**I. Research Title**

**II. Research Involving Pregnant Women or Fetuses [**[**45 CFR 46 (Subpart B)]**](https://www.ecfr.gov/cgi-bin/text-idx?SID=541c957f5bfccefc47f1cc9587eb8cf1&mc=true&node=sp45.1.46.b&rgn=div6)

* **Pregnancy** encompasses 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.
* **Fetus** means the product of conception from implantation until delivery.
* **Delivery** means complete separation of the fetus from the woman by expulsion or extraction or by any other means.

**[ ]  N/A – Research does not involve pregnant women or fetuses; skip to Section III.**

**[ ]  Research meets the exemption criteria as described in UIC HSPP policy,** [***Exempt Review of Research*.**](https://go.uic.edu/irb0282) **This form is not required; upload the Claim of Exemption form.**

**A. Scientific background of proposed clinical investigation**

If this involves a clinical investigation, explain whether appropriate, pre-clinical studies, including studies on pregnant animals and clinical studies, including those involving non-pregnant womenhave been conducted, and provide data for assessing potential risks to pregnant women and fetuses in relation to this study.

[ ]  N/A – The research does not involve a clinical investigation

**B. Anticipated risk to the fetus**

1. Check the box that best identifies the anticipated level of risk to the fetus:

[ ]  Research involves no greater than minimal risk to the fetus.

[ ]  Research involves greater than minimal risk to the fetus and the risk is caused solely by interventions or procedures that hold out the prospect of direct benefit to the woman or the fetus.

[ ]  Research involves greater than minimal risk to the fetus and the risk is caused by interventions or procedures that do NOT hold out the prospect of direct benefit to the woman or the fetus.

2. Justify the anticipated risk to the fetus:

3. Explain why any risks associated with the research are the least possible (minimized) for achieving the objectives of the research, including whether the biomedical knowledge could be obtained by another means:

4.Describe the safeguards that will be put into place to protect the rights and welfare of the pregnant women and fetuses in this research:

5. The following conditions must be met for approval of research involving fetuses:

* There will not be any inducements, monetary or otherwise, offered to terminate a pregnancy.
* Researchers will not have any part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
* Researchers will not have any part in determining the viability of a fetus at the termination of the pregnancy.

[ ]  Check here to confirm all of the above are true.

**C. Procedures to Obtain Informed Consent**

All informed consent/permission/assent documents must contain a clear explanation of the reasonably foreseeable impact of the research on the fetus.

1. Check the appropriate box as it applies to this research.

[ ]  The research holds out the prospect of direct benefit only to the pregnant woman;

[ ]  Research holds out the prospect of direct benefit both to the pregnant woman and the fetus;

[ ]  Research does not hold out the prospect of direct benefit to the pregnant woman or the fetus, but the 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.

If any of the statements above are checked, informed consent must be obtained from the pregnant woman in accordance with federal regulations regarding adult consent.

[ ]  Research holds out the prospect of direct benefit only to the fetus.

*Informed consent must be obtained from the pregnant woman AND the father in accordance with federal regulations regarding adult consent (unless the father is unavailable, incompetent, temporarily incapacitated, or the pregnancy resulted from rape or incest).*

2.Research involves pregnant womenwho are less than 18 years of age (i.e., minors). *Note: Pregnant minors are not automatically considered to be “emancipated”; this status requires a court order.*

[ ]  No – *Skip to III*

[ ]  Yes

The Illinois Consent by Minors to Medical Procedures Act (“Act”) (410 ILCS 210/1) permits a pregnant minor to provide her own informed consent to the performance of a necessary medical or surgical procedure performed by:

 (i) a physician licensed to practice medicine and surgery,

 (ii) an advanced practice nurse who has a written collaborative agreement with a collaborating physician that authorizes provision of services for minors, or

 (iii) a physician assistant who has been delegated authority to provide services for minors.

Under the circumstances or for the conditions stipulated in the Act, the UIC IRB views the minor to have the same legal capacity to act and having the same powers and obligations as a person of legal age to consent for research involving such necessary medical or surgical procedures only. The IRB does not apply the Act to all research procedures, only those allowed for clinical purposes.

3. Does the proposed research involve medical or surgical procedures expected to be performed in pregnant women by the individuals listed in the Act?

[ ]  No - Assent of the minor subject and permission of their parent or guardians must be obtained as described in the UIC HSPP policy [*Research Involving Children (Including Wards of the State)*](https://go.uic.edu/irb0910).

