OBJECTIVE

To describe policies and procedures for reviewing protocol submissions involving vulnerable populations of participants.

GENERAL DESCRIPTION

The Nova Southeastern University (NSU) Institutional Review Board (IRB) gives special consideration to protecting the welfare of vulnerable populations of participants such as children, prisoners, fetuses/neonates, pregnant women, and individuals with consent capacity impairment. The IRB also recognizes that additional populations such as employees, students, and patients of investigators may qualify as vulnerable populations and need safeguards in place for their protection while participating in a research study.

Definitions

Age of majority: The threshold of adulthood as recognized or declared in law, which varies from state to state. It is the moment when a *minor* ceases to be considered a *child* and assumes legal control over their person, actions, and decisions. Reaching this age terminates the control and legal responsibilities of their parents or guardian over them.

Children (or minors): Individuals who have not attained the legal *age of majority* for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Employees: An individual employed for wages or salary. While not considered a vulnerable population per regulations, they may perceive that they are under some pressure from a superior or supervisor to agree to participate.

Fetuses: The product of conception from implantation to delivery.

Neonates: A newborn from birth to 30 days.

Nonviable neonate: A neonate after delivery that, although living, is not viable as it pertains to the neonate. Which means that after delivery, the neonate is not able to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

Patients of Investigator: A patient is an individual receiving or registered to receive treatment from a care provider, such as their doctor. While not considered a vulnerable population per regulations, patients of an investigator may perceive that they are under some pressure from their care-provider to agree to participate or mistake a recommendation to enroll in a research study as a clinical recommendation.

Pregnant Women: 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. Encompasses the period from implantation until delivery. A pregnant woman shall only be deemed a "vulnerable population" when they are being recruited for participation specifically because they are pregnant or may become pregnant.

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.

Students: A person who is studying at a school, college, or university. A student shall only be deemed a "vulnerable population" when they are being recruited for participation specifically because they are a student.

Vulnerable Population: A population whose members may not be able to make informed decisions for themselves, may be in situations in which they can easily be manipulated, or may be a convenient and readily available study population.

RESPONSIBILITY

Execution of SOPP: Principal Investigator (PI)/Research Personnel, IRB Office Staff, IRB Members, IRB Chairs

PROCEDURES

A. Investigator Responsibilities

1. The investigator identifies the categories of vulnerable participants involved in the research in the IRB protocol submission.
2. When research on vulnerable participants is conducted outside the state of Florida, the investigator is responsible for identifying the applicable state law(s) to the determination of legally authorized representative and age of majority. Documentation must be submitted to the IRB for review with the protocol submission.
3. The investigator will complete specific sections in the protocol submission, which focus on the ethical and regulatory issues pertaining to research that involves vulnerable populations as defined in this SOPP.

4. The IRB Office provides specific guidance sheets on their website that detail the ethical and regulatory logistics regarding each type of vulnerable population.

B. Protocol Submission Review Process

1. The IRB reviews the protocol submission to determine whether the research includes enrollment of vulnerable populations and whether appropriate safeguards are in place.
2. When applicable, IRB Office staff may provide additional materials pertaining to the regulations regarding the category of vulnerable participant to the IRB Chair or the convened IRB depending on the level of review required.
3. The IRB considers, but is not limited to, reviewing the following elements for research involving vulnerable participants:
   a. Inclusion/exclusion criteria;
   b. Over-selection or exclusion of certain groups based on perceived limitations (i.e., targeting prisoners as research participants because they are a readily available "captive" population);
   c. Knowledge of applicable or local laws that bear on the decision-making process (i.e., emancipated individuals, legally authorized representatives, age of majority for research consent).
4. The IRB follows all applicable federal and state regulations and IRB policy to assist in reviewing and approving proposed research that involves vulnerable participants such as:
   a. Pregnant Women, Human Fetuses, and Neonates (45 CFR 46, Subpart B) - (See IRB guidance sheet titled "Vulnerable Populations: Pregnant Women, Human Fetuses, and Neonates").
   b. Research Involving Prisoners (45 CFR 46, Subpart C) – (See IRB guidance sheet titled "Vulnerable Populations: Prisoners").
   c. Research Involving Individuals with Impaired Consent Capacity – (See IRB guidance sheet titled "Vulnerable Populations: Individuals with Impaired Consent Capacity).
   d. Research Involving Employees, Students, and/or Patients of the Investigator – (See IRB guidance sheet titled "Vulnerable Populations: Enrolling Employees, Students, and/or Patients of the Investigator).
5. IRB membership includes representation with expertise in selected vulnerable populations routinely reviewed by the IRB, such as children or prisoners. For full review submissions, IRB Office staff will ensure reviewers with the appropriate expertise are consulted for research involving prisoners or research involving children that is greater than minimal risk or requires consultation for other issues. These reviewers may either attend the convened meeting or provide written comments, upon request.

6. For exempt/expedited reviewed submission, determinations regarding vulnerable populations will be documented in the reviewer notation section of the protocol submission. For full review by the convened IRB, IRB Office staff document specific findings in the meeting minutes.

REFERENCES

45 CFR 46 Subpart B
45 CFR 46 Subpart C
45 CFR 46 Subpart D
21 CFR 50 Subpart D
34 CFR 97 Subpart D