

**SYRACUSE UNIVERSITY
HUMAN RESEARCH PROTECTION PROGRAM
STANDARD OPERATING PROCEDURES**

GLOSSARY:

Administrative Hold (initiated by the investigator): A voluntary action by the investigator to put research activities on hold temporarily while additional information is obtained.

Administrative Hold (initiated by the IRB): An action initiated by the IRB to place specific research activities on hold temporarily to allow for additional information to be obtained. An administrative hold is a form of Suspension of IRB approval.

Adverse Event: An untoward or undesirable experience or any undesirable experience associated with human participant research. An adverse event may include either psychological or physical harm or both.

Advertising: A public announcement usually by a printed notice or voice or data broadcast that describes a research study including contact information. Typically this is used for recruitment purposes for a research study.

Agent: An individual employed by SU who is authorized to act on its behalf.

Amendment: Any change to an IRB-approved study protocol regardless of the level of review it receives initially.

Assent: The affirmative agreement to participate in a research study given by a child, or an adult who lacks full decision-making capacity or authority to give legal informed consent. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Assurance: A contract or agreement that establishes standards for human participants research as approved by the Office for Human Research Protections (OHRP).

Bonus Payment: Compensation tied to the rate or timing of recruitment. Examples of bonus payments include but are not limited to the following: The sponsor announces that the highest enrolling site in the nation will receive a \$10,000 bonus; The sponsor offers to pay an additional \$10,000 to any site that enrolls five participants within a week; The sponsor offers to pay an additional \$10,000 to any site that fulfills its recruitment target by the end of the month; The sponsor offers to pay an additional \$1,000 for any subject who agrees to enroll within one day of initial contact.

Children: By regulatory definition, children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under applicable law of the jurisdiction in which the research will be conducted. Generally the law considers any person under 18 years old to be a child.

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Clinical Investigation/Research (as defined by FDA regulations): Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the FDA under these Sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding non-clinical laboratory studies.”

Cognitively Impaired: Having a psychiatric disorder (e.g., psychosis, neurosis, personality or behavioral disorder), an organic impairment (e.g., dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including individuals under the influence of or dependant on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and individuals with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interest.

Collaborative IRB Training Initiative (CITI): An internet-based set of educational modules on the protection of human participants in research. It is sponsored by a consortium of IRB professionals and investigators from universities and medical schools across the country and is administered by the University of Miami.

Community Based Participatory Research (CBPR): Research that is designed and conducted as an equal partnership between traditionally trained "experts" and members of a community.

Continuing Non-compliance: A pattern of repeated actions or omissions taken by an Investigator that indicates a deficiency in the ability or willingness of an Investigator to comply with Federal regulations, SU IRB Policy, or determinations or requirements of the SU IRB.

Continuing Review: Periodic review of a research study by an IRB to evaluate whether risks to participants remain reasonable in relation to potential benefits and to verify that the study continues to meet organizational and regulatory requirements. Federal regulations stipulate that continuing review should be conducted at intervals appropriate to the level of risk involved in the study, and not less than once per year.

Data and Safety Monitoring: A plan to oversee the implementation of a study protocol for compliance monitoring.

Department of Health and Human Services (DHHS): The United States government's agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.

Deviation: An incident involving noncompliance with the protocol, but one that typically does not have a significant effect on the participant's rights, safety or welfare, or on the integrity of the resultant data. Deviations may result from the action of the participant, Investigator or staff.

Directed Audit: These audits are conducted by the ORIP Director and IRB Chair to assess the Investigator's compliance with federal regulations, state and local laws, and SU IRB policies and procedures. These audits of IRB approved research studies are in response to identified

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concern(s). Concerns may be identified by an IRB Committee, an external source (e.g. OHRP, or Sponsor), or an internal source (e.g. participant, family member, or Institutional personnel).

Dissent: An individual's negative expressions, verbal and/or non-verbal, that they object to participation in the research or research activities.

Exempt Review: Studies determined by the IRB to meet the exempt criteria as defined by the Federal regulations. Exempt studies do not require periodic review by the IRB unless a change in the project is planned which requires the completion of an amendment application.

