

## DIVISION OF RESEARCH

<b>SUBJECT:</b> Research with Vulnerable Populations	<b>Policy Number:</b> 10.3.6	<b>Effective Date:</b> October 20, 2023
	<b>Supersedes:</b> Children in Research 10.3.2 “Research Subjects with Cognitive Impairment”	<b>Pages:</b> 3
	<b>Responsible Authorities:</b> Vice President for Research Assistant Vice President, Research Integrity Institutional Review Board	

### I. Background

It is the responsibility of the Florida Atlantic University (FAU) IRB to ensure that procedures are in place in a research activity to protect the subjects taking part. This is especially true when a research activity involves a vulnerable population group as research subjects. Special circumstances are sometimes necessary and special protections must be put in place to adequately protect vulnerable populations. This includes the categories of vulnerable subjects categorized by the Federal regulations and those which might be vulnerable due to other considerations or the circumstances of the research activity itself.

### II. Purpose

The purpose of this policy is to set forth the definitions and regulations which define vulnerable populations, and to codify FAU’s position that any human subjects research involving vulnerable populations conducted under its auspices, regardless of funding mechanism, must undergo regulatory review and adhere to the principles outlined in the [Belmont Report](#).

### III. General Statement

A “vulnerable population” is any population at risk for coercion or undue influence that may require special protections. A vulnerable population may have a limited ability to make a free and uninfluenced decision to provide consent to participate in research. There are some groups who have been identified by the federal regulations as vulnerable populations: pregnant women and fetuses, minors, prisoners, persons with impaired decision making capacity, and those who are educationally or economically disadvantaged. Pregnant women, prisoners, and minors have specific sections in the federal regulations that provide additional rules for studying these participants. Inability to consent does not limit participation in a study but instead requires that additional safeguards and consent procedures are followed.

#### Definitions

**Economically or educationally disadvantaged persons:** those persons placed at special risk by socioeconomic and educational background.

(i) Economically disadvantaged persons include those persons who struggle to provide basic necessities for themselves and their families or communities.

(ii) Educationally disadvantaged persons may have educational deficits, learning disabilities, or cultural backgrounds that limit communication and understanding with a researcher.

**Individuals With Impaired Decision-Making Capacity:** those persons having a psychiatric or developmental disorder that affects cognitive or emotional functions to the extent that the capacity for judgment and reason is significantly diminished. Other persons, including those under the influence of or dependent on alcohol or drugs, those affected by degenerative brain diseases, those who are terminally ill, and those who have severe physically disabling handicaps, may be compromised in their ability to make decisions in their best interests.

The following definitions are reflective of Federal law (45CFR46; 21CFR50).

*Research Involving Pregnant Women, Human Fetuses, and Neonates* (45CFR46.202)

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

Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.

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

**Neonate:** a newborn.

**Nonviable neonate:** a neonate after delivery that, although living, is not viable (defined herein).

**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 a pregnancy test are negative or until delivery.

**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.

*Research Involving Prisoners* (45CFR46.303)

**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.

*Research Involving Minors* (45CFR46.402)

**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.

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

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

research.

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

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

**Ward:** a child who is placed in the legal custody of the State or other agency, institution, or entity, consistent with applicable Federal, State, or local law.

IV. Policy

Any research involving vulnerable population as defined in this policy, and is conducted under the auspices of FAU, must be submitted to the FAU Institutional Review Board, or other appropriate IRB, for review prior to initiation.

V. Accountability

**The Principal Investigator (PI) will be responsible for:**

- Ensuring that any proposed study that includes vulnerable populations is submitted to the FAU IRB, or other appropriate IRB, in a timely fashion for review, prior to initiating the study.
- Following all FAU policy, procedure, and guidance related to the conduct of research with vulnerable populations.

VI. Procedures

For procedures and guidance on conducting research with vulnerable populations, refer to the applicable documents:

- 405 Investigator Guidance- Research Involving Pregnant Women, Fetuses, and Neonates
- 406 Investigator Guidance- Research Involving Prisoners
- 407 Investigator Guidance- Research Involving Children
- 408 Investigator Guidance- Classroom Research
- 409 Investigator Guidance- Research Involving Other Vulnerable Populations

VII. Policy Renewal: As needed

VIII. References

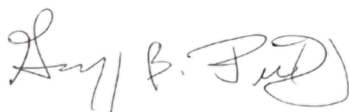
45 CFR 46.202  
45 CFR 46.303  
45CFR 46.402  
21 CFR 50

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POLICY APPROVAL

*Initiating Authority*

Signature:



Date: 10/18/2023

Name: Gregg Fields, Ph.D., Vice President for Research

Executed signature pages are available in the Initiating Authority Office(s)