

ELECTRONIC SUBMISSION REQUIRED

APPENDIX F
Pregnant Women

Complete this form to request inclusion of participants who are pregnant in the proposed research. The inclusion of this group as participants in research requires that the investigator comply with the additional protections provided in [45 CFR 46 Subpart B](#).

Do not complete Appendix F unless pregnant women will be intentionally recruited and/or studied.

Investigator Name

A. Pregnant Women

1. Describe preclinical studies (including studies on pregnant animals) and clinical studies (including studies on non-pregnant women), where scientifically appropriate, that provide data for assessing potential risks to pregnant women and fetuses.

2. Indicate for whom the prospect of **direct benefit** exists:

- Pregnant woman
 Fetus
 Both
 Neither

The father's consent must be obtained for research that holds the prospect of direct benefit solely to the fetus, unless he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

3. The risk to the fetus is (check one):

- Not greater than minimal risk – prospect of direct benefit for the woman and/or fetus
 Not greater than minimal risk – without prospect of direct benefit but the purpose of the research is development of important knowledge that cannot be obtained by any other means
 Greater than minimal risk – caused solely by procedures that hold the prospect of direct benefit for the woman and/or fetus

4. Explain how the risks are the least possible for achieving the objectives of the research.