Expedited Review: Studies determined by the IRB to meet the expedited criteria as defined by the Federal regulations.

Experts: persons who, by virtue of their training or expertise, have information and knowledge in a substantive area beyond that of the average person and who regularly share this information and knowledge through consultation, teaching or public speaking, or publications and written reports.

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

Federal-Wide Assurance (FWA): An agreement between a federally funded institution and OHRP that stipulates method(s) by which the organization will protect research participants.

Finder's Fee: Compensation of any type (cash, office or medical supplies, educational stipends, gift certificates, priority in authorship listings, travel reimbursement, or anything else of value) to an individual made in exchange for referral or recruitment of a participant to a research study. Such payments, generally, are made to residents, physicians, nurses, or others in a position to identify potential participants that might qualify for enrollment into a study. The fee is paid only for participants who are actually enrolled into the study.

Financial Conflict of Interest:

- Ownership interest (equity or stock options) of any value, unless it meets four tests:
 - Value when aggregated for the immediate family does not exceed \$10,000 when referenced to publicly traded prices or other measure of fair market value.
 - Value when aggregated for the immediate family does not exceed 5% in any one entity.
 - Publicly traded on a stock exchange.
 - No arrangements have been made where the value of the interest will be affected by the outcome of the research.
- Compensation of any amount, unless it meets two tests:
 - Amount when aggregated for the immediate family did not exceed \$10,000 in the past 12 months.
 - No arrangements have been made where the amount of compensation will be affected by the outcome of the research.
- Proprietary interest related to the research of any value including, but not limited to, a patent, trademark, copyright or licensing agreement.
- Board or executive relationship related to the research, regardless of compensation.

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

Generalizable Knowledge: Those designed to draw general conclusions, inform policy, or apply findings to populations outside of the specific study population.

Health Care Decision-Maker: In the case of an incompetent individual, or an individual who lacks decision-making capacity, the individual's health care decision-maker is designated in order of preference as one of the following: the individual's court-appointed legal guardian or conservator with health care decision-making authority (e.g., Durable Power of Attorney for Health Care); the individual's health care agent as specified in an advance directive; or the individual's Health Care Decision-Maker.

Human Research Protection Program (HRPP): A system that includes all structural units, policies, and activities critical to protecting individuals studied in research and that is managed in accordance with these standards and with applicable federal, state and local laws.

Human Subject/Participant Research: Research projects involving human participants include all activities that are "research," and involve, "human participants" according to The Common Rule, and to include all activities that are "research" according to FDA regulation. According to The Common Rule, "research" is a systematic investigation, including clinical investigations, research development, testing and evaluation, designed to develop or contribute to generalizable knowledge and "human participants" are living individuals about whom the investigator conducting research obtains a.) data through intervention or interaction with the individual or b.) identifiable private information (**45 CFR 46**). According to FDA regulations "research" is any experiment that involves: a.) "test article," that is any drug or biological product for human use, a medical device for human use, a food additive or color additive intended for human use, an electronic product or any other article subject to regulation by the Food, Drug, and Cosmetic Act; and one or more individuals who are either recipients of the test article or controls; and that either involves a drug or medical device (other than the use of an approved drug or device in the course of medical practice) or the results of the research are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

Human Subject/Participant: As defined in DHHS regulations, a human subject is a living individual about whom an investigator, or in the case of a student researcher, a Faculty Sponsor obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. As defined in FDA regulations an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. In the case of a medical device, a human subject/participant also means a human on whose specimen an investigational device is used.

Immediate Family Member: Spouse, domestic partner, or child.

Individual Conflict of Interest: A circumstance such that any action or decision in which an individual is substantially involved may have a direct or predictable effect on a financial interest of the individual, spouse, minor child, or organization in which the individual serves as an officer, trustee, partner or employee.

Informed Consent: An agreement to participate in research that is made voluntarily by an individual with legal and mental competence and the capacity to understand the information

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transmitted and its implications, after having been informed of the physical, psychological and personal risks and potential benefits entailed by the research protocol. Informed consent is usually demonstrated by signing a consent form, but it may be oral (under specific criteria approved by an IRB).

