1.0 Purpose:

1.1 Although pregnant women represent a medically complex population that may necessitate special scientific and ethical considerations, they are no longer considered a defined vulnerable population under the federal regulations. This policy, therefore, describes the conditions in which the Institutional Review Board (IRB) will approve research involving pregnant women, fetuses, and/or neonates.

1.1.1 The IRB will approve research regardless of funding source if, in addition to meeting all other requirements, the research satisfies the conditions of 45 CFR 46, Subpart B - Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research.

1.1.2 These regulations also cover research using human fetal tissue, placenta, or post-delivery fetal material.

1.1.3 The IRB will continue to ensure that research is conducted in an environment that allows all subjects to make informed and voluntary decisions about initial and ongoing research participation

2.0 Definitions:

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

2.2 **Delivery –** complete separation of the fetus from the woman by expulsion or extraction or any other means

2.3 **Fetus** - the product of conception from implantation until delivery

2.4 **Neonate** - a newborn

2.5 **Non-viable neonate** – a neonate after delivery that, although living, is not viable

2.6 **Pregnancy** - 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

2.7 **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. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A (Basic DHHS Policy for Protection of Human Research Subjects) and D (Additional Protections for Children Involved as Subjects in Research) of 45 CFR 46.

3.0 Procedure:

3.1 Research involving **pregnant women or fetuses** may be approved by the IRB only if the IRB finds that all of the following ten (10) conditions are met and the findings are documented:

3.1.1 Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

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 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 45 CFR 46.116 and 117;

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 45 CFR 46.116 and 117, 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 individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;

3.1.7 For children as defined in 45 CFR 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of 45 CFR 46;

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

3.2 Research involving **neonates of uncertain viability and nonviable neonates** may be approved by the IRB only if the IRB finds that all of the following conditions are met and the findings are documented:

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

3.2.2 Each individual providing consent under paragraph (3.2.4.1.1.2) or (3.2.4.2.5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

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

3.2.4 The requirements of paragraph (3.2.4.1) or (3.2.4.2) of this section have been met as applicable.

3.2.4.1 **Neonates of uncertain viability** - Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research unless the IRB finds that the following two (2) additional conditions are met and the findings are documented:

3.2.4.1.1 The IRB determines that:

3.2.4.1.1.1 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

3.2.4.1.1.2 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

3.2.4.1.2 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 subpart A of 45 CFR 46, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

3.2.4.2 **Nonviable neonates** - After delivery, a nonviable neonate may not be involved in research unless the IRB finds that all of the following five (5) additional conditions are met and the findings are documented:

3.2.4.2.1 Vital functions of the neonate will not be artificially maintained;

3.2.4.2.2 The research will not terminate the heartbeat or respiration of the neonate;

3.2.4.2.3 There will be no added risk to the neonate resulting from the research;

3.2.4.2.4 The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and

3.2.4.2.5 The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of 45 CFR 46, except that the waiver and alteration provisions of 45 CFR 46.116(c) and (d) 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, 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.

3.2.4.3 **Viable neonates** - A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D, Additional Protections for Children Involved as Subjects in Research.

3.3 **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.

3.3.1 If information associated with material described in paragraph 3.3 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 the provisions of 45 CFR 46, subparts A and D, must be met as applicable.

3.4 **Research not Otherwise Approvable** - If 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, the research may only be conducted after the Secretary of DHHS has consulted with an expert panel and there has been opportunity for public review and comment. The required findings for such research are that the research does present the aforementioned opportunity, the research will be conducted in accord with sound ethical principles and informed consent will be obtained.

4.0 Documentation:

4.1 The HRPP office will maintain documentation related to IRB review of studies conducted under Subpart B, including initial submissions, continuing reviews, and modifications, as well as reports of unanticipated problems, complaints, deviations, non-compliance, and correspondence related to review of such items, as well as checklists pertinent to the reviews, for a minimum of 6 years after completion of the study.

5.0 References:

5.1 45 CFR 46 Subpart B – Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research (45 CFR 46.201-207)

5.2 Institutional Review Board Management and Function, Bankert, E. A., Amdur, R. J., 2nd Edition, 2006

6.0 Revision History:

Rev #	Initials	Effective Date	Description of Change(s)
01	CLB	7/1/11	Conversion to new policy template; general expansion of policy
02	CLB	3/15/20	General review. Update to reflect the removal of pregnant women as a vulnerable category of research subjects

Element II.4.A. and III.1.C.