SUNY Downstate IRB & Privacy Board

FORM 11-9: Research involving Pregnant People and/or Fetuses

(Version 02.02.2022)

Instructions: 1) Open form in Adobe Reader. 2) Use Fill & Sign tool to complete. 3) Confirm any preformatted fields are correct. 4) Save file. 5) Submit completed form to IRB.

Note: Free Adobe Reader available at: www.adobe.com

Section 1: General Information:

A. IRBNet Number:

B. Protocol Title:

C. PI* Name and Degree

**Note: Provide "Principal Clinician" for HUD for clinical use and expanded access projects.*

Section 2: Pre-Clinical and Clinical Studies to Assess Potential Risks:

A. Where scientifically appropriate, describe any preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant people of childbearing potential. Describe data for assessing the potential risks to pregnant people, fetuses, and neonates. Indicate separate supporting documents are attached.

Section 3: Risks, Discomforts, and Benefits:

A. Describe any foreseeable risks/discomforts of the research to pregnant persons:

B. Describe any foreseeable risks of the research to fetuses and neonates:

C. Explain why the risks involved are the least possible for achieving the objectives of the research, including any risk mitigation strategies:

D. Describe any prospect of direct benefit to pregnant persons:

E. Describe any prospect of direct benefit to fetuses and neonates:

F. Please provide any additional relevant information regarding risks, discomforts, and benefits for the IRB to consider:

Section 4: Select Risks/Benefit Profile:

☐ A. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the pregnant person or the fetus/neonate.

If (A) is selected, choose subcategory:

◯ (A1) The research holds out the prospect of direct benefit to pregnant people.
Note: For A1, only the pregnant person's consent is required, unless waived.

◯ (A2) The research holds out the prospect of a direct benefit both to pregnant people and the fetus/neonate.
Note: For A2, only the pregnant person's consent is required, unless waived.

◯ (A3) This research holds out the prospect of a direct benefit solely to the fetus/neonate.
Note: For A3, both parents must provide their consent; however, the father's consent need not be obtained if he is unable to provide consent because of unavailability, incompetence, or temporary incapacity or if the pregnancy resulted from rape or incest.

If (A) is selected, explain why the risk to the fetus/neonate is caused solely by interventions or procedures that hold out the prospect of direct benefit for the pregnant person or the fetus/neonate.

☐ B. There is no prospect of benefit for the pregnant people nor the fetus/neonate. The risk to the fetus/neonate is not greater than minimal. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.
Note: For B, the pregnant person's consent is required unless otherwise waived.

If (B) is selected, answer the following:

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

2. Explain why the biomedical knowledge cannot be obtained by any other means.

☐ C. The research does not meet the criteria for (A) or (B):

If (C) is selected, explain why the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant persons, fetuses or neonates.
Note: May require additional approval from OHRP and/or FDA.

Section 5: Additional Regulatory Details:

A. Explain how everyone providing their consent will be fully informed regarding the reasonably foreseeable impact/risks of the research on the fetus or neonate:

B. Will the research involve pregnant persons under the age of 18?

◯ NO ◯ YES

C. ☑ Check box to confirm all the following are true:

- There will be no inducements, monetary or otherwise, offered to terminate a pregnancy.
- Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy
- Individuals engaged in the research will have no part in determining the viability of a fetus or neonate.

Section 6: Additional information (optional):