

Columbia University  
Institutional Review Board

# Clinical Research Involving Pregnant Women

- In the Labor and Delivery Suites at NYP and CUMC  
(Reference Document #103)
- IRB Considerations for Review of Research Involving Pregnant Women, Fetuses, and Neonates (Reference Document #357)

## **Clinical Research Involving Pregnant Human Subjects in the Labor and Delivery Suites at NewYork-Presbyterian Hospital and Columbia University Medical Center**

**PURPOSE:** To describe the circumstances and safeguards surrounding the appropriate participation of pregnant human subjects in clinical research studies performed at NewYork Presbyterian Hospital – Columbia University Medical Center.

**POLICY:** Pregnant patients presenting for care at the Labor and Delivery suites of this institution may appropriately be enrolled into clinical research studies, according to the procedures described below.

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### **GENERAL PRINCIPLES**

- Clinical research in the field of obstetrics, including research conducted during the intrapartum period, is vital for the achievement of continued advances in the healthcare of women and children.
- All clinical research involving pregnant subjects must adhere to the same high standards applied throughout the institution.
- The health and wellbeing of the mother and the fetus should take priority over the goals of any research project.
- Research investigators should acknowledge and be sensitive to the vulnerability of patients within the unique environment of the Labor and Delivery suite.
- Labor and delivery should be viewed as a process, not a single event or state, which implies that the final decision on whether to approach a pregnant patient for research participation must be individualized in all cases.
- It may be inappropriate to approach for research participation some patients at certain times during the labor and delivery process.
- It is inappropriate to arbitrarily deny all pregnant patients the opportunity to participate in clinical research during the labor and delivery process simply because they are experiencing labor.
- Most laboring women are competent to consent to research and other procedures after the administration of neuraxial (spinal or epidural) local anesthesia since the doses commonly used have little to no sedative effect, and the decrease in pain may make patients more able to consider and discuss options in their care.
- Each Principal Investigator is responsible for ensuring the highest possible standards in the conduct of research involving pregnant patients, including ensuring that multidisciplinary cooperation is obtained from all those involved in the labor process (such as the primary labor room nurse and the obstetric care provider).

## INFORMED CONSENT

- Whenever practical and feasible, information about research conducted in the Labor and Delivery suite should be made available to patients prior to labor.
- Investigators who plan on approaching a patient in the labor room should first obtain the permission of the patient's obstetric care provider and should also involve the patient's primary nurse in discussions regarding the appropriateness of such an approach.
- If the patient's obstetric care provider and / or primary labor room nurse feel that a particular patient is not in a position to comprehend a research protocol and give informed consent, then that patient may not be approached for research participation, until the circumstances have changed to the satisfaction of the primary care providers.
- Whenever possible, research investigators should discuss proposed research and obtain informed consent in the presence of one of the patient's independent labor support persons (provided that such a support person is available and the patient has no objection to that person's involvement).
- Patients in labor must not be approached for participation in a research study until at least 2 hours have passed since the administration of systemic opioids or sedative medications.
- If feasible for the particular research study, it may be preferable to delay approaching pregnant patients for research participation until after the placement of epidural analgesia, if such analgesia is desired by the patient.
- Written evidence of informed consent must be obtained in all cases. In selected cases, depending on the degree of perceived vulnerability of the patient, the IRB may require that the consent be co-signed by an independent person, such as the patient's physician or primary labor room nurse, who should also witness the process of obtaining consent.
- Patients in the labor room may only be solicited for research participation using the patient's personal language of preference.

## **IRB Considerations for the Review of Research Involving Pregnant Women, Fetuses, and Neonates**

Pregnant women, fetuses, and neonates are a vulnerable population and, as such, require additional protections when they are research subjects. It is recognized, however, that pregnant women, fetuses, and neonates should not be denied the benefits of participating in research. Distinction must be made between studies for which the reproductive status of the pregnant woman or the unique characteristics of fetuses and neonates are criteria for inclusion in the research, and studies for which the pregnancy status of the woman is incidental. In regards to the latter, Subpart B requirements need not be met although in all cases, risks specific to pregnant women, neonates, or fetuses should be addressed during the consent process.

During their review of research that involves pregnant women, the Columbia IRBs consider the requirements of the DHHS and FDA regulations for the protection of vulnerable human subjects and must make specific determinations related to risk, benefit, and informed consent. When research is supported by other federal agencies, the IRBs must also consider whether the funding agency has additional requirements for the inclusion of pregnant women (See Reference Document #356, Additional Requirements for Protocols Funded by Specific Federal Agencies or Subject to Specific Federal Policies). These requirements are in addition to the requirements for approval of research that the IRB considers for all research involving human subjects. Awareness by researchers of the regulations and affiliated required determinations will facilitate inclusion, in the submission to the IRB, of the information that must be considered before these determinations can be made. This document addresses the considerations relative to the protocol and to the informed consent process.