Institutional Conflict of Interest: When the institution, any of its senior management or trustees, or a department, school, or other sub-unit, or an affiliated foundation or organization, has an external relationship or financial interest in a company that itself has a financial interest in a faculty research project. Senior managers or trustees may also have conflicts when they serve on the boards of (or otherwise have an official relationship with) organizations that have significant commercial transactions with the University.

Institutional Official: The individual authorized to act for the institution and, on behalf of the institution, obligates the institution to the terms of the assurance.

Institutional Review Board (IRB): An independent committee comprised of scientific, non-scientific, and non-affiliated members established according to the requirements outlined in 45 CFR 46. The SU IRB is formally designated by the Vice President for Research to review, approve, and conduct continuing review of research involving human participants at Syracuse University.

Interaction: Includes communication or interpersonal contact between investigator and subject.

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.

Investigators: Those responsible for the design, conduct, or reporting of research.

IRB 101: A course presented by PRIM&R that covers the ethics, history, and federal regulations related to the conduct of research on human subjects.

IRB Approval: The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements.

IRB Associate Chair or Designee: The individual appointed by the Vice President for Research to assist the IRB Chair in overseeing the review functions of the IRB.

IRB Chair or Designee: The individual appointed by the Vice President for Research to oversee the review functions of the IRB.

IRB Member: An individual serving as an IRB Member including Chairs, the IRB scientific and non-scientific reviewers, alternates or expert consultants regardless of voting privileges.

IRB Member Conflicting Interest:

IRB Members are considered to have a conflicting interest when the member, or an immediate family member of the member is the Principal Investigator, faculty advisor, or member of the research team on any research being reviewed by the IRB or when the member has a financial

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interest in the sponsor of research under consideration, or when the outcome of the research could materially impact financially the member or the member's immediate family.

IRB of Record: An IRB is considered the IRB of Record when it assumes IRB responsibilities for another institution and is designated to do so through an approved Assurance with OHRP. A Memorandum of Understanding is required, designating the relationship, for SU to serve as the IRB of Record.

IRB: The committee formally appointed by the Vice President for Research to review, approve, and conduct continuing review of research involving human participants at Syracuse University.

Legal Guardian: An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

Legally Authorized Representative: An individual, judicial or other body authorized under applicable law to consent on behalf of a prospective participant to that individual's participation in research.

Local Research Context: Knowledge of the institution and community environment in which human participant research will be conducted.

Major Amendment: A proposed change in research related activities that materially affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.

Memorandum of Understanding (MOU): A formal agreement between SU and another institution that identifies the SU Institutional Review Board as the IRB of record for that institution, or identifies another institution's IRB as the IRB of record for SU.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. An example of minimal risk is the risk of drawing a small amount of blood from a healthy individual for research purposes (because the risk of doing so is no greater than the risk of doing so as part of a routine physical examination). In research involving prisoners, minimal risk is also defined as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

Minors: Individuals under the age of 18.

Minor Amendment/Minor Modifications: A proposed change in research related activities that presents no more than minimal risk to research participants, does not materially affect an assessment of the risks and benefits of the study, does not substantially change the specific aims or design of the study, or makes no addition of procedures not included in categories (1)-(7) of research that can be reviewed using an expedited procedure.

Non-compliance: Failure to comply with Federal regulations, SU IRB Policy, or the determinations or requirements of the SU IRB.

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Not Less Than Once Per Year: All research proposals, with the exception of application exempt from review, must receive IRB continuing review at a minimum of once every 365 days, per Federal regulations. There are no exceptions or grace periods allowed.

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

Office of Research Integrity and Protections (ORIP): The office at Syracuse University which encompasses the administrative aspects of the IRB and the HRPP program.

Off-site Sponsored Research: Activities conducted by non-SU faculty or staff supported by subcontracts or subawards to another organization, governed by a prime agreement to SU.

ORIP Director: The individual responsible for directing the operations of the Office of Research Integrity and Protections, which encompasses administrative aspects of the HRPP program.

ORIP/IRB Administrator: The individual responsible for assisting the ORIP Director in the administration of HRPP program.

ORIP/IRB Assistant: The individual responsible for assisting the ORIP Director and ORIP Administrator in the clerical aspects of the HRPP.

