Cleveland Clinic Akron General

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☐ Exempt ☐ Expedited ☐ Full

Institutional Research Review Board Akron General Medical Center
Research Involving Pregnant Women, Fetuses, and Neonates

Please type all of the required information. HAND WRITTEN FORMS WILL NOT BE ACCEPTED. Submit the completed form with all required attachments to the Institutional Research Review Board (IRRB) IRRB@akrongeneral.org. Questions regarding IRRB submissions can be directed to (330) 344-6497, or by emailing IRRB@akrongeneral.org.

Project Title:

I. RESEARCH INVOLVING PREGNANT WOMEN AND FETUSES

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 results of a pregnancy test are negative or until delivery.

Fetus: The product of conception from implantation to delivery.

Delivery: Complete separation of the fetus from the woman by expulsion, extraction, or any other means.

A. Explain the pre-clinical studies that have been conducted, including those in pregnant animals and non-pregnant women. Provide data for assessing the risk to pregnant women and fetuses in relationship to this study.

B. Anticipated Risk (Check one of the boxes below)

☐ 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 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 solely by interventions or procedures that do NOT hold the prospect of direct benefit to the woman or the fetus.

C. Explain why the risks associated with this research are the least possible for obtaining the objective, including whether or not the biomedical knowledge could be obtained by other means.

D. Will there be any inducements, monetary or otherwise, to encourage termination of the pregnancy?

☐ Yes ☐ No

E. Will researchers have any part in making decisions as to the timing, methods, or procedures used to terminate the pregnancy? ☐ Yes ☐ No

F. Will researchers have any part in determining the viability of a fetus at the termination of a pregnancy?

☐ Yes ☐ No

G. Checking any of the boxes below requires the researchers to obtain informed consent from the pregnant woman prior to enrollment.

☐ The research will directly benefit the pregnant woman only.
☐ The research will directly benefit both the pregnant woman and the fetus.
☐ The research will NOT benefit the pregnant woman nor the fetus, but the risk to the fetus is not greater than minimal and the purpose of the research is the development of biomedical knowledge that cannot be obtained by other means.

H. Checking the box below requires the researchers to obtain informed consent from both the pregnant woman and the father; unless the father is unavailable, incompetent, temporarily incapacitated, or the pregnancy is a result of rape and/or incest.

☐ The research directly benefits the fetus only

I. Does the research involve pregnant women under the age of 18 years? ☐ Yes ☐ No
If 'yes', then you need to complete the "Research Involving Children and Minors" form.

II. RESEARCH INVOLVING NEONATES

Neonate: a newborn.

Viable neonate: a neonate being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

Nonviable neonate: a neonate after delivery that, although living, is not viable.

A. Explain the pre-clinical and clinical studies, related to this research, that have assessed potential risk to neonates.

B. Will the researchers have any part in determining the viability of the neonate? ☐ Yes ☐ No

C. Does the research include viable neonates? ☐ Yes ☐ No
If 'yes', complete the "Research Involving Children and Minors" form.

D. Does the research include neonates of uncertain viability? ☐ Yes ☐ No
If 'yes', answer i) and ii) below.

(i) Check the box below that 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 the risk is the least possible to reach that objective.
☐ The research has the main purpose of development of biomedical knowledge that cannot be obtained by other means, and there will be no added risk to the neonate as a result of the research.

(ii) Explain your procedure(s) for obtaining informed consent. (Informed consent must be obtained from the mother and the father of the neonate; unless the father committed rape/incest against the mother. If the mother and/or father is not available, incompetent, or temporarily incapacitated; then the informed consent from the parents legal representative may be obtained. The procedures must assure that the informed consent provider is fully informed of the impact of the research on the neonate.)

E. Does the research include non-viable neonates? ☐ Yes ☐ No
If 'yes', answer i) through v) below.

i) Will the vital functions of the neonate be artificially maintained? ☐ Yes ☐ No

ii) Does the research contain procedures to terminate the heartbeat and/or respiration of the neonate? ☐ Yes ☐ No

iii) Will the research present any added risk to the neonate? ☐ Yes ☐ No

iv) Is the development of biomedical knowledge, not obtainable by other means, the sole purpose of this research? ☐ Yes ☐ No

v) Explain your procedure(s) for obtaining informed consent. (Informed consent must be obtained from the mother and the father of the neonate; unless the father committed rape/incest against the mother. Parental consent from a legal representative is not acceptable. Parental consent may not be waived. The procedures must assure that the informed consent provider is fully informed of the impact of the research on the neonate.)

III. RESEARCH INVOLVING, AFTER DELIVERY, THE PLACENTA, DEAD FETUS, OR FETAL MATERIAL

Dead fetus: A fetus that does not exhibit a heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, or pulsation of the umbilical cord.

A. Will research data be collected in such a way that living individuals (i.e. parents) will be identifiable?
☐ Yes ☐ No

If 'yes', then this is considered human subjects research and all applicable federal regulations for protection of human subjects apply.