Department: **UAMS Institutional Review Board**
Policy Number: **17.8**
Section: **Special Populations**
Effective Date: **July 31, 2002**
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SUBJECT: Pregnant Women, Fetus, and Human In Vitro Fertilization

This policy applies to all research, development, and related activities involving: (1) the fetus, (2) pregnant women, and (3) human *in vitro* fertilization and is based on the Federal Regulations at 45 CFR 46 Subpart B. The requirements in this Policy are in addition to those imposed under the other IRB policies and other applicable federal, state and local laws.

Research involving women who are or may become pregnant should receive special attention from the IRB because of women's additional health concerns during pregnancy and because of the need to avoid unnecessary risk to the fetus. Further, in the case of a pregnant woman, the UAMS IRB will determine when the informed consent of the father to the research is required. Special attention is justified because of the involvement of a third party (the fetus) who may be affected but cannot give consent and because of the need to prevent harm or injury to future members of society. Procedural protections beyond the basic requirements for protecting human subjects are prescribed in federal regulations for research involving pregnant women.

Definitions

"Pregnancy" encompasses the period of time from confirmation of implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.

"Fetus" means the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until a determination is made, following expulsion or extraction of the fetus, that it is viable.

"Viable" as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. If a fetus is viable after delivery, it is a premature infant.

"Nonviable fetus" means a fetus *ex utero*, which, although living, is not viable.

"Dead fetus" means a fetus *ex utero*, which exhibits none of the following: heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).

"*In vitro* fertilization" means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

Additional Requirements For Activities Involving Fetuses, Pregnant Women, or Human In Vitro Fertilization. In addition to all other requirements for approval, the UAMS IRB will determine that:

1. Adequate consideration has been given to the manner in which potential subjects will be selected; and
2. Adequate provision has been made by the investigator for monitoring the actual informed consent process (e.g., through such mechanisms, when appropriate, as participation by the IRB or subject advocates in (i) overseeing the actual process by which individual consents are secured either by approving induction of each individual into the activity or verifying, perhaps through sampling, that approved procedures for induction of individuals into the activity are being followed, and (ii) monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen).
3. No person on the research team should play any role in the determination of fetal viability.

Activities Directed Toward Pregnant Women as Subjects

1. No pregnant woman may be involved as a subject unless: (1) the purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal.

2. Father's Consent. Research may be conducted only if the mother and father are legally competent and have both given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (1) the purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot reasonably be ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape.

Activities Directed Toward Fetuses *In Utero* as Subjects

1. No fetus *in utero* may be involved as a subject in any research activity covered by this Policy unless the IRB determines either: (1) the purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

2 Research may be conducted only if the mother and father are legally competent and have both given their informed consent, except that the

father's consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

Activities Directed Toward Fetuses *Ex Utero*, Including Nonviable Fetuses, as Subjects

1. Until it has been ascertained whether or not a fetus *ex utero* is viable, a fetus *ex utero* may not be involved as a subject in an activity covered by this Policy unless:

   a. there will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or

   b. the purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

   2. No nonviable fetus may be involved as a subject in an activity covered by this Policy unless:

   a. vital functions of the fetus will not be artificially maintained,

   b. experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and

   c. the purpose of the activity is the development of important biomedical knowledge that cannot be obtained by other means.

3. In the event the fetus *ex utero* is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other parts of this Policy.

4. Research may be conducted only if the mother and father are legally competent and have both given their informed consent, except that the father's informed consent need not be secured if: (1) his identity or whereabouts cannot reasonably be ascertained, (2) he is not reasonably available, or (3) the pregnancy resulted from rape.

Activities Involving the Dead Fetus, Fetal Material, or the Placenta. 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 State or local laws regarding such activities.

Modification or Waiver of Specific Requirements. Upon the request of the investigator (with the approval of the IRB), the Secretary of the Department of Health and Human Services may modify or waive any of the above requirements of this Policy.

Studies in Which Pregnancy is Coincidental to Subject Selection. Any study in which women of childbearing potential are possible subjects may inadvertently include pregnant women. Federal regulations require that, when appropriate, subjects be provided a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable as part of the informed consent process.

The IRB must judge whether the mother's participation would pose any risk to the fetus or nursing infant. In some studies, the IRB may need to ensure that non-pregnant subjects are advised to avoid pregnancy or nursing for a time during or following the research. Furthermore, where appropriate, subjects should be advised to notify the investigator immediately should they become pregnant. In some instances, there may be potential risk sufficient to justify requiring that pregnant women either be specifically excluded from the research or studied separately.

Exemption from Review. Note that the exemptions from IRB review **DO NOT** apply to research involving pregnant women.