Research Involving Pregnant Women and Fetuses (HRPP 4.2) (*45 CFR 46 Subpart B*)

Description:
This policy describes UNMC's requirements for IRB review and approval of research involving pregnant women and fetuses.

Research Involving Pregnant Women and/or Fetuses:

If **research is subject to HHS regulations at 45 CFR 46 Subpart B**, pregnant women may be involved in research on **if ALL of the following conditions are met:**

- When appropriate, pre-clinical studies have been conducted and provide data for assessing potential risks for enrollment of pregnant women and fetuses
- Risk to the fetus is:
  - Only due to interventions offering direct benefit to the woman or fetus; or
  - If no prospect of direct benefit, the risk to the fetus must be no more than minimal and the purpose of the research cannot be obtained in any other way
- Any risk to the woman or fetus must be the least possible to achieve research objective(s)
- No inducements may be offered to terminate a pregnancy
- All individuals providing consent must be fully informed of reasonably foreseeable impact on the fetus or neonate
- Research personnel may not be involved in decisions regarding pregnancy termination
- Research personnel may not be involved in determining the viability of a neonate

If the **research is NOT subject to 45 CFR 46 Subpart B,** the IRB may allow enrollment of pregnant women **if ALL of the above conditions are met except:**

- The IRB may waive the requirement for preclinical studies
- The IRB may accept that the development of knowledge justifies inclusion
- The IRB may waive the father's consent even if the prospect of direct benefit is solely to the fetus

Obtaining Consent:

No benefit for the pregnant woman OR the fetus (is not greater than minimal risk)	**Direct benefit to the pregnant woman only**	**Direct benefit to the pregnant woman AND the fetus**	**Direct benefit to the fetus only**
Consent from the pregnant woman only	Consent from the pregnant woman only	Consent from the pregnant woman only	Consent from the pregnant woman AND the father

- Consent of the father is not required if he is unavailable, incompetent, temporarily incapacitated, or if the pregnancy resulted from rape or incest
- **For MINORS-** assent from the pregnant minor must be obtained as well as permission from the parent(s)

Research Involving Placenta, Dead Fetuses, or Fetal Material:

- **Does NOT constitute human subjects research under 45 CFR 46 unless data can be linked to a living person**
- Research is allowed only if all applicable federal, state, and local regulations are followed
- Research involving dead fetuses or fetal material is prohibited under the University of Nebraska Board of Regents policies

Subjects Who Become Pregnant During the Research:

If a non-pregnant subject becomes pregnant while actively participating in a research study:

- All research activities and interventions involving the pregnant subject must be PAUSED until the protocol is reviewed, unless:
  - The PI determines that continued participation is in the best interest of the subject, and
  - Provides a justification to the IRB Chair, who is authorized to make the final determination
- **If continued participation IS NOT in the subject's best interest:**
  - The subject's participation must be terminated
  - The PI must arrange for appropriate continued treatment for the subject, if necessary
- **If continued participation IS in the subject's best interest:**
  - Research activities may resume for the pregnant subject
  - The study must be re-reviewed by the full IRB as soon as possible