Research Involving Pregnant Women, Human Fetuses, and Neonates	Effective Date	
	Revisions Date	11.2.20

1.0 Purpose: The purpose of this SOP is to outline the regulatory requirements to conduct human research targeting pregnant women, fetuses, and neonates.

2.0 Persons Affected:

2.1 Investigators and study team members
2.2 University & Medical Center Institutional Review Board (UMCIRB) Chairpersons and members
2.3 UMCIRB staff members

3.0 SOP: The federal regulations have designated this population as a vulnerable group and, as such, additional protections must be in place and documented prior to beginning the research.

4.0 Definitions:

4.1 Dead fetus means a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.
4.2 Delivery means complete separation of the fetus from the woman by expulsion or extraction or any other means.
4.3 Fetus means the product of conception from implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until delivery.
4.4 Neonate means a newborn.
4.5 Nonviable neonate means a neonate after delivery that, although living, is not viable.
4.6 Pregnancy encompasses the period of time from implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until delivery.
4.7 Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.
4.8 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 heart beat and respiration. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the regulatory requirements for all research, as well as, those regulations applicable to children.

5.0 Responsibilities:

5.1 The Principal Investigator (PI)/Study Team Members will
5.1.1 Provide accurate information in the IRB application about the inclusion of pregnant women, fetuses or neonates.
5.1.2 Provide justification for the use of pregnant women, fetuses, or neonates as the targeted population in the proposed research (See Section 6.0 for acceptable regulatory justifications).
5.1.3 Respond in a timely fashion to any requests for changes or clarification needed prior to review or approval.

5.1.4 Plan for appropriate consent procedures as described below in section 6.0 as determined by protocol.

5.2 UMCIRB office staff will

5.2.1 Pre-review all applicable studies to ensure all required information has been provided.

5.2.2 Request changes or clarifications in the IRB application or other materials if needed.

5.2.3 Offer training and guidance to investigators and other study team members.

5.2.4 Revise this SOP accordingly as new information becomes available.

5.3 Institutional Review Board/IRB Chairperson or designee will

5.3.1 Review the research study to ensure it has addressed all requirements for inclusion of pregnant women, fetuses, and neonates.

5.3.2 Request necessary changes or clarification about any component of the research study prior to granting approval.

6.0 Procedures:

6.1 Research activity involving pregnant women or fetuses may be undertaken if all of the following are satisfied:

6.1.1 Appropriate studies on pregnant animals and non-pregnant individuals have been completed and provide data for assessing potential risk to pregnant women and fetuses.

6.1.2 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,

6.1.2.1 if there is no such prospect of 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.

6.1.3 Risks have been minimized to the least possible for achieving the objectives of the research.

6.1.4 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 standard informed consent procedures (see Informed Consent SOP).

6.1.5 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 standard informed consent procedures, 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.

6.1.6 Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

6.1.7 For children who are pregnant, assent and permission are obtained in accord with the provisions of the regulations applied to children (see Research Involving Children SOP).

6.1.8 No inducements, monetary or otherwise, will be offered to terminate a pregnancy.

6.1.9 Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

6.1.10 Individuals engaged in the research will have no part in determining the viability of a neonate.

6.2 Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are satisfied:

6.2.1 Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

6.2.2 Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

6.2.3 Individuals engaged in the research will have no part in determining the viability of a neonate.

6.3 Neonates of uncertain viability may be involved in research if the following *additional* conditions have been met:

6.3.1 The IRB determines that the research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective; or the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and

6.3.2 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 standard informed consent procedures, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

6.4 Nonviable neonates may be involved in research if all of the following *additional* conditions are satisfied:

6.4.1 Vital functions of the neonate will not be artificially maintained.

6.4.2 The research will not terminate the heartbeat or respiration of the neonate.

6.4.3 There will be no added risk to the neonate resulting from the research.

6.4.4 The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.

6.4.5 The legally effective informed consent of both parents of the neonate is obtained (a waiver or alteration of consent is not allowed). 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, 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 these requirements.

6.5 Viable neonates, as determined after delivery, may be included in research according to the provisions of the regulations applied to children (see Research Involving Children SOP).

6.6 Research involving, after delivery, the dead fetus, fetal material, or the placenta

6.6.1 Activities involving the dead fetus, macerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable federal, state, or local laws regarding such activities.

6.6.2 If information associated with the above biological materials 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 the research must follow all pertinent regulations.

6.7 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates. The Secretary will conduct or fund research that the IRB does not believe meets the requirements of 6.1 and 6.2 above only if:

6.7.1 The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and

6.7.2 The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the Federal Register, has determined either:

6.7.2.1 That the research in fact satisfies the conditions of section 6.1 above, as applicable; or

6.7.2.2 All of the following apply:

6.7.2.2.1 The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates.

6.7.2.2.2 The research will be conducted in accord with sound ethical principles.

6.7.2.2.3 Informed consent will be obtained in accord with the informed consent provisions within the federal regulations and other applicable subparts.

Revision History:

Date	Change	Reference Section(s)
1.27.2016	Pulled information to a stand-alone document.	All
11.2.2020	Added footer; changed office name from ORIC to UMCIRB	Section 2.3, 5.2

References

DHHS, OHRP. Code of Federal Regulations: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

DHHS, FDA. Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials Guidance for Industry, Draft Guidance, April, 2018.