# IRB Policy Glossary

**Adverse Events:**
Is research-related events that cause direct harm to human subjects. Any research-related physical, psychological, or social harm to subjects occurring during the course of the research.

**Affiliation Status:**
An individual's relationship with the University of Illinois Springfield. Non-affiliated status means that neither the individual nor an immediate family member of the individual are affiliated with the campus.

**Allegation of Non-Compliance:**
Is defined as an as-yet unproved assertion of non-compliance.

**Approval in Principle:**
There are two circumstances in which the IRB may grant approval required by a sponsoring agency without having reviewed all of the study procedures and consent documents. The first occurs when the study procedures are to be developed during the course of the research, but human subjects approval is required by the sponsoring agency. The other circumstance occurs when the involvement of human subjects depends on the outcomes of work with animal subjects. The IRB may then grant approval without having reviewed the as-yet undeveloped recruitment, consent, and intervention materials. However, if the proposal is funded, the Principal Investigator must submit such materials for approval at least 60 days before recruiting human subjects into the study, or into any pilot studies or pre-tests. Approval in principle is granted to satisfy sponsoring agency requirements or to allow investigators to have access to funding to begin aspects of the project that do not involve human subjects.

**Approval:**
The study is approved as submitted.

**Assent:**
A child's affirmative agreement to participate in research. Mere failure to object, absent affirmative agreement, should not be construed as assent.

**Certification:**
The official notification by the institution to the supporting Department or Agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

**Child:**
In Illinois, a *child* is defined as an individual who has not attained 18 years of age.

**Classified Research:**
Is research that involves information, research, or results of research that are classified by the sponsor or a third party (i.e., research for the federal government under an agreement which is classified as secret or confidential). UIS will not accept or perform research that is considered classified.

**Coded:**
(a) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and (b) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

**Conditional Approval:**
The protocol and/or consent form require revisions, as agreed upon during the IRB meeting. These revisions are presented to the Principal Investigator for incorporation by simple concurrence. Only the IRB Chair, Vice Chair, or a designated subcommittee of the IRB may approve the study upon receipt and approval of the revisions without further action by the IRB. Approval of the protocol application will not be granted until all IRB stipulations are met.

**Confidentiality:**
Using effective methods to ensure that information obtained by researchers about their subjects is not improperly divulged.

**Continuing Non-Compliance:**
Is defined as a pattern of non-compliance that, in the judgment of the IRB Chair or full IRB committee, suggests a likelihood that instances of non-compliance will continue without intervention. Continuing non-compliance also includes failure to respond to a request to resolve an episode of non-compliance.

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

**Deferred:**
This action is taken if substantial modification or clarification is required, or insufficient information is provided to judge the protocol application adequately (e.g., the risks and benefits cannot be assessed with the information provided). Substantive issues regarding the protocol and/or consent form must be addressed before approval can be given. IRB approval of the proposed research must not occur until subsequent review, by the full IRB committee, of the new material submitted by the RPI.

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

**Disapproved:**
Questions are of such significance that the IRB believes approval of the study is unwarranted. Only the full IRB may deem a protocol disapproved. Approval of a previously disapproved protocol requires full IRB review.

**Exculpatory language:**
Means language in the consent form where the participant in research appears to waive certain legal rights, or to indemnify the researcher in the event the participant is injured.

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

**Finding of Non-Compliance:**
Is an authoritative determination that non-compliance has occurred. The determination can be supported by a finding of fact or by investigator self-report of non-compliance.

**Guardian:**
In Illinois, a *Guardian* of a minor means someone who has the duty and authority to act in the best interests of the minor, subject to residual parental rights and responsibilities, to make important decisions in matters having a permanent effect on the life and development of the minor and to be concerned with his or her general welfare.

**Human Research Protection Program (HRPP):**
A systematic and comprehensive approach, taken by an organization, to ensure human subject protection in all human research conducted under the auspices of the institution.

**Human Subject:**
Is an individual who is or becomes a subject 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.

**Human Subjects Research:**
Is defined as an activity that meets the definition of *research* and involves *human subjects* as defined by HHS regulations.

**Identifiable information:**
Is information through which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

**Indemnify:**
Means to release, or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence.

**Interaction:**
Communication or interpersonal contact between investigator and subject.

**Intervention:**
Physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subjects environment that are performed for research purposes.

**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:**
An Institutional Review Board established in accord with and for the purposes expressed in this policy.

**Legally authorized representative:**
Means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subjects participation in the procedure(s) involved in the research.

**Minimal Risk:**
The determination of the IRB that 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.

**Minimal Risk:**
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.

**Neonate:**
A newborn.

**Non-Compliance:**
Is defined as failure to comply with any of the regulations and policies described in this document and failure to follow the determinations of the IRB.

