

## SVSU GLOSSARY OF IRB-RELATED TERMS

### Acronyms

**CFR:** Code of Federal Regulations

**DHHS:** U.S. Department of Health and Human Services, an agency of the federal government; formerly the Department of Health, Education and Welfare (DHEW)

**FDA:** Food and Drug Administration; an agency of the federal government established by Congress in 1912 and presently part of the Department of Health and Human Services.

**IRB:** Institutional Review Board (see definition below)

**NIH:** National Institutes of Health: a federal agency within the Public Health Service, DHHS. Comprised of 21 institutes and centers, it is responsible for carrying out and supporting biomedical and behavioral research.

**OHRP:** Office for Human Research Protection (see definition below)

### Definitions

#### A

**Administrative Hold:** a temporary hold on the ability investigators to enroll new human subjects on a research protocol until the IRB Committee has determined that changes in adequate safeguards for the protection of human subjects have been implemented.

**Adverse Effect:** an undesirable and unintended, although not necessarily unexpected, negative result of participation in research (e.g., headache following spinal tap or intestinal bleeding associated with aspirin therapy, or a panic attack following an emotional experience).

**Adverse Event:** any occurrence of an adverse effect; any adverse finding (including a sign, symptom, or abnormal assessment (e.g., lab, EKG)); any report regarding the quality, safety, or performance of a medical product; or any other unfavorable outcome that affects a human subject detrimentally, or that worsens an existing condition, as a result of participation in a study.

**Anonymous:** the state of being unknown and not identifiable in any way (different from confidential identity, see below)

**Assent:** affirmative agreement by an individual not competent to give legally valid informed consent (e.g., a child or person who is cognitively impaired) to participate in research. Assent is always affirmative or active; mere failure to object should not be construed as assent.

**Assurance:** a formal, written, binding commitment that is submitted to a federal agency through which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.

**At-risk populations:** Includes people identified as requiring special attention, such as pregnant women, human fetuses, neonates, prisoners, children, individuals with cognitive or emotional impairments.

**Autonomy:** Personal capacity to process information, consider alternatives, make choices, and act without undue influence or interference of others.

#### B

**Belmont Report:** a statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.

**Beneficence:** an obligation to go beyond minimizing harm so as to maximize benefits for research subjects

**Benefit:** a valued or desired outcome; an advantage, a consideration

## C

**Children:** persons who have 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.

**CFR:** See: Code of Federal Regulations

**Clinical trial:** controlled study involving human subjects designed to evaluate prospectively the safety and effectiveness of new drugs or devices or of behavioral interventions.

**Co-investigator:** any individual who collaborates with the principal investigator in the design and/or conduct of a research project, including those with access to data. For IRB purposes, status as a co-investigator includes no presumption about authorship status; all members of a research team are considered to be co-investigators.

**Code of Federal Regulations:** compilation of federal executive agency regulations organized into 50 Titles and published in the Federal Register as they are promulgated. The relevant code for human-subjects research is Title 45, Chapter 46, also known as 45 CFR 46

**Cognitively impaired:** Having either a medical disorder (e.g., psychosis, encephalopathies, traumatic brain injury, or 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. The label includes, but is not necessarily limited to, persons under the influence of, or dependent on drugs or alcohol, who may be compromised in their ability to make decisions in their best interests.

**Common Rule (The):** see Federal Policy, specifically 45 CFR 46.

**Compensation:** payment, medical care, or other consideration provided to subjects injured in research; does not refer to payment (remuneration) for participation in research (Compare: remuneration).

**Competence:** capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, to make a choice, and have the ability to express that choice. (See also: incompetence, incapacity)

**Confidentiality:** pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure. This is different from anonymity.

**Consent:** see: informed consent

## D

**Debriefing:** Giving subjects previously undisclosed information about the research project following completion of their participation in the research. This can include providing written material to participants.

## E

**Emancipated minor:** legal status conferred upon persons who have not yet attained the age of legal competency as defined by state law (for such purposes as consenting to medical care),

but who are entitled to treatment as if they were “of age” by virtue of assuming adult responsibilities such as being self-supporting and not living at home, marriage, or procreation.