Parent: A child's biological or adoptive parent.

Periodic Compliance Review: Random assessments of the internal IRB department and external departments or sites involved in the conduct of human subjects research at SU conducted by the IRB Compliance Team. These reviews are used to evaluate proper execution and accurate documentation of an IRB approved research project. Internal compliance reviews monitor the adherence to federal regulations, state and local law, and IRB policies and procedures as well as accurate documentation between the IRB database and the IRB paper files. External compliance reviews monitor the adherence to federal regulations, state and local law, SU IRB policies and procedures, adherence to the study protocol, accurate documentation and reporting of study related activities, and evaluation/observation of the informed consent process.

Permission: The agreement of parent(s) or guardian to the participation of their child or ward in research.

Persons with Cognitive Disabilities: Having a psychiatric disorder (e.g., psychosis, neurosis, personality or behavioral disorder), an organic impairment (e.g., dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including individuals under the influence of or dependant on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and individuals with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interest.

Potential Conflict of Interest: A potential conflict of interest involves a situation that may develop into an actual conflict of interest. A potential conflict of interest implies only the potential for bias, not a likelihood.

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PRIM&R: Public Responsibility in Medicine and Research
(<http://www.primr.org/education/doorstep.html>)

Primary Reviewer: Institutional Review Board member responsible for making a presentation at the Committee meeting, including any important human participants protection issues.

Principal Investigator: An individual(s) who has responsibility for the design, conduct, data collection, management, analysis, or reporting of research; and has responsibility for supervising staff and carrying out a protocol at a specific site.

Prisoner: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Private Information: Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.

QA Activities: These activities focus on assessing compliance with the HRPP by the IRB and the investigators involved with human participant research.

Quality Assurance (QA): Assessment of whether individuals are following HRPP policies and procedures (compliance). Evaluation and correction of individual problems.

Quality Assurance Reviews: Quality Assurance reviews are performed by the IRB Teams to verify that the electronic database is consistent with the IRB paper files and the paper files are collated in accordance with IRB policy and procedure.

Quality Control (QC): Assessment of whether mechanisms work correctly or are optimized. Evaluation and correction of basic functioning. Examples are ORIP Staff responsibilities to examine the ORIP website for broken links, make sure the latest forms are posted on the internet, and ensure the Standard Operating Procedures are updated and available.

Quality Improvement (QI): Assessment of whether changes made to the HRPP improve its effectiveness or quality. Evaluation and correction of the system.

Recruitment: Seeking individuals to enroll or participate in a research project.

Related: An event is “related” if it is likely to have been caused by the research procedures.

Research: “A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”. This definition may include qualitative and quantitative research studies, surveys, case studies, experiments, interventions, analysis of specimens, demographic and epidemiological research, program evaluations, oral histories, secondary analyses of documents and records, and other methods associated with the

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biomedical, behavioral, and social sciences. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. FDA regulations define research as clinical investigation, which is any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the FDA or which is intended to be submitted later to the FDA as part of an application for a research or marketing permit.

Research Misconduct: Any fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

Research Payment: Cash or non-cash payments for reimbursement of time and expenses associated with participation in research activities (Payments may include monetary payment, course credit, gift certificates, toys or educational materials for children, and other items or services).

Risk-Potential Benefit Profile: A summary of the risks and potential benefits that may occur during the course of the study.

Secretary: The Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

Serious Adverse Event (SAE): Any event that results in death, a life-threatening situation, hospitalization or prolonged hospitalization, persistent or significant disability/incapacity or a congenital anomaly/birth defect or requires medical intervention to prevent one of the outcomes listed above.

Serious: An event is “serious” if it involved a serious harm to one or more persons (who may or may not be participants), or required intervention to prevent one or more persons from experiencing serious harm.

Serious Non-compliance: An action or omission taken by an Investigator that any other reasonable Investigator would have foreseen as compromising the rights and welfare of a participant.

Short Form Consent: A written informed consent document that summarizes the required elements of informed consent to be presented orally to the participant or his or her legally authorized representative.

