1. Applicability

This policy applies to all non-exempt human subject research involving pregnant women, fetuses and neonates in which CUNY becomes engaged.

2. Definitions

2.1. Dead fetus

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

2.2. Delivery

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

2.3. Fetus

The product of conception from implantation until delivery

2.4. Neonate

A newborn

2.5. Nonviable neonate

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

2.6. Pregnancy

The period of time from implantation until delivery. A woman shall be 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.

2.7. Viable neonate

Being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

PREGNANT WOMEN OR HUMAN FETUSES

3. Conditions for Inclusion of Pregnant Women or Human Fetuses in Research

CUNY UI-IRBs may approve research involving pregnant women or human fetuses as subjects only if all of the following conditions are met:

3.1. 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.

3.2. The risk to the fetus is:

a. Caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; OR

b. 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.

3.3. Any risk is the least possible for achieving the objectives of the research.

3.4. No inducements, monetary or otherwise, will be offered to terminate a pregnancy.

3.5. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

3.6. Individuals engaged in the research will have no part in determining the viability of a neonate.

4. Informed Consent Provisions

4.1. Informed consent in accordance with CUNY HRPP Policy: Informed Consent Process and Documentation of ONLY the pregnant woman is sufficient when:

a. The research holds out the prospect of direct benefit to the pregnant woman;

b. The research holds out the prospect of a direct benefit both to the pregnant woman and the fetus; OR

c. The research holds out 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.

4.2. Informed consent in accordance with CUNY HRPP Policy: Informed Consent Process and Documentation of the pregnant woman AND the father is required when the research holds out the prospect of direct benefit solely to the fetus.

4.2.1. EXCEPTION: the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or if the pregnancy resulted from rape or incest.

4.3. Each individual providing consent must be fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

4.4. For children who are pregnant, child assent and parent or guardian permission must be obtained in accordance with CUNY HRPP Policy: Children as Research Subjects.

5. Exclusion of Pregnant Women

If a research requires the exclusion of pregnant women, the Principal Investigator (PI) is required to include the following information in both the application to the IRB and the informed consent document(s) for the subjects:

a. Rationale for the exclusion of pregnant women
b. Description of the pregnancy test that may be conducted at screening in order to ensure that potential subjects meet this exclusionary criterion
c. Description of the repeat pregnancy test(s) and its frequency in order to ensure that subjects continue to meet this exclusionary criterion
d. Instructions or guidance for subjects on how to avoid pregnancy while participating in the research
e. Description of the process by which the PI will withdraw subjects who may become pregnant while participating in the research

NEONATES

6. Viable Neonates

A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accordance with CUNY HRPP Policy: Children as Research Subjects.

7. Conditions for Inclusion of Neonates of Uncertain Viability AND Nonviable Neonates

CUNY UI-IRBs may approve research involving neonates of uncertain viability and nonviable neonates as subjects only if all of the following conditions are met:

7.1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

7.2. Individuals engaged in the research will have no part in determining the viability of a neonate.

8. Additional Conditions for Inclusion of Neonates of Uncertain Viability

Even when the conditions outlined in section 7 above are met, research involving neonates of uncertain viability may not be approved unless the IRB determines that:

a. 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

b. The purpose of the research is the development of important biomedical knowledge, which cannot be obtained by other means, and there will be no added risk to the neonate resulting from the research.

c. 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 accordance with CUNY HRPP Policy: Informed Consent Process and Documentation, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

   i. Each individual providing consent must be fully informed regarding the reasonably foreseeable impact of the research on the neonate.

9. Additional Conditions for Inclusion of Nonviable Neonates

In addition to the conditions outlined in section 7 above, all of the following conditions must be met in order for the CUNY UI-IRB to approve research involving nonviable neonates:

9.1. Vital functions of the neonate will not be artificially maintained.

9.2. The research will not terminate the heartbeat or respiration of the neonate.

9.3. There will be no added risk to the neonate resulting from the research.

9.4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.

9.5. The legally effective informed consent of BOTH parents of the neonate must be obtained in accordance with CUNY HRPP Policy: Informed Consent Process and Documentation. Each individual providing consent must be fully informed regarding the reasonably foreseeable impact of the research on the neonate.

9.5.1. The waiver of informed consent and the alteration of informed consent provisions provided for in the CUNY HRPP Policy: Informed Consent Process and Documentation DO NOT apply.

9.5.2. If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of ONE parent of a nonviable neonate will suffice, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest.

9.5.3. 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 section.

PLACENTA, DEAD FETUS OR FETAL MATERIAL

10. 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, shall be conducted only in accordance with any applicable federal, state, or local laws and regulations regarding such activities.

10.1. If information associated with such material 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 CUNY HRPP policies and procedures are applicable.

WAIVER

11. Waiver of this Policy

Research that is not otherwise approvable based on the requirements of this policy, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the

health or welfare of pregnant women, fetuses, or neonates may be a approved by a CUNY UI-IRB ONLY if:

a. The CUNY UI-IRB finds and documents that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; AND

b. One of the following consultations have taken place:

   i. For research that is conducted or supported by US Department of Health and Human Services (HHS), the Secretary of HHS, after consultation with a panel of experts (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in FEDERAL REGISTER, has determined either:

      1. The research in fact satisfies the conditions of this policy, as applicable; OR

      2. The following:
         a) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;
         b) The research will be conducted in accord with sound ethical principles; AND
         c) Informed consent will be obtained in accord with the informed consent provisions of HHS regulations at 45 CFR 46.

   ii. For research that is NOT conducted or supported by US Department of Health and Human Services (HHS), the Vice Chancellor for Research, after consultation with a panel of experts (for example: science, medicine, ethics, law) has determined that:

      1. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;
      2. The research will be conducted in accordance with sound ethical principles; AND
      3. Informed consent will be obtained in accordance with the CUNY HRPP Policy: Informed Consent Process and Documentation.

Reference

Code of Federal Regulations, Title 45 – Public Welfare DHHS, Part 46 – Protection of Human Subjects