MUSC
Medical University of South Carolina

I. Policy

A. Procedures When Pregnancy is Coincidental to Subject Selection

1. Women of childbearing potential will be included in all study populations unless the investigator provides clear, sound rationale for excluding this population group. If exclusion of pregnant women, nursing women, or women who wish to start a pregnancy is justified, the protocol and informed consent document should explain the reasons for the exclusion.

2. If the research study poses known risks and/or lack of knowledge relative to the risks to a pregnant woman and/or fetus, the eligibility screening will include a pregnancy test; pregnancy tests will be performed throughout the woman's participation as appropriate.

3. As appropriate, the informed consent will include statements regarding:

   a) the need for pregnancy testing before and during the study,

   b) the recommended contraceptive methods based on the known risks,

   c) the need to notify the Principal Investigator immediately if pregnancy occurs and

   d) the possibility of unforeseen risks to the subject and/or fetus.

B. Procedures for Studies Directed Primarily Toward the Mother's and/or Fetus's Health

1. The "Special Subject Populations – Pregnant Women, Fetuses, Neonates" checklist will be used as a guide for IRB evaluation and will be completed by the primary reviewer.

2. If the research holds the prospect of direct benefit to the mother or to the mother and the fetus, a greater than minimal risk to the fetus is acceptable if:

a) where appropriate, data are available from prior animal studies and nonpregnant women clinical studies to assess potential risks to pregnant women and fetuses;

b) the risk to the fetus is caused solely by interventions or procedures that hold the prospect of direct benefit for the woman or the woman and fetus; and,

c) 3) 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.

The pregnant woman's consent is sufficient to enroll in the study. The informed consent document will fully describe the reasonably foreseeable impact of the research on the fetus or neonate [45 CFR 46.204]

3. If the research holds the prospect of direct benefit solely to the fetus, a greater than minimal risk to the fetus is acceptable if:

a) where appropriate, data are available from prior animal studies and nonpregnant women clinical studies to assess potential risks to pregnant women and fetuses;

b) the risk to the fetus is caused solely by interventions or procedures that hold the prospect of direct benefit for the fetus; and

c) any risk is the least possible for achieving the research objectives.

Informed consent must be obtained both from the mother and the father unless he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest. The reason for not obtaining the father's informed consent must be documented in the research record. The informed consent document will fully describe the reasonably foreseeable impact of the research on the fetus or neonate (45 CFR 46.204).

4. If the research does not hold the prospect of direct benefit to the woman or fetus, the research is acceptable if the risk to the fetus is not greater than minimal and:

a) where appropriate, data are available from prior animal studies and nonpregnant women clinical studies to assess potential risks to pregnant women and fetuses,

b) the study intends to develop important biomedical knowledge that cannot be obtained by any other means, and

c) any risk is the least possible for achieving the research objectives.

The pregnant woman's consent is sufficient to enroll in the study. The informed consent document will fully describe the reasonably foreseeable impact of the research on the fetus or neonate (45 CFR 46.204)

5. Research involving pregnant women and fetuses can only be conducted if:

a) no inducements, monetary or otherwise, will be offered to terminate a pregnancy;

b) 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

c) individuals engaged in the research will no part in determining the viability of a neonate [45 CFR 46.204].

6. For children who are pregnant, assent and permission will be obtained in accordance with regulations.

C. Procedures for Research Involving nonviable Neonates

1. The "Special Subject Populations – Pregnant Women, Fetuses, Neonates" checklist will be used as a guide for IRB evaluation and will be completed by the primary reviewer.

2. A "nonviable neonate" means a neonate after delivery that, although living is not viable (45 CFR 46.202). Nonviable neonates may be involved in research if: 1) where appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates; 2) individuals engaged in the research will have no part in determining the viability of the neonate; 3) vital functions of the neonate will not be artificially maintained; 4) the research will not terminate the heartbeat or respirations of the neonate; 5) there will be no added risk to the neonate resulting from the research; and, 6)the purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means [45 CFR 46.205].

