

# 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 Fetuses- Additional Protections:**

Research that IS subject to 45 CFR 46 Subpart B:

- Where appropriate, pre-clinical studies have been conducted and provide data for assessing potential risks for enrollment of pregnant women and fetuses.
- 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 for direct benefit, the risk to the fetus must not be greater than minimal risk and the purpose of the research cannot be obtained in any other way.
- Any risk to the pregnant woman or fetus is the least possible to achieve the research objective(s).
- No inducements will be offered to terminate a pregnancy.
- Individuals engaged in research will have no part in any decisions about terminating the pregnancy.
- Individuals engaged in research will have no part in determining the viability of a neonate.

Research that is NOT subject to 45 CFR 46 Subpart B:

- ALL of the above apply but the following exceptions may be made:
  - The IRB may decide preclinical studies are not reasonable requirements.
  - The IRB may decide the purpose of the research need only be development of knowledge which has sufficient value which justifies the enrollment of pregnant women.
  - The IRB may decide the consent of the father is not a requirement of research which holds the prospect of direct benefit solely for 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).

### **If a Subject Becomes Pregnant During Research:**

- All research activities for this subject must STOP until the protocol is reviewed,
  - unless the PI determines it is in the best interest of the subject to continue participation and provides justification to the IRB Chair who makes the final determination.
- If it's determined it's **NOT in the best interest of the subject to remain in the study**, their participation will be terminated and the PI must make provisions for continuation of necessary treatment, as applicable.
- If it's determined that **it IS in the best interest of the subject to remain in the study**, research activities may continue but the study must be re-reviewed by the full IRB ASAP.