IRB, such as an independent IRB or another institution’s IRB. The agreement may apply to a single study or to certain categories of studies.

**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.

**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.

**RSRB On-line Submission System (ROSS)** – The web-based submission and review system used to manage all aspects of research review for the RSRB.

**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).

**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.