# Pennsylvania Department of Education Institutional Review Board (PDE IRB) Application for PDE IRB Review

# Attachment E-1: Research Involving Pregnant Women, Human Fetuses, and Neonates as Subjects

Inclusion of pregnant women, human fetuses, and neonates as subjects requires the investigator to comply with 45 CFR 46 Subpart B.

NOTE: This Appendix must also be completed even if you may only incidentally enroll pregnant women/fetuses/neonates (e.g., they are not your target subjects). For example, if some subjects would be women of reproductive age, this Appendix should be completed.

## Pregnant Women and Human Fetuses

1. Does the research involve pregnant women, human fetuses, neonates, or women of reproductive age as subjects?

   ☐ No - Go to Question 6.

   ☐ Yes

2. Confirm that the study will comply with all of the following requirements:

   ☐ Where scientifically appropriate, pre-clinical 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.

☐ No inducements, monetary or otherwise, will be offered to terminate a pregnancy.

☐ Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedure to terminate a pregnancy.

☐ Individuals engaged in the research will have no part in determining the viability of a neonate.

☐ Each individual providing consent or assent will be fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

Indicate which category this research falls into and complete the corresponding sections.

☐ The research holds out the prospect of direct benefits for the pregnant woman, the fetus, or both the pregnant woman and the fetus.

Explain why any risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit to the pregnant woman or fetus.

Describe plans for obtaining consent from the pregnant woman. Consent must also be obtained from the father if the prospect of benefit is solely for the fetus and not the pregnant woman (unless he is unavailable, incompetent, incapacitated, or the pregnancy resulted from rape or incest).

OR

☐ The research offers no prospect of benefit for the woman or fetus.

- Explain why the risk to the fetus is not greater than minimal.

- Explain why the biomedical knowledge potentially gained from the research cannot be achieved by any other means.

- Describe plans for obtaining consent from the pregnant woman.

4. Explain how the risks to the fetus will be minimized.

5. Will pregnant children (under 18) be included in the research?
   ☐ No

   ☐ Yes - Describe plans for obtaining assent from the pregnant child and permission from the pregnant child's parent(s)

## Neonates

If neonates are viable, do not use this Appendix. Complete Appendix D: Research Involving Children as Subjects.

6. Will neonates of uncertain viability be included in the research?
   ☐No ☐Yes

- Indicate which category the research falls into:
  ☐ The research holds out the prospect of enhancing the probability of survival to the point of viability, and any risk is the least possible for achieving that objective.

  Explain your answer.

OR

☐ The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means, and there will be no additional risk to the neonate resulting from the research.

Explain your answer.

- Describe plans for obtaining consent from either parent or either parent's legally authorized representative.

7. Will non viable neonates after delivery be included in the research?
   ☐No ☐Yes

- Confirm that the study will comply with all of the following requirements:

☐ The vital functions of the neonate will not be artificially maintained.

☐ The research will not terminate the heartbeat or respiration of the neonate.

☐ There will be no added risk to the neonate resulting from the research.

8. Confirm that research involving neonates of uncertain viability and non-viable neonates will comply with all of the following requirements:

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

☐ Each individual providing consent or assent will be fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

☐ Individuals engaged in the research will have no part in determining the viability of a neonate.