**Embryo:** early stages of a developing organism, broadly used to refer to stages immediately following fertilization of an egg through implantation and very early pregnancy (*i.e.*, from conception to the eighth week of pregnancy). (*See also: fetus.*)

**Equitable:** fair or just; often, but not exclusively, used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed; generally receiving some consideration based on entitlement or earning, as opposed to receiving consideration equally.

**Ethics:** the study of the general nature and purpose of morals and the process of specific moral choices to be made by the individual in his/her relationship with others.

**Exculpatory:** clearing or tending to clear from alleged fault or guilt. Statements of informed consent may not include exculpatory language that would justify, excuse, or clear an investigator from alleged fault or guilt (in the case of an adverse event), or through which the subject waives their legal rights

**Exempt:** more fully described as exempt from continuing review and refers to research as defined in 45 CFR 46 in paragraph 46.101(b). Projects that meet these criteria in their initial review by the IRB need not be reviewed further by the IRB, are exempt from the continuing-review requirements, unless changes are made to the protocol or problems arise during the conduct of the research.

**Expedited Review:** review of proposed research by designated IRB member(s) instead of the entire IRB. Federal rules and SVSU policy permit expedited review for certain kinds of research and for minor changes in previously approved research. This category of review is described in 45 CFR 46 at paragraph 46.110. Generally, Expedited Review may be employed for research that involves no more than minimal risk for participants and does not include any special classes of participants, or for minor changes to approved projects.

**Expiration date:** date after which a protocol is no longer approved for use with human subjects. No protocols are approved for more than one year; except for exempt (see above) projects, renewal applications are required for projects that extend beyond one year from the initial date of approval

## F

**Family member:** defined to include spouses, parents, children (including adopted children), siblings, spouses of siblings, and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship.

**Federal Policy (The):** policy that provides regulations for the involvement of human subjects in research, 45 CFR 46. The Policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that takes appropriate administrative action to make the Policy applicable to research. Currently, sixteen federal agencies have adopted the Federal Policy. (Also known as the “Common Rule” and 45 CFR 46.) SVSU has also adopted the Federal Policy.

**Fetus:** product of conception from the time of implantation until delivery. If the delivered or expelled fetus is viable, it is designated an infant. The term “fetus” generally refers to later phases of development; the term “embryo” is usually used for earlier phases of development. (*See also: embryo.*)

**Fieldwork:** Behavioral, social, anthropological, or other research involving the study of persons or groups in their own environment, often without manipulation for research purposes (distinguished from laboratory or controlled settings).

**45 CFR 46:** See: *Title 45 Code of Federal Regulations Part 46*

**Full Board Review:** process that occurs during a formal meeting of the IRB. For a project to be approved, it must receive the approval of a majority of those members present at the meeting. This category of review applies to all research that does not fall into other categories. In general, full board review will be required for all projects involving: a) more than minimal risk to participants, b) the deception of subjects, c) sensitive behavioral research (such as research relating to illegal or sexual activity), and d) at-risk populations (e.g., pregnant women, human fetuses, neonates, prisoners, children, individuals with cognitive impairments).

## G

**Generalizable knowledge:** knowledge "expressed in theories, principles, and statements of relationships" that can be widely applied to our experiences [the *Belmont Report*]. The term "generalizable knowledge" is used to distinguish the results of research from the results of non-research activities such as "practice" activities. "For the most part, the term 'practice' refers to interventions that are designed solely to enhance the well-being of an individual patient or client. By contrast, the term "research" designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge [the *Belmont Report*]. Knowledge is generalized through activities including, but not limited to, publication, presentation (including posters), posting on a website, and/or generally disseminating a "white paper."

**Guardian:** in the context of research, an individual who is authorized under applicable state or local law to give consent and make other decisions on behalf of someone else.

## H

**Human Subject:** defined in 45 CFR 46 at paragraph 46.102(f). Consistent with this definition, "human subject" activity involves any interaction with humans, access to identified samples obtained from humans, or existing archives that contain identifiable information about or obtained from humans.

## I

**Identifiable private information:** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place, and information that has been provided for specific purposes by an individual and for which the individual can reasonably expect will not be made public (for example, a medical record).

**Identifiers:** characteristics about an individual (e.g. Name, Social Security Number, Hospital Admission Number, Specimen Number, or codes linked to the research subject) that could be used to connect the project to a specific research subject.

