University of Ghana Medical Centre
Medical and Scientific Research Centre(MSRC)
Standard Operating Procedure and Policy on Research involving Pregnant Women, Human Fetuses and Neonates

The IRB will ensure that research that involves pregnant women, human fetuses, and neonates complies with safeguard requirements set forth as follows;

A. Research involving pregnant women or human fetuses will be approved only when the outlined conditions have been met.
   1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
   2. There is a potential for direct benefit for the pregnant woman and fetus which cannot be obtained by any other means and the risk to the woman and fetus is not greater than minimal.
   3. Any risk is the least possible for achieving the objectives of the research;
   4. research with prospect of direct benefit to the woman and fetus must obtain informed consent from the woman in accordance with the informed consent provisions. Research with prospect of direct benefit to the fetus only should obtain informed consent from both parents, except that the partner's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
   5. Each individual providing consent under paragraph (4) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
   6. For children (below age of 18) who are pregnant, assent and permission are obtained in accord with the provisions on informed consent and assent. Emancipated minors may not be involved in research, except when the research will provide potential benefits to the minors, fetus, or neonates.
   7. Individuals involved in the research shall not provide inducements (monetary or otherwise) to terminate a pregnancy, shall not be involved in decisions as to the timing, method, or procedures used to terminate a pregnancy; and shall not be part in determining the viability of a neonate

B. Research involving neonates will be approved only when the applicable conditions outlined herein have been met.

1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
2. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
3. Individuals engaged in the research will have no part in determining the viability of a neonate.
4. For neonates of uncertain viability, there may be engaged in research only if the research has prospect of enhancing their viability or important biomedical knowledge cannot be obtained by no other means and there will be no added risk to the neonate
5. Informed consent should be obtained from the parents or legally authorized representative if for some reason the parents are unavailability, incompetence, or temporary incapacity, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.
    a. Non-viable neonates: After delivery non-viable neonate may not be involved in research unless all of the following additional conditions are met:
        i. Vital functions of the neonate will not be artificially maintained;
        ii. The research will not terminate the heartbeat or respiration of the neonate;
        iii. There will be no added risk to the neonate resulting from the research;
        iv. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
        v. The legally effective informed consent of both parents of the neonate is obtained accordingly. If the parents are not available, incompetence, or temporary incapacity, the non-viable neonates may not be involved in research.

C. When reviewing research that involves pregnant women, human fetuses, or neonates, the IRB may invite outside expertise or consultants as needed.

D. When approving research that involves pregnant women, human fetuses, neonates of uncertain viability, the IRB minutes will document the justifications and findings regarding the determinations in accordance with conditions in set out in this SOP.

E. When research includes women of childbearing potential, when appropriate, the participants should be informed of the currently unforeseeable risks to the

participant, fetus, or nursing infant. In addition, the IRB will determine whether:

a) the participant should be advised to avoid pregnancy or nursing during or following participation in the research and/or notify the PI immediately should the participant become pregnant; or
b) The PI should specifically exclude pregnant women from the research and/or require specified methods of contraception during and/or following participation in the research.

F. Research involving, after delivery, the placenta, the dead fetus, macerated fetal material, or cells, tissue, or organs excised from a dead fetus, will be conducted only in accordance with any applicable national laws. Fetal tissue obtained either prior to or subsequent to any nonspontaneous abortion procedure cannot be used for any research purpose.