The information provided in this document supplements information found in the following sections of the IRB Standard Operating Procedures:

- III.E.5. Submission materials Pregnant Women, Fetuses, and Neonates
- VI.B.4. Review of Research Involving Pregnant Women, Fetuses, and Neonates

Relevant regulations:

[45 CFR 46 Subpart B Additional Protections for Pregnant Women, Fetuses, and Neonates](#)

This document addresses:

[Considerations and Determinations Related to the Protocol](#)

[Considerations and Determinations Related to the Informed Consent Process](#)

## **Considerations and Determinations Related to the Protocol**

The IRBs make and document the following protocol-specific determinations:

- Where scientifically appropriate, preclinical 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.
- One of the following is true:
  - 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.
  - 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.
- For children who are pregnant, assent and permission are obtained in accordance with the regulations.
- No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
- Individuals engaged in the research have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
- Individuals engaged in the research have no part in determining the viability of a neonate.

The IRBs make and document the following protocol-specific determinations when the research involves neonates:

- Where scientifically appropriate, preclinical and clinical studies has been conducted and provided data for assessing potential risks to neonates.
- Individuals engaged in the research have no part in determining the viability of a neonate.
- One of the following is true:
  - The research held 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.
  - The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there is no added risk to the neonate resulting from the research.

The IRBs determine whether the criteria for approval of research are met when research involves nonviable neonates. The IRB Chair or designee, for reviews conducted at convened meetings, or an experienced member of the IRB, in the case of an expedited review, ensures that the following determinations are made and documented:

- Where scientifically appropriate, preclinical and clinical studies has been conducted and provided data for assessing potential risks to neonates.
- Individuals engaged in the research have no part in determining the viability of a neonate.
- Vital functions of the neonate are not artificially maintained.
- The research will not terminate the heartbeat or respiration of the neonate.
- There is 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.

### **Considerations and Determinations Related to the Informed Consent Process**

When research involves pregnant women, the IRBs determine that the consent of the pregnant women is required if the research holds out:

- The prospect of direct benefit to the pregnant woman.
- The prospect of direct benefit both to the pregnant woman and the fetus.
- No prospect of benefit for the woman or 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.
- When research involves pregnant women, the IRBs determine that the consent of the pregnant woman and the father is required, 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 if the research holds out the prospect of direct benefit solely to the fetus.
- When the research involves neonates of uncertain viability, the IRBs determine that the consent of either parent of the neonate is required or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective consent of either parent's legally authorized representative is required, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.
- When the research involves non-viable neonates, the IRBs determine that the consent of both parents is required, except:

- If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the consent of one parent is required.
- If the pregnancy resulted from rape or incest the consent of the father need not be obtained.
- When the research involves non-viable neonates, the IRB is not allowed to approve the consent of a legally authorized representative.

The IRBs determine whether the approval criteria for consent and permission are met when research involves pregnant women or fetuses. The IRB Chair or designee, for reviews conducted at convened meetings, or an experienced member of the IRB, in the case of an expedited review, ensures that the following determinations are made and documented:

- The consent of the mother is obtained in accordance with the regulations.
- If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the father is also obtained in accordance with the regulations, except that the father's consent does not need to be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
- Individuals providing consent are fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

The IRBs determine whether the approval criteria for consent and permission are met when research involves neonates of uncertain viability. The IRB Chair or designee, for reviews conducted at convened meetings, or an experienced member of the IRB, in the case of an expedited review, ensures that the following determinations are made and documented:

- Individuals providing consent are fully informed regarding the reasonably foreseeable impact of the research on the neonate.
- The legally effective consent of either parent of the neonate is obtained in accordance with the regulations.
  - If neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective consent of either parent's legally authorized representative is obtained.
  - The consent of the father or his legally authorized representative does not have to be obtained if the pregnancy resulted from rape or incest.

The IRBs determine whether the approval criteria for consent and permission are met when research involves nonviable neonates. The IRB Chair or designee, for reviews conducted at convened meetings, or an experienced member of the IRB, in the case of an expedited review, ensures that the following determinations are made and documented:

- Individuals providing consent are fully informed regarding the reasonably foreseeable impact of the research on the neonate.
- The legally effective consent of both parents of the neonate is obtained in accordance with the regulations.
  - If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the consent of one parent of a nonviable neonate is sufficient, except that the consent of the father does not have to 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 is not allowed.
- The waiver and alteration provisions are not applied.