**Incapacity:** refers to a person's mental status; means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, to make a choice, and to express that choice. Often used as a synonym for incompetence. (See also: *incompetence*).

**Incompetence:** legal term meaning inability to manage one's own affairs. Often used as a synonym for incapacity. (See also: *incapacity*.)

**Information Sheet:** written statement that contains the same elements as a written consent. It differs only in that it does not require research subjects to provide a signature indicating agreement to participate in a research study. It is used in a study for which a waiver of documentation of consent has been granted. The SVSU IRB may approve the use of an information sheet if either: 1) the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality, or (2) the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Investigators must provide justification for a request to waive written documentation of consent.

**Informed Consent:** a person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventative procedure. It is characterized by the provision of complete and accurate information to potential research subjects, facilitating full and genuine comprehension of this information by potential research subjects, and assuring the voluntary nature of any consent obtained. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence. *Note: Human subjects cannot be fully protected if they are not fully informed. Therefore, the consent form becomes a major focus of scrutiny. In order to inform subjects fully, consent forms must be clear and concise, in most cases in language understandable by a person with no more than an eighth grade education. In particular, unambiguous identification of procedure, objectives, and risks is an absolute requirement.*

**Institutional Review Board:** a specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in human-subjects research.

**Interaction:** includes any communication or contact between any member of the research team and research participants

**Intervention:** includes "both physical procedures by which data are gathered, and manipulations for the subject or the subject's environment that are performed for research purposes" [45 CFR 46.102(f)(2)].

**Investigator:** Any member of a research team. (*See also: principal investigator.*)

**IRB:** See Institutional Review Board

## J

**Justice:** an ethical principle discussed in the *Belmont Report* requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly. In the context of research, justice is often used to refer to the questions of fairness in the selection of human subjects for study, such as whether or not subjects are selected for study merely because they are conveniently available or unable to protect themselves from potential exploitation, and the relative distribution of benefits of research to subjects and society in general

## K

**Key Personnel:** all individuals responsible for the design and conduct of the study. This includes those individuals responsible for the recruitment and consent of potential study participants.

## L

**Legally authorized representative:** an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. In the case of children, this would most likely be a parent or legal guardian. For adults, a legally authorized representative would have durable power of attorney or some other court order authorizing him/her to be the legal representative.

## M

**Major modification:** A significant change to a protocol where subjects would be engaging in activities not previously approved during the review process or where there is an increased level of risk to the physical, emotional, or psychological well-being of participants, including loss of confidentiality.

**Mental disability(ies):** *See: cognitively impaired.*

**Mentally disabled:** *See: cognitively impaired*

**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.

**Minors:** persons who have 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

**Minor modification:** Protocol modifications that might include minor wording changes in the consent form, small changes in compensation, time of participation, or subject recruitment, or the use of a new investigation site that is not materially different from a previously approved site. There may also be changes to other parameters whereby the investigator provides the subjects with more accurate information as a result of additional experience with the protocol.

## N

**National Commission:** National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. An interdisciplinary advisory body, established by Congressional legislation in 1974, which was in existence until 1978, and which issued a series of reports and recommendations on ethical issues in research and medicine, many of which are now embodied in federal regulations.

## O

**Office for Human Research Protections (OHRP):** New name for the OPRR after it was moved out of the NIH and directly under the purview of the DHHS in June 2000; this office is currently responsible for implementing and enforcing DHHS regulations governing human subjects research, including the imposition of sanctions on institutions not in compliance with the regulations.

**Office For Protection From Research Risks (OPRR):** The office that, until June 2000, was within the National Institutes of Health, an agency of the Public Health Service,

Department of Health and Human Services, and responsible for implementing DHHS regulations (45 CFR Part 46) governing research involving human subjects.

**Oral Assent:** an affirmative verbal agreement by an individual not competent to give legally valid informed consent to participate in a research study.

**Oral Consent:** When the research is of minimal risk, (e.g. research involving telephone surveys or interviews), the IRB may approve the use of oral consent. In research projects that involve greater than minimal risk, documentation of oral consent must involve three individuals: the subject, the research staff member obtaining consent, and a witness (who may also serve as the translator).