[ ]  Yes - Consent may be obtained from the pregnant minor. *Note: The IRB may require additional protections to be put into place to protect the minors.* Justify your response:

**III. Research Involving Neonates**

* **Neonate** means a newborn.
* **Viable neonate** means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration. If a neonate is viable then it may be included in research only to the extent permissible, and in accordance with the requirements of subparts A and D of 45 CFR 46.
* **Nonviable neonate** means a neonate after delivery that, although living, is not viable. Viable neonates may be included in the research only to the extent permissible, and in accordance with, federal regulations and state and local laws.

**[ ]  N/A – Research does not involve neonates; skip to Section IV.**

**A. Neonates**

1. Explain the scientific justification for the proposed research, including descriptions of pre-clinical and clinical studies which have been conducted and provide data for assessing potential risks to neonates:

2. Will researchers have any part in determining the viability of a neonate?

[ ]  No

[ ]  Yes – Research cannot be approved

**B. Viable Neonates** - *Complete and upload UIC OPRS form* [*Appendix B – Children as Subjects in Research*](https://go.uic.edu/irb0207)

All informed consent/permission/assent documents must contain a clear explanation of the reasonably foreseeable impact of the research on the viable neonate/child.

**C. Neonates of uncertain viability: Additional requirements**

**[ ]  N/A – Research does not involve neonates of uncertain viability; skip to section III D.**

1. Check the appropriate box as it applies to this research.

[ ] 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.

[ ]  The research has the main purpose of the development of important medical knowledge, which cannot be obtained by other means, and there will be no added risk to the neonate resulting from the research.

2. Explain the procedures that will be used to obtain legally effective consent ofeither parent of the neonate in accordance with federal regulations.

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 (LAR) will be obtained in accordance with federal regulations. The father’s informed consent need not be obtained if the pregnancy resulted from rape or incest. These procedures must assure that each individual providing informed consent will be fully informed regarding the foreseeable impact of the research on the neonate.

**D. Nonviable Neonates: Additional Requirements**

**[ ]  N/A – Research does not involve nonviable neonates; skip to Section IV.**

1. The following conditions must be met for approval of research involving nonviable neonates:

* The vital functions of the neonate will not be artificially maintained.
* The research does not include procedures to terminate the heartbeat or respiration of the neonate.
* The research will not present any added risk to the neonate.
* The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.

[ ]  Check here to confirm all of the above are true.

2. Explain the procedures that will be used to obtain legally effective consent ofboth parents of the neonate.

The legally effective informed consent of both parents of the neonate is obtained in accord with 45 CFR 46 Subpart A, except that the waiver and alteration provisions of §46.116 (c) and (d) do not apply. 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. The consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a LAR for either or both parents of a nonviable neonate will NOT suffice. These procedures must assure that each individual providing informed consent will be fully informed regarding the foreseeable impact of the research on the neonate.

**IV. Research Involving, After Delivery, the Placenta, Dead Fetus, or Fetal Material**

* **Dead fetus** means a fetus that does not exhibit heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, or pulsation of the umbilical cord.
* The use of the placenta, dead fetus, or fetal material in research must be conducted in accordance with all applicable federal, state, local, or institutional laws, regulations, and policies.

**[ ]  N/A – Section is not applicable.**

A. The following are proposed for use in this research (check all that apply):

[ ]  Placenta [ ]  Cells Excised from Dead Fetus

[ ]  Dead Fetus [ ]  Tissue Excised from Dead Fetus

[ ]  Macerated Fetal Material [ ]  Organs Excised from Dead Fetus

[ ]  Other Describe:

B. Describe the source of the materials being used in this research:

C. Will any information associated with the above material be recorded for research purposes in any way such that living individuals (i.e., parents) will be identifiable (including any of the [18 HIPAA elements](https://go.uic.edu/irb0274)) either directly or indirectly?

[ ]  No - Subjects may not be considered human research subjects according to federal regulations and UIC policy. Please complete and submit the [*Determination of Whether an Activity Represents Human Subject Research*](https://go.uic.edu/irb0255) form.

[ ]  Yes - Explain the reason for the recording of identifiable information *(Note: Those individuals will be considered research subjects and all applicable federal regulations must be observed with regards to the protections of their rights and welfare as research subjects.)*