

Checklist for Research Involving Pregnant Women and Fetuses

Principal Investigator (Last, First):

Protocol # (XX-XX-XXXX):

Project Title:

NOTE: If the research project involves only a survey or interview with pregnant women and **does not** include any biomedical or social interventions, this checklist **does not** need to be submitted

1. Have scientifically appropriate, preclinical studies (including studies on pregnant animals) and clinical studies (including studies on nonpregnant women) been conducted that provide data for assessing potential risks to pregnant women and fetuses?

Yes No

If Yes,

Is the risk to the fetus caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus?

Yes No

OR

If there is no prospect of benefit, is the risk to the fetus not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means?

Yes No

2. Is the risk minimized as much as possible for achieving the objectives of the research?

Yes No

3. Will informed consent be appropriately obtained?

Yes No

4. For research of direct benefit solely to the fetus (not the pregnant woman), has informed consent been obtained from both the father and the mother?

Yes No

If "No,"

Is the father unable to consent because of unavailability, incompetence, or temporary incapacity or did the pregnancy result from rape or incest?

Yes No

5. For research of direct benefit to the pregnant woman, has informed consent of the pregnant woman been obtained? If no direct benefit to either pregnant woman or fetus when the risk to the fetus is minimal and the purpose of the research is to develop important biomedical knowledge that cannot be obtained by other means, informed consent is still required.

Yes No

6. For research in which the pregnant woman is a child, has assent been obtained from the child and permission from the child's parent(s) or guardians?

Yes No

7. Have inducements, monetary or otherwise, been offered to terminate a pregnancy?

Yes No

8. Do individuals engaged in the research have any part in decisions regarding timing, method, or procedures for termination of a pregnancy?

Yes No

9. Do individuals engaged in research play any part in determining the viability of a neonate?

Yes No