SUNY Downstate IRB & Privacy Board

FORM 11-8: Exclusion of Pregnant People and/or Plans to Study Outcomes of Unexpected Pregnancies

(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

This form is required in the following circumstances:

1. **When excluding pregnant people from a study/project that involves an intervention upon the body (e.g., drug, biologic, medical device, physical intervention, etc.).**
2. **When requiring contraception for research participants of childbearing potential.**
3. **When the study involves the prospective enrollment of research participants whose sexual partners may become pregnant AND the research may cause possible risk to the sexual partner, fetus, or neonate**
4. **Plans to study the outcomes of unexpected pregnancies for either a) research participants or b) sexual partners of research participants.**
5. **Whenever this form is requested by the Downstate IRB.**

Note: In general, this form is not required for social behavioral research (e.g., educational tests, survey, focus groups, observations, benign behavioral interventions, etc.) or retrospective research involving data or specimens that have already been collected.

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: Please answer the following questions when excluding pregnant people from a study/project:

1. Why are pregnant people excluded?

2. Are there plans to enroll those under the age of 18? ◯ YES ◯ NO

3. Are people excluded who disclose a known pregnancy? ◯ YES ◯ NO

4. For those who do not know they are pregnant, provide the details on pregnancy testing and sharing of results:

   a. Time frame and frequency for pregnancy testing (screening and repeat testing):

   b. Type of testing:
      - ☐ Urine
      - ☐ Blood/Serum
      - ☐ Other (e.g., ultrasound) - if checked, describe below:

   c. Process for disclosing pregnancy test results with participants over the age of 18:

   d. Process for disclosing pregnancy test results with participants under the age of 18:

   e. Process for providing or referring people for appropriate care or options counseling related to a positive pregnancy test:

   f. Describe methods to keep test results private and confidential:

   g. Describe any differences for the process in confirmatory pregnancy testing, if applicable, including any confirmation of unexpected pregnancies.

4. Describe any requirements for contraception during the research:

5. Describe the plans for assessment of birth control practices of research participants:

6. Does the study team provide contraception to the participants?

◯ YES ◯ NO

Section 3: Counseling

A. Check the items below if participants are counseled on the topic:

- ☐ Inadvisability of pregnancy during the research
- ☐ Inadvisability of pregnancy during any washout period
- ☐ Commitment of the participant to use one or more contraceptive method
- ☐ Information and resources for contraceptives
- ☐ Risks including risks of pregnancy
- ☐ Reminders to study participants of pregnancy-related risk through the study's duration
- ☐ Opportunities to withdraw from the study
- ☐ Risks to sexual partners of the research participant
- ☐ Other (describe):

Section 4: Unexpected Pregnancies:

1. Describe the potential risk to a research participant, partner of the research participant, the fetus, and neonate if an unexpected pregnancy occurs:

2. Will outcomes of the pregnant person be studied? ◯ YES ◯ NO

3. Will outcomes of the fetus, neonate, or child be studied ◯ YES ◯ NO

4. Describe the process for recruiting and obtaining consent from sexual partners of research participants if they become pregnant, including disclosures of any risk.

6. Describe the plans to obtain the outcomes of the pregnancy:

Section 5: Additional information (optional):