**Outside IRB Purview:** category of research that includes activities not subject to IRB oversight. This category will be applied by the IRB to activities that do not meet either the definition of human subject or the Common Rule definition of research

## P

**Parent:** a child's adoptive or biological parent [45 CFR 46.402(d)].

**Passive consent:** Consent that is deemed to have been provided when a subject voluntarily participates in or allows their child to participate in a research protocol without actively agreeing (in writing or verbally) to participation. For example, when parents do not return a signed statement disallowing their child's participation in a study, they are deemed to have provided passive consent. Passive consent cannot be approved under any circumstances.

**Permission:** the agreement of parent(s) or guardian to the participation of their child or ward in research[45 CFR 46.402(c)].

**Pregnancy:** encompasses the period of time from implantation 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 pregnancy test are negative or until delivery.

**Principal Investigator (PI):** The individual with primary responsibility for the design and conduct of a research project.

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

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

**Private:** affecting or belonging to private individuals rather than to the general public for public use or consumption.

**Protocol:** the formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes the purpose of the research, a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

## R

**Remuneration:** payment or consideration for participation in research. (Note: It is wise to confine use of the term "compensation" to payment or provision of care for research-related injuries.) (*Compare: compensation.*)

**RPA:** Request for Project Approval (RPA) is the form through which investigators request that the IRB review a proposed project

**Research:** is defined in 45 CFR 46 at paragraph 46.102(d). Consistent with this definition, "research" involves systematic investigation designed to develop or contribute to generalized knowledge, regardless of other purposes or designs that may attend the investigation.

**Research Supervisor (RS):** faculty or staff member who has qualifications and expertise sufficient to oversee the conduct of research and who has adequate supervisory capacity for ensuring that all individuals involved in the research will conform to all federal and institutional requirements for protecting human subjects. Research conducted by students at SVSU must have an individual designated as Research Supervisor.

**Risk:** the probability of harm, injury, or loss (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant.

- a. Physical risks may arise from the use of test agents such as chemicals or therapeutic drugs, devices, physical agents (including radiation), and clinical procedures.
- b. Psychological risks may arise from the utilization of behavioral questionnaires or surveys, interview interactions, the collection of sensitive data, or the emotional stress of study participation.
- c. Social risks may arise from actual or potential breaches of confidentiality such as harm to interpersonal relationships, damage to reputation or social standing, or exposure to legal sanctions.
- d. Economic risks may affect an individual's financial status, employability or insurability.

## S

**Special Groups** (of Human Subjects): The Office for Human Research Protections (OHRP) has identified populations in need of special protections in research. IRBs must apply additional regulations and criteria and give special consideration to recruitment, subject selection, informed consent, privacy, and confidentiality issues before approving research involving these populations.

**Subjects:** See: human subjects

## V

**Viable:** As it pertains to a neonate, able to survive after delivery to the point of independently maintaining heartbeat and respiration. The Secretary may, from time to time, take in account medical advances and publish in the *Federal Register* guidelines to assist in determining whether a neonate is viable for purposes of 45 CFR 46. If a neonate is viable, then it may be included in research only to the extent permitted and in accordance with the requirements of 45 CFR 46.

**Voluntary:** free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

**Vulnerable:** see "at risk"

**W**

**Waiver of Consent:** consent may be waived by the IRB if the following four conditions are met:

1) the risk to the subject is not more than minimal; 2) the waiver will not adversely affect the rights and welfare of the research participants; 3) the research could not practicably be carried out without the waiver; and 4) the subjects will be provided with additional pertinent information after participation when appropriate. Note that waiver of consent is different from a waiver of written documentation of consent, in which consent is required but no written record of consent is maintained.

**Waiver of Consent in Emergency Situations:** in acute medical emergency research, situations may arise in which neither the patient can give consent, nor can his/her legally authorized representative be contacted in time to consent to the investigational therapy. Waiver of written informed consent must be pre-approved by the IRB prior to enrollment of patients under these conditions.

**Ward:** A person placed by the court under the care of a guardian [*Black's Law Dictionary*, 5th ed.].

**Written Assent:** a signed document used to record the agreement by an individual not competent to give legally valid consent (e.g., a child or cognitively impaired person) to take part in a research study.

**Written Consent:** a signed document used to record the agreement by an individual competent to give legally valid consent to take part in a research study.