# Research Involving Pregnant Women, Fetuses and Neonates

## Definitions

The following definitions should be used to clarify the information in the provided guidance.

#### Dead Fetus

a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord

#### Delivery

Complete separation of the fetus from the woman by expulsion or extraction or any other means

#### Fetus

The product of conception from implantation until delivery

#### Neonate

A newborn

#### Nonviable neonate

A neonate after delivery that, although living, is not viable

#### Pregnancy

Encompasses the period of time from implantation until delivery. A woman is assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery

#### Viable

As it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration

## Applicability

At NYU SoM, federal regulations for research involving pregnant women, fetuses or neonates applies regardless of funding source. In addition to the general requirements for review of research by the IRB, the IRB makes the following additional determinations with respect to research that involves pregnant women or fetuses:

* that adequate consideration has been given to the manner in which potential subjects will be selected; and
* that adequate provision has been made for monitoring the actual informed consent process (e.g., when appropriate, the IRB or subject advocates participate in overseeing the actual process by which subject consent is secured and monitoring the progress of the activity).

Before approving any research protocol directed towards pregnant women and fetuses, the IRB must determine that the following conditions are met:

* Where scientifically appropriate, pre-clinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
* The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefits, 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;
* Any risk is the least possible for achieving the objectives of the research;
* If the research holds out the prospect of direct benefit to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;
* If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father’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;
* Each individual providing consent under paragraph (4) or (5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
* For children as defined in 45 CFR 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;
* No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
* 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
* Individuals engaged in the research will have no part in determining the viability of a neonate.

Before approving any research regardless of funding source, involving neonates of uncertain viability and nonviable neonates, the IRB must determine and document:

* 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;
* Individuals engaged in the research will have no part in determining the viability of a neonate.
* the requirements of Neonates of Uncertain Viability or Nonviable Neonates (see below in this sections have been met as applicable.

## Neonates of Uncertain Viability

Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the IRB determines and documents that:

* 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 of the research, or
* The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the neonate resulting from the research; and
* The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent’s legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

After delivery, nonviable neonate may not be involved in research unless all of the following conditions are met:

* Vital functions of the neonate will not be artificially maintained;
* The research will not terminate the heartbeat or respiration of the neonate;
* there will be no added risk to the neonate resulting from the research;
* the purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and
* The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of Sec. 46.116(c) and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements of this paragraph, (c)(5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph.

A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.

## Research Involving (After Delivery) the Placenta, the Dead Fetus or Fetal Material

Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, must be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities. If information associated with material described above in this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent sections of the NYU SoM IRB Policies and Procedures are applicable.