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| SOP: 501 Effective Date: 07/01/2019 | RESEARCH INVOLVING PREGNANT WOMEN, FETUSES, AND NEONATES | Supersedes Document Dated: 12/05/2017 |
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1. POLICY

A central principle of Human Subjects Research is that participants should grant informed consent prior to the commencement of any research. This process is complicated in research involving pregnant women, fetuses, and neonates, as one party that will be affected the research is incapable of granting consent.

As a result, the Institutional Review Board (IRB) must take additional criteria into account when evaluating proposed research involving pregnant women, fetuses, and neonates, and the IRB should consider engaging experts or consultants to assist with the review. An IRB may only approve research involving pregnant women, fetuses, or neonates that fulfills the criteria listed below, in addition to the standard approval criteria found in SOP 302: Initial Review.

These policies and procedures apply to all research submitted to the IRB.

2. DEFINITIONS

- 2.1 *Fetus.* The product of conception from implantation until delivery.
- 2.2 *Neonate.* A newborn.
- 2.3 *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.
- 2.4 *Viable (as it pertains to the neonate).* Being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the Federal Register guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of this SOP.

3. PROCEDURES

- 3.1 **Pregnant Women and Fetuses.** Pregnant women or fetuses may be involved in research if all of the following conditions are met:
 - 3.1.1 Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

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- 3.1.2 The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of specific benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means
- 3.1.3 Any risk is the least possible for achieving the objectives of the research;
- 3.1.4 If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of SOP 320: Informed Consent Requirements;
- 3.1.5 If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions SOP 320: Informed Consent Requirements, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
- 3.1.6 Each person providing consent under paragraph 3.1.4 or 3.1.5 above is fully informed regarding the reasonably foreseeable impact of the research on the fetus and/or resultant child;
- 3.1.7 For children who are pregnant, assent and permission are obtained in accord with the provisions of SOP 502: Research Involving Children;
- 3.1.8 No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
- 3.1.9 Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
- 3.1.10 Individuals engaged in the research will have no part in determining the viability of a fetus.

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3.2 Neonates.

3.2.1 Neonates of Uncertain Viability. After delivery, a neonate of uncertain viability may not be involved in research unless all of the following additional conditions are met:

- (a) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates;
- (b) The individual(s) providing consent under the applicable regulations is/are fully informed regarding the reasonably foreseeable impact of the research on the neonate;
- (c) Individuals engaged in the research will have no part in determining the viability of a neonate.
- (d) The IRB determines that:
 - i. The research holds out the prospect of enhancing the probability of survival of the particular neonate to the point of viability, and any risk is the least possible for achieving that objective; or
 - ii. The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the neonate resulting from the research; and
- (e) The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with SOP 320: Informed Consent Requirements, unless altered or waived in accordance with SOP 321: Waiver or Alteration of Informed Consent

3.2.2 Nonviable Neonates: After delivery, a nonviable neonate may not be involved in research unless all of the following additional conditions are met:

- (a) Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates;

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- (b) The individual(s) providing consent under the applicable regulations is/are fully informed regarding the reasonably foreseeable impact of the research on the neonate;
- (c) Individuals engaged in the research will have no part in determining the viability of a neonate.
- (d) Vital functions of the neonate will not be artificially maintained;
- (e) The research will not terminate the heartbeat or respiration of the neonate;
- (f) There will be no added risk to the neonate resulting from the research;
- (g) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
- (h) The legally effective informed consent of both parents of the neonate is obtained in accordance with SOP 320: Informed Consent Requirements, except that the waiver and alteration provisions of SOP 321: Waiver or Alternation of Informed Consent do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of the regulations.

3.2.3 Viable Neonates. A neonate, after delivery, that has been determined to be viable is a child and may be included in research only to the extent permitted by and in accord with the requirements of SOP 502: Research Involving Children.

3.3 Research Involving, After Delivery, the Placenta, the Dead Fetus, or Fetal Material.

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

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- 3.3.2 If information associated with material described in paragraph (a) of this section is recorded for research purposes 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 regulations apply.

4. RESPONSIBILITY

When proposed research involves special populations, the IRB must take precautions to ensure research participants' rights, safety, and welfare. In all cases involving special populations, the IRB Administrator must stay abreast of applicable regulations and guidelines. IRB Chair and Members must be cognizant of the subjects' needs when evaluating the protocol and are responsible for determining any additional protective stipulations to be applied to the research.

When proposed research involves pregnant women, fetuses, and neonates, HRPP Support Staff, IRB Chair, and IRB Members will ensure that the protocol contains consent and assent documents, as appropriate.

IRB Administrator is responsible for maintaining up-to-date review tools for review of research pertaining to special populations based on new and evolving applicable regulations and guidelines.

IRB Chair, IRB Associate Chairs, and IRB Administrator are responsible for ensuring the IRB Members are well versed in new and evolving regulations and guidelines pertaining to special populations, for selecting primary reviewers with appropriate expertise to conduct the reviews of such research, and for securing appropriate consulting expertise as needed for selected reviews.

IRB Members are responsible for conducting appropriate review of research planned for special populations, including an assessment of potential for coercion, in consultation with any appropriate experts and resources.

5. APPLICABLE REGULATIONS AND GUIDELINES

The Belmont Report

45 CFR 46; Subpart B

45 CFR 46.122

21 CFR 56.111

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6. REFERENCES TO OTHER APPLICABLE SOPs

This SOP affects all other SOPs.