**Supplement Form P**

**Research Involving Pregnant Women, Fetuses and Neonates**

|  |  |
| --- | --- |
| **PI Name:**  | **Date**  |
| Title:  |

1. **Does this research pose greater than minimal risk to the woman, fetus, or neonate?** *Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

[ ]  Yes [ ]  No

If yes, please explain:

1. **Is the research funded or otherwise supported (e.g., staffed) by the US Department of Health and Human Services (e.g., NIH)?** [ ]  Yes [ ]  No

If Yes, go to the next questions and complete this form.

If the research does not pose greater than minimal risk and is not funded or otherwise supported by HHS, stop here. Include this form with your submission.

1. **Does this research involve pregnant women or fetuses?** [ ]  Yes [ ]  No, skip ahead to question 4
	1. **Does the research offer the prospect of direct benefit to pregnant subjects?**

[ ]  Yes [ ]  No

If Yes, explain:

* 1. **Does the research offer the prospect of direct benefit to the fetuses involved?**

[ ]  Yes [ ]  No

If Yes, explain:

* 1. **Explain how each of the following criteria are satisfied:**
		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

* + 1. 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 benefit, 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

* + 1. Any risk is the least possible for achieving the objectives of the research

* 1. **Explain the steps you plan to take to ensure that each individual being asked to provide consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate:**

**NOTE:** *If the research holds out the prospect of direct benefit solely to the fetus, then the consent of the pregnant woman and the father must be obtained, 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. Otherwise, the consent of the mother is sufficient.*

* 1. **Will inducements, monetary or otherwise, will be offered to terminate a pregnancy?**

[ ]  Yes [ ]  No

If Yes, explain:

* 1. **Will individuals engaged in this research have any part in decisions as to the timing, method, or procedures used to terminate a pregnancy?**

[ ]  Yes [ ]  No

If Yes, explain:

* 1. **Will individuals engaged in the research have any part in determining the viability of neonates?**

[ ]  Yes [ ]  No

If Yes, explain:

**NOTE for Research Not Conducted or Supported by DHHS:**

*From NJH HRPP SOP 16.4.1.1: The IRB may allow individuals whose normal responsibilities include determining the viability of fetuses to be engaged in the*research,*if their involvement in the determination of viability for an individual fetus cannot be avoided. Confirmation of the determination regarding viability will be sought from a qualified individual who is not otherwise engaged in the research whenever possible prior to involving the subject(s) in the research. The opinion of the independent qualified individual will be documented and made available upon request to the IRB or HRPP representative. When advance confirmation is not possible, the investigator will obtain it as soon as s/he can after enrollment, but in all cases within 5 business days. The circumstances that prohibited prospective confirmation of viability and the outcome of the subsequent consultation will be reported to the IRB within 10 business days.*

1. **Does this research include neonates of uncertain viability and/or nonviable neonates?**

[ ]  Yes [ ]  No, skip ahead to question 5

**NOTE:** *Newborns are only considered neonates until they are determined to be viable. 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. Once neonates are determined to be viable, they are considered children; Supplement A should be completed for viable newborns.*

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

[ ]  Yes. Summaries of the studies and data must be included in the protocol or other documentation provided with the submission

[ ]  No, explain:

* 1. **Will individuals engaged in the research have any part in determining the viability of neonates?**

[ ]  Yes [ ]  No

If yes, explain:

**NOTE** for Research Not Conducted or Supported by DHHS:

*From NJH HRPP SOP 16.4.2.1: The IRB may allow individuals whose normal responsibilities include determining the viability of neonates to be engaged in the research, if their involvement in the determination of viability for an individual neonate cannot be avoided. In such cases, confirmation of the determination regarding viability must be made by a qualified individual who is not otherwise engaged in the research whenever possible prior to involving the subject(s) in the research. The opinion of the independent qualified individual will be documented and made available upon request to the IRB or HRPP representative. When advance confirmation is not possible, the investigator will obtain it as soon as s/he can after enrollment, but in all cases within 5 business days. The circumstances that prohibited prospective confirmation of viability and the outcome of the subsequent consultation will be reported to the IRB within 10 business days.*

* 1. **If the research includes neonates whose viability has not yet been established (i.e., neonates with uncertain viability), answer the following questions.** [ ]  NA
		1. Does the research hold out the prospect of enhancing the probability of survival of the neonate to the point of viability?

[ ]  Yes [ ]  No

Explain:

* + 1. If yes to (i) above, explain how any risk is the least possible for achieving the objective of enhancing the probability of survival of the neonate to the point of viability:

* + 1. If no to (i) above, explain if and how the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and describe why there will be no added risk to the neonate resulting from the research:

* + 1. Explain the steps you plan to take to ensure that each individual being asked to provide consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate:

**NOTE:** *For research involving neonates of uncertain viability,**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 must be obtained, unless the criteria for a waiver of consent are determined satisfied. The consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.*

* 1. **If the research includes non-viable neonates answer the following questions.** [ ]  NA
		1. Will the vital functions of the neonate be artificially maintained?

[ ]  Yes [ ]  No

If yes, explain:

* + 1. Will the research terminate the heartbeat or respiration of the neonate?

[ ]  Yes [ ]  No

If yes, explain:

* + 1. Will there be any added risk to the neonate resulting from the research?

[ ]  Yes [ ]  No

Explain:

* + 1. Is the purpose of the research the development of important biomedical knowledge that cannot be obtained by other means?

[ ]  Yes [ ]  No

Explain:

* + 1. Explain the steps you plan to take to ensure that each individual being asked to provide consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate:

**NOTE:** *For research involving nonviable neonates, the legally effective informed consent of both parents of the neonate must be obtained. However, 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. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice for research involving nonviable neonates.*

1. **Does this research involve after delivery, the placenta, the dead fetus or fetal material?**

[ ]  Yes [ ]  No

If yes, will any information or tissues be included or recorded for the research such that living individuals can be identified, directly or through identifiers linked to those individuals?

[ ]  Yes [ ]  No

If yes, explain: