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Human Research Protection Program

Institutional Review Board (IRB) Researcher Education Series

VULNERABLE POPULATIONS

SUBPART B: PREGNANT WOMEN, FETUSES, & NEONATES

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Defining Vulnerable Populations

"Vulnerability, in the context of research, should be understood to be a condition, either intrinsic or situational, of some individuals that puts them at greater risk of being used in eithically inappropriate ways in research" (National Bioethics Advisory Counsel, 2001)

Two general themes:

1. Have difficulty providing voluntary, informed consent arising from limitations in decision-making capacity or situations circumstances
2. Especially at risk for explotation or coercion

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Vulnerable Populations as defined by DHHS

As defined in the Common Rule:

subpart B: Pregnant Women, Fetuses, & Neonates

subpart C: Prisoners

subpart D: Children

Adults with Impaired Decision-Making Capacity

While the subparts outline additional requirements for each vulnerable population, those requirements are in addition to the ones outlined in 45 CFR 46 which apply to all research conducted using Human Subjects.

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Research with Pregnant Women

After the implementation of the 2018 Common Rule, pregnant women are no longer considered examples of populations that are vulnerable to coercion or undue influence.

Guidance now frames pregnant women as a "complex" population.

The American College of Obstetricians and Gynecologists has endorsed the term "scientifically complex" to describe pregnant women and their fetuses who, even though not considered vulnerable in the traditional sense, do require additional protections

Institutional Review Board Managment and Function, 3rd Edition

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Important Definitions

Fetus: unborn child from time of implantation to birth

Neonate: new born child

Pregnancy: encompasses time from implantation to birth

Viable, *as it pertains to the neonate*: after birth, being able to survive on one's own, including independently maintaining a heartbeat and respiration

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Requirements for Inclusion of Pregnant Women & Fetuses

1. Risk must be reasonable and the least possible for achieving the objective(s)
2. Informed Consent must be obtained before research proceeds
3. Preliminary data, including data from studies conducted on pregnant animals and non-pregnant women, is available to assess potential risks to pregnant women & fetuses, where scientifically appropriate
4. The risk to the fetus is minimal or caused solely by interventions/procedures that hold out the prospect of direct benefit to the pregnant woman and/or fetus

See 45 CFR 46.204(a-c)

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Special Circumstances

Paternal Permission

In cases where the prospect of direct benefit is limited to the fetus (the pregnant woman will not benefit at all), the consent of the father is required.

Exceptions include cases of rape, incest, or when the father is unavailable/incapacitated

Pregnant Children

In cases where you are enrolling pregnant children, provisions in both subpart B and subpart D must be applied.

See 45 CFR 46.204(d-g)

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Parameters for Inclusion of Neonates

1. Researchers and study staff cannot play a role in assessing or determining a neonate's viability.
2. If a neonate is determined nonviable, research activities cannot maintain neonate's vital functions or terminate its heartbeat or respiration. Research on nonviable neonates must be in service to important biomedical knowledge not otherwise obtainable.
3. If a neonate is of uncertain viability, research may be undertaken if (a) it carries out the prospect of enhancing the survival to viability; or (b) it is in service to important biomedical knowledge not otherwise obtainable.
4. If/once a neonate is determined to be viable, the research must be evaluated under subpart D.

See 45 CFR 46.205

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Parameters for Use of After Delivery, Placenta, Dead Fetus, or Fetal Material

Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, must be conducted in accordance with any applicable federal, state, or local laws and regulations regarding such activities

- Louisiana RS 14:87.2: https://legis.la.gov/Legis/Law.aspx?d=78690

If information derived from the after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus is recorded in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of subpart B are applicable

See 45 CFR 46.206

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Modifications to subpart B When the DoD is Involved

DoD research involving pregnant women, fetuses, & neonates must comply with subpart B of 45 CFR 46, with the following modifications:

- For purposes of applying Subpart B, the phrase “biomedical knowledge” must be replaced with “generalizable knowledge.”
- The applicability of Subpart B is limited to research involving pregnant women as participants in research that is more than minimal risk and included interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as participants.

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Additional Resources

45 CFR 46, subpart B
https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-b/index.html

LSUHSC - NO HRPP Policies and Procedures 7.01
https://www.lsuhsc.edu/administration/academic/ors/policies_procedures.aspx