

Date:
CPHS#:

OPHS WORKSHEET - 45 CFR 46.204
RESEARCH INVOLVING PREGNANT WOMEN OR FETUSES

The Committee for Protection of Human Subjects may approve research involving pregnant women or fetuses, provided that the Committee finds that all of the conditions below are met:

- A. Where scientifically appropriate, preclinical 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.

Protocol-specific comments:

- B. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is 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.

Protocol-specific comments:

- C. Any risk is the least possible for achieving the objectives of the research.

Protocol-specific comments:

- D. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of IC701 – General Requirement and Documentation of Informed Consent.

Protocol-specific comments:

- E. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accordance with the informed consent provisions of IC701 – General Requirement and Documentation of Informed Consent, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

Protocol-specific comments:

- F. Each individual providing consent under paragraph D or E above is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

Protocol-specific comments:

- G. For children who are pregnant, assent and parental permission are obtained in accord with the provisions of SC503 – Children as Vulnerable Population.

Protocol-specific comments:

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

Protocol-specific comments:

- I. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

Protocol-specific comments:

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

Protocol-specific comments: