

RESEARCH INVOLVING PREGNANT WOMEN & FETUSES

Definitions

Subpart B: This term refers to the regulations which apply to research involving pregnant women and fetuses as subjects. Subpart B is found in 45 CFR 46 (DHHS).

Pregnancy: Encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

Fetus: The product of conception from implantation until delivery.

Dead Fetus: A fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

Federal Research Regulations

Federal regulations require additional safeguards when approving research involving pregnant women and fetuses. These special protections are found in Subpart B. The IRB may approve research involving pregnant women or fetuses only if all conditions for research are met (see description of conditions below) provided that the research also meets the general criteria for approval.

Description

The IRB must consider the general criteria for IRB approval for all studies, including those that involve pregnant women and fetuses. In determining whether the general criteria for approval are met, the IRB may have additional considerations for the research that would generally not be of concern in the general adult population.

Risks

Risks that may be considered minimal when dealing with adults may be riskier when applied to pregnant women and fetuses. Efforts should be made to minimize any potential harm.

There may also be unforeseeable risks to an embryo or fetus for a particular treatment or procedure. The possibility of unforeseeable risks must also be taken into consideration.

Additional Protections for the Inclusion of Pregnant Women and Fetuses in Research

The IRB must consider the degree of risk and discomfort involved in the research in relation to the direct benefits it offers to the pregnant woman or fetus in order to determine whether the study is approvable under the federal regulations. The standard of review is conducted consistently, regardless of full board or expedited review. The IRB may approve studies involving pregnant women and/or fetuses only if the research fits into either category 1 or 2 below and also meets all of the following considerations 1-6: ^[45 CFR 46.204]

Category 1:

The research holds the prospect of direct benefit for the woman or the fetus. Any 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.

Category 2:

- The research holds NO prospect of direct benefit to the woman or the fetus, and
- The risk to the fetus is not greater than minimal, and

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- The purpose of the research is to develop important biomedical knowledge which cannot be obtained by other means.

Additional Considerations (1-6):

(1) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies on non-pregnant woman have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

(2) The risks to pregnant women and fetuses have been minimized, while still allowing the objectives of the research to be achieved.

(3) The individual(s) providing consent will be fully informed regarding the reasonably foreseeable impact of the research on the fetus.

(4) The individuals conducting the research are prohibited from offering inducements, monetary or otherwise, to terminate a pregnancy.

(5) The individuals conducting the research are prohibited from taking part in the decisions as to the timing, method, or procedures used to terminate a pregnancy.

(6) The individuals conducting the research are prohibited from determining the viability of a fetus.

Obtaining Consent for Research Involving Pregnant Women or Fetuses

Informed consent must be obtained from the necessary individuals as described below, unless the study meets the criteria to waive informed consent.

For research that falls into category 1 above, the board will make a determination based on the risk vs. benefit ratio as to which consent process method is appropriate for the study:

- If the research holds the prospect of direct benefit to the **pregnant woman and fetus**, consent must be obtained from the pregnant woman.
- If the research holds the prospect of direct benefit to the **pregnant woman only**, consent must be obtained from the pregnant woman.
- If the research holds the prospect of direct benefit to the **fetus only**, consent must be obtained from the pregnant woman and the father of the fetus.
 - The father's consent does not need to be obtained if he is unable to consent because of unavailability, incompetence, temporary incapacity, or if the pregnancy resulted from rape or incest.

For research that falls into category 2 above, consent from the pregnant woman only is required.

Pregnancy During Research Participation

Despite the warnings provided and precautions taken, pregnancy may occur during research participation. Investigators must be aware of the requirements related to reporting and follow-up in the event a research participant or a research participant's partner becomes pregnant. Investigators may update the application to include any consent forms via amendment, should the need arise. Please refer to the IGS: Pregnancy During Research Participation for a detailed description of the follow-up guidelines the investigator should follow if pregnancy occurs during research participation.

Research on Dead Fetuses or Fetal Material (after delivery)

Research involving dead fetuses or fetal material obtained after delivery must be conducted in accord with any applicable federal, state, or local laws and regulations regarding such activities.

For more information about research involving the transplantation of fetal tissue, please see the Investigator