**Serious Non-Compliance:**
Failure to follow any of the regulations and policies described in this document or failure to follow the determinations of the IRB and that, in the judgment of either the HSRO or the full IRB committee, increases risks to participants, decreases potential benefits, or compromises the integrity of the human research protection program. Research being conducted without prior IRB approval is considered serious non-compliance.

**Nonviable Neonate:**
A neonate after delivery that, although living, is not viable. See definition of *viable* below.

**Obtaining:**
Means receiving or accessing identifiable private information or identifiable specimens for research purposes.

**Parent:**
A child's biological or adoptive parent.

**Participant:**
Is the preferred reference in some academic disciplines

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

**Pregnancy:**
The period of time from implantation until delivery. A woman is 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.

**Primary Reviewer:**
An IRB member formally designated by the IRB Chair to lead a protocol review on behalf of the IRB and make a recommendation to the chair or full IRB regarding protocol approval.

**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 that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

**Privacy:**
Having 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 that 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 subjects.

**Protocol:**
An application for approval of proposed research, submitted to the institution’s IRB.

**Quorum:**
Consists of a simple majority of the voting membership, including at least one member whose primary concern is in a non-scientific area.

**Related to the research:**
An event is related to the research procedures if, in the opinion of the Responsible Primary Investigator or the Responsible Research Supervisor, the event is more likely than not to be caused by the research procedures and/or affects the rights and welfare of current participants.

**Research:**
A ***systematic investigation***, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition may be funded or unfunded, or maybe conducted as a component of another program not usually considered research. For example, demonstration and service programs may include evaluation components, which constitute research activities under this definition.

**Research:**
As defined by the Food and Drug Administration (FDA) regulations under Title 21, Part 56, Institutional Review Boards, 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 under Section 505(i) or 520(g) of the Act, or is not subject to requirements for prior submission to the Food and Drug Administration 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.

**Experiment:**
As defined in 21 CFR 312, includes any use of a drug other than the use of a marketed (approved) drug in the course of medical practice.

**Response Principle Investigator (RPI; also known as Lead Investigator):**
The individual who has lead responsibility for conducting the research. The RPI may be a UIS employee, student, or external individual. Whenever the Responsible Primary Investigator is not a UIS faculty or staff member, the research must be supervised by a non-visiting UIS faculty or staff member, who will be designated as the Responsible Research Supervisor (RRS).

**Responsible Research Supervisor (RRS):**
A non-visiting member of the UIS faculty or staff (i.e., an employee of UIS) who has supervisory responsibility for the protection of the subjects and the conduct of the human subjects research described in the research protocol submitted for review under the UIS Policy and Procedures for Human Research Protection. UIS students and graduate assistants may serve as RPI but cannot serve as RRS.

**Significant Financial Interest:**

A Significant Financial Interest (SFI) (42 CFR 50.603) is identified when:

- The value of any remuneration received from an external entity at present or in the 12 months preceding the disclosure that when aggregated for the individual, one's spouse or domestic partner, parents, siblings, and children totals or exceeds $5,000. The $5,000 threshold also applies to salary, royalties, and other payments aggregated for the individual, one's spouse or domestic partner, parents, siblings, and children.
- Publicly-traded equity if the value of the equity (plus any remuneration) meets or exceeds $5,000.
- Any level of ownership of privately-held equity regardless of the dollar value.

**Subject:**

Will be used throughout this policy because it has a long history of use across disciplines and continues to be the standard term used in applicable federal policies.

**Systematic Investigation:**

Is an activity that involves a prospective research plan which incorporates data collection, both quantitative and qualitative, and data analysis to answer a research question. ***Investigations designed to develop or contribute to generalizable knowledge*** are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.

**UIS Employee:**

Any faculty or staff member employed by UIS including non-visiting UIS faculty or staff. UIS students, including graduate assistants, are not considered UIS employees and cannot be designated as the RRS under this policy.

**Unanticipated Problem Involving Risks to Participants or Others (Unanticipated Problem):**

Any event or information that (1) was unforeseen and (2) indicates that the research procedures caused harm to participants or others, or that participants or others are at increased risk of harm.

**Unexpected:**

An event is unexpected when its specificity and severity are not accurately reflected in the informed consent document.

**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.

**Vulnerable Populations:**

Is a subgroup of the population who because of their status are at greater risk to be coerced or influenced to participate in human subject's research. This subgroup includes individuals with acquired immune deficiency syndrome (AIDS), fetuses, pregnant women, minorities (including women), children (minors), prisoners, decisionally impaired persons, elderly and aged persons, international research subjects, terminally ill patients, traumatized and comatose patients,

students, and employees. (See the Office of Human Research Protections (OHRP) guidelines at http://www.hhs.gov/ohrp/irb/irb_guidebook.htm). Researcher should consider the fact that vulnerability can also be context-specific. It is important for researchers to consider the context as well as what is being asked of whom, and under what conditions. The same factors that make subjects available for research make them vulnerable to overuse.