



**FRIENDS RESEARCH INSTITUTE, INC.
 INSTITUTIONAL REVIEW BOARD
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**Supplementary Application for Research Involving Pregnant Women,
 Human Fetuses, and Neonates**

Name of Investigator:

IRB Study #:

Title of Protocol:

Date of Submission:

Please complete this form only if applicable to your research study.

Research involving pregnant women, human fetuses, and neonates is governed by 45 CFR 46 Subpart B. Please refer to the following definitions, as defined by this subpart of the federal regulations.

- (1) Dead fetus: a fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord
- (2) Delivery: complete separation of the fetus from the woman by expulsion or extraction or any other means
- (3) Fetus: the product of conception from implantation until delivery
- (4) Neonate: a newborn
- (5) Nonviable Neonate: a neonate after delivery that, although living, is not viable
- (6) 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. The Secretary of Health and Human Services may from time to time, taking into account medical advances, publish in the Federal Register guidelines to assist in determining whether a neonate is viable for purposes of this subpart. If a neonate is viable then it may be included in research only to the extent permitted and in accordance with the requirements of subparts A and D.
- (7) 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.

<input type="checkbox"/>	1. 46.204 – Research involving pregnant women or fetuses:	
	a. When appropriate, have studies been done on animals and non-pregnant individuals? If yes, please briefly explain the nature and findings of these previous studies.	<input type="checkbox"/> Yes <input type="checkbox"/> No
	b. Please check one of the following: <input type="checkbox"/> The risk to the fetus is caused solely by interventions/procedures that hold out the prospect of direct benefit for the woman or the fetus. <input type="checkbox"/> There is no prospect of direct 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 maintained by any other means.	
	c. Is the risk the least possible for achieving the objectives of the research?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	d. If the research falls into either category listed in ‘b’ (above), will consent be obtained in accordance with the federal regulations and the FRI IRB’s policies?	<input type="checkbox"/> Yes <input type="checkbox"/> No

	e. If the research holds out the prospect of direct benefit solely to the fetus, will consent be obtained from the pregnant women and the father in accordance with the federal regulations and the FRI IRB's policies (consent from the father is required unless (a) he is unable to consent because of unavailability, incompetence, or temporary incapacity, or (b) the pregnancy resulted from rape or incest)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	f. Will each individual providing consent be fully informed regarding the reasonably foreseeable impact of the research on the fetus?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	g. For children as defined in Sec. 46.402 (a) who are pregnant, will assent and permission be obtained in accord with the provisions of 45 CFR 46 Subpart D?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	h. The PI assures that no inducements, monetary or otherwise, will be offered to terminate the pregnancy?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	i. The PI assures that individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	j. The PI assures that individuals engaged in the research will have no part in determining the viability of the neonate?	<input type="checkbox"/> Yes <input type="checkbox"/> No

<input type="checkbox"/>	2. 46.205 – Research involving neonates:	
<input type="checkbox"/>	a. Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met:	
	1. Where scientifically appropriate, have preclinical and clinical studies been conducted and provide data for assessing potential risks to neonates?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	2. Has each individual providing consent been fully informed regarding the reasonably foreseeable impact of the research on the neonate?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	3. Individuals engaged in the research will have no part in determining the viability of the neonate?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<input type="checkbox"/>	b. 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 following additional conditions have been met and determined by the IRB:	
	1. Does the research hold 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	<u>Or</u> Is the purpose of the research 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?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	2. Has 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) been obtained in accordance with the federal regulations and the FRI IRB's policies?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<input type="checkbox"/>	c. Nonviable neonates: After delivery nonviable neonates may not be involved in research covered by this subpart unless all of the following additional conditions are met:	
	1. The vital functions of the neonate will not be artificially maintained?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	2. The research will not terminate the heartbeat or respiration of the neonate?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	3. There will be no added risk to the neonate resulting from the research?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	4. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	5. Has 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) been obtained in accordance with the federal regulations and the FRI IRB's policies?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<input type="checkbox"/>	d. 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 accord with the requirements of 45 CFR 46 Subparts A and D.	

<input type="checkbox"/>	3. 46.206 – Research involving, after delivery, the placenta, the dead fetus or fetal material	
	a. Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, is conducted in accord with any applicable Federal, State, or Local laws and regulations regarding such activities?	<input type="checkbox"/> Yes <input type="checkbox"/> No
	b. Is information associated with material described above recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals? (if yes, those individuals are research subjects/participants and all pertinent subparts of 45 CFR 46 are applicable)	<input type="checkbox"/> Yes <input type="checkbox"/> No

<input type="checkbox"/>	4. 46.207 – Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.	
	The Secretary of Health and Human Services will conduct or fund research that the IRB does not believe meets the requirements of Sec. 46.204 or Section 46.205 only if:	
	(a) The IRB finds 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) The Secretary of Health and Human Services, after consultation with a panel of experts in pertinent disciplines and following opportunity for public review and comment including a public meeting announced in the Federal Register, has determined either:	
	(1) That the research in fact satisfies the conditions of Sec. 46.204, as applicable; or	
	(2) The following:	
	(i) 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;	
	(ii) The research will be conducted in accord with sound ethical principles; and	
	(iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.	