3. The informed consent of both parents is required. The informed consent of one parent is acceptable if either parent is unable to

consent because of unavailability, incompetence, or temporary incapacity. The consent of the father is not required if the pregnancy resulted from rape or incest. The consent of a legal representative of either parent is not acceptable. The reason for not obtaining both parents' informed consent must be documented in the research record. The informed consent document will fully describe the reasonably foreseeable impact of the research on the neonate [45 CFR 46.205].

D. Procedures for Research Involving Neonates of Uncertain Viability

1. The "Special Subject Populations – Pregnant Women, Fetuses, Neonates" checklist will be used as a guide for IRB evaluation and will be completed by the primary reviewer.

2. Neonates of uncertain viability may be involved in research if:

   a) where appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates;

   b) individuals engaged in the research will have no part in determining the viability of the neonate; and

   c) 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** the purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means and there will be no added risk to the neonate resulting from the research [45 CFR 46.205].

3. The informed consent of either parent is required. The informed consent of one parent is acceptable if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity. The consent of the father is not required if the pregnancy resulted from rape or incest. The consent of a legal representative of either parent is not acceptable. The reason for not obtaining both parents' informed consent must be documented in the research record. The informed consent document will fully describe the reasonably foreseeable impact of the research on the neonate [45 CFR 46.205].

E. Research Involving Pregnant Women as Participants is Not Approved Unless All of the Following Conditions are Met:

1. Appropriate studies on animals and non-pregnant individuals have been completed, and for data assessing risks to pregnant women and fetuses are provided.

2. The purpose of the activity is to meet the health needs of the mother or the particular fetus.

3. The risk to the fetus is minimal.

4. The risk to the fetus is the least possible risk for achieving the objectives of the activity.

5. Individuals engaged in the activity have no part in:

    a) Any decisions as to the timing, method, and procedures used to terminate the pregnancy.

    b) Determining the viability of the fetus at the termination of the pregnancy.

    c) Introducing any procedural changes, for research purposes, into the procedures for terminating the pregnancy.

6. No inducements, monetary or otherwise, are offered to terminate pregnancy for purposes of research.

7. One of the following is true:

    a) The fetus is placed at risk only to the minimum extent necessary to meet the heath care needs of the mother.

    b) The risk to the fetus is minimal.

8. Consent is obtained from the mother and father, except that the father's consent need not be secured if:

    a) The purpose of the activity is to meet the health needs of the mother.

    b) His identity or whereabouts cannot reasonably be ascertained.

    c) He is not reasonably available.

9. The pregnancy resulted from rape

F. Guidance on Additional Requirements of Federal Funding Agencies

Please note that protocols conducted by MUSC and sponsored by any of the following federal agencies

- the Department of Defense (DOD),
- Department of Education,
- Department of Energy,
- Department of Justice (DOJ) / National Institute of Justice (NIJ) and Bureau of Prisons (BOP) or
- Environmental Protection Agency (EPA)

have additional operational and review requirements. Further information available on the MUSC IRB Resources & Guidance Webpage <http://research.musc.edu/ori/irb/resources.html>).

G. ICH – Good Clinical Practice (GCP)

The MUSC IRBs operate in accord with ICH-GCP guidelines only to the extent that they are compatible with FDA and DHHS regulations. CGP standards contained in the ICH document are not regulatory requirements in the United States and vary from FDA and DHHS regulations. As such, the MUSC IRBs do not voluntarily agree to comply with all of the GCP statements unless requested to do so by sponsors as documented in contractual agreements. The MUSC IRBs comply with most aspects of ICH-GCP, and the MUC polices, procedures and forms require investigators to com ploy with most ICH-GCP guidance. In addition, protocols following the International Committee on Harmonisation – Good Clinical Practices (ICH-GHP) have additional requirements. Further information available on the MUSC IRB Resources & Guidance Webpage <http://research.musc.edu/ori/irb/resources.html>).

II. References

A. Special Subject Populations Checklist – Pregnant Women, Fetuses, and Neonates