Significant Financial Interest: Anything of monetary value - aggregated for the Investigator and the Investigator’s spouse, domestic partner, and dependent children - including but not limited to the following:

- a. Salary or other payment for services (e.g. consulting fees) of \$10,000 or greater in the past year when aggregated for the immediate family;
- b. Any equity interest (e.g. stocks, stock options or other ownership interests) unless it meets the following three tests:
 - i. less than \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value (e.g. most recent sales price recognized by the company),
 - ii. constitutes less than a 5% ownership interest in any single entity, or

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- iii. publicly traded on a national stock exchange.
- iv. no arrangements have been made where the value of the interest will be affected by the outcome of the research.
- c. Intellectual property rights (e.g. patents, copyrights and royalties from such rights).
- d. Services as an officer, director, or in any other executive position in an outside business, whether or not remuneration is received for such service.
- e. Any compensation or equity interests that may be influenced by a particular outcome in sponsor-funded research, even if the identified thresholds are not met.

Sponsor-Imposed Suspension: A determination from the sponsor of the study to place specific research activities on hold.

Sponsors: The agencies, institutions, companies, organizations, foundations, or individual grantors responsible for the initiation, management, or financing of a research study. The term sponsor is understood to include any intermediaries, such as contract research organizations or coordinating centers, acting as agents of the sponsor in carrying out the responsibilities above. All research falling under these types of agreements is considered sponsored research.

Standard Operating Procedure (SOP): A procedure written in a standardized format, giving detailed instructions, which describe a routine activity so that each person following the SOP will perform the activity in a consistent and repeatable manner.

Suspension of IRB Approval: An action initiated by the IRB to stop temporarily some or all research procedures pending future action by the IRB or by the Investigator or his/her study personnel.

Systematic Investigation: An activity that involves a prospective research plan which incorporates data collection, either quantitative or qualitative, and data analysis to answer a research question.

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

Third Party Information: Information that is collected about persons other than the participants who have provided informed consent to be part of a study. For example, medical histories often collect information about conditions and diseases among a person's relatives or sociological, anthropological, or psychological research may obtain information about people's experiences with and perspectives on others in their lives. Persons who are not the primary subjects of research, but about whom information is collected are sometimes referred to as third parties or secondary subjects.

An unanticipated problem involving risk to participants or others: Any event that was

- (1) unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- (2) related or possibly related to participation in the research (*possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

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(3) suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Unanticipated: An event is “unanticipated” when it was unforeseeable at the time of its occurrence. The word unanticipated, is not a synonym for unexpected. A research protocol can monitor for an unexpected event, but cannot monitor for an unforeseen event. All unanticipated events are unexpected, but not vice versa.

Unanticipated Problems Involving Risk to Participants or Others: Any event that was (1) unanticipated, and (2) caused harm or increased risk of harm to participants or others (regardless of the level of seriousness of the harm).

Unexpected: An event is unexpected when its nature, severity or incidence are not accurately reflected in the information previously reviewed and approved by the IRB.

Unexpected Adverse Event (UAE): Any adverse event that was unanticipated or not previously observed (e.g., not included in the consent form or investigator brochure). This includes adverse effects that occur more frequently or with greater severity than anticipated. Events that are unexpected and serious require prompt reporting to the Sponsor, the FDA and the IRB. An event is “unexpected” when its specificity, nature, severity or incidence are not accurately reflected in the information previously reviewed and approved by the IRB.

Vice President for Research: The individual appointed by the Chancellor to be the Institutional Official and to oversee all research activities at SU.

Violation: Accidental or unintentional changes to or not compliant with the IRB approved protocol that affect the participant’s rights, safety, welfare, or the integrity of the resultant data.

Vulnerable Population: Groups of persons who may lack the capacity to freely decide whether to participate in research due to any number of circumstances such as age, health status, etc. 45 CFR 46 identifies prisoners; children; pregnant women and human fetuses and neonates as vulnerable populations; however, mentally handicapped, educationally and economically deprived individuals are also vulnerable populations.

Whistle-blower: An individual who reports sensitive information to the SU IRB regarding potential non-compliance issues or research activities that have potentially placed participants or others at increased risk in relationship to the conduct of the research.