1.0 Purpose
The purpose of SOP is to describe the IRB requirements for research involving pregnant women, fetuses, and neonates.

2.0 Policy
UNL HRP policies provide for additional protections for pregnant women, fetuses, and neonates involved in research. These policies are described below.

Research, which is funded by DHHS must satisfy the additional protections described in 45 CFR §46 subpart B. For all other research, additional protections are identical to those found in 45 CFR §46 subpart B except as indicated in 2.2 (A) (2) (b)

2.1 Definitions
A. Pregnancy: Period from confirmation of implantation of a fertilized egg within the uterus until the fetus has been delivered. Implantation is confirmed through a presumptive sign of pregnancy (e.g., missed periods or a positive pregnancy test). While confirmation may be in error, investigators must presume that a living fetus was present until evidence is presented to the contrary.

B. Fetus: The product of conception from implantation until delivery.

C. Viable neonate: A neonate, after delivery that can survive to the point of independently maintaining heartbeat and respiration. (A viable neonate is covered by Health and Human Services regulations at 45 CFR §46, Subparts A and D.)

D. Nonviable neonate: A neonate after delivery that, although living, is not viable.

2.2 IRB Review
In addition to review of research under Health and Human Services regulations at 45 CFR §46 (Subpart A), the IRB must provide special review of all behavioral/social science research where pregnant women, fetuses and/or neonates are involved.

A. Research involving pregnant women or fetuses
1. Pregnant women may be involved in research funded by DHHS if all of the following conditions are met:
   a) Appropriate preclinical studies, including studies on pregnant animals and clinical studies involving non-pregnant women, have been conducted and provide data for assessing potential risks of pregnant women and fetuses.
   
   b) Any risk to the fetus is caused solely by interventions that offer direct benefit for the woman or fetus, or if there is no prospect of direct benefit:
1) the risk to the fetus must not be greater than minimal and 2) the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

c) Any risk to the pregnant woman or the fetus is the least possible to achieve the research objectives.

d) Consent of the pregnant woman alone is required for research which:
   1) Offers direct benefit to the pregnant woman only, OR
   2) Will not directly benefit the woman or fetus but: a) there is no more than minimal risk to the fetus, and b) the purpose of the research is to develop important knowledge and the data cannot be obtained by any other means.

e) Consent of the pregnant woman and father is required if the research offers direct benefit to only the fetus. However, the father’s consent is not required if he is unavailable, decisionally impaired, temporarily incapacitated, or if the pregnancy resulted from rape or incest.

f) The consent must fully disclose the reasonable foreseeable impact of the research on the fetus (e.g., risk).

g) Assent and parental permission for pregnant children participation in research must be obtained in accordance with Health and Human Services regulations 45 CFR §46, Subpart D (see HRPP policy # 5.004).

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

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

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

2. Pregnant women may be involved in research if all of the following conditions are met:

   a) Appropriate preclinical studies, including studies on pregnant animals and clinical studies involving non-pregnant women, have been conducted and provide data for assessing potential risks of pregnant women and fetuses.

   b) If any risk to the fetus is caused solely by interventions that offer direct benefit for the woman or fetus, or if there is no prospect of direct benefit, the risk to the fetus must not be greater than minimal.

   c) Any risk to the pregnant woman or the fetus is the least possible to achieve the research objectives.

   d) Consent of the pregnant woman alone is required for research which:
1) Offers direct benefit to the pregnant woman only, OR

2) Offers direct benefit to the woman and fetus, OR

3) Will not directly benefit the woman or fetus but there is no more than minimal risk to the fetus.

e) Consent of the pregnant woman and father is required if the research offers direct benefit to only the fetus. However, the father’s consent is not required if he is unavailable, decisionally impaired, temporarily incapacitated, or if the pregnancy resulted from rape or incest.

f) The consent must fully disclose the reasonable foreseeable impact of the research on the fetus (e.g., risk).

g) Assent and parental permission for pregnant children participation in research must be obtained in accordance with Health and Human Services regulations 45 CFR §46, Subpart D (see HRPP policy # 5.004).

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

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

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

B. Research involving placenta, dead fetus(s) or fetal material
Research involving the placenta, dead fetus, or fetal material after delivery may occur if all federal, state, or local laws and regulations are met. If any information associated with the material used in the research can be linked in any way to a living person, Health and Human Services regulations view the living person as a research participant and the research is subject to the regulations discussed in this policy. Note: The State of Nebraska has no applicable local or state laws or regulations.

C. Research not otherwise approvable
The Health and Human Services Secretary may conduct or fund research that the IRB does not feel meets the above policy if the following conditions are met:

1. The IRB finds that the research, which will be funded by Health and Human Services, 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 the Secretary has determined through consultation with a panel of experts that the research does, in fact, meet the requirements of 45 CFR 46.204;

   OR

2. The Secretary determined that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem
affecting the health and welfare of pregnant women, fetuses or neonates; is conducted in accord with sound ethical principles; and informed consent will be obtained. \textit{Note: For non-Health and Human Services funded research, involving pregnant women, fetuses, or neonates, the UNL IRB will convene an equivalent panel of experts to advise the IRB.}

2.3 Non-pregnant participants who become pregnant during research
If a participant becomes pregnant while actively participating in a research protocol, the investigator must:

A. Determine if it is in the best interest of the pregnant participant to continue participating in the study or terminate participation in the study by completing the report on unanticipated problems or adverse event(s) involving risks to research participants or others, as described in HRPP Policy # 13.001.

B. If it is in the best interest of the pregnant participant to remain in the study, adequate justification must be provided to receive IRB Chair approval for the participant to continue participation. If it is not in the best interest of the participant to continue, the participant’s participation must be terminated.

C. The study must be re-reviewed by the full IRB, as soon as possible, in consideration of this policy.

2.4 Documentation of IRB findings under Subpart B
The IRB will fully document compliance with Subpart B in the minutes of the IRB meeting by documenting the required determinations and protocol–specific findings justifying those determinations.

\textbf{Administrative Approval:}

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Dan R. Hoyt, Ph.D. & Kimberly Andrews Espy, Ph.D. \\
IRB Chair & Associate Vice Chancellor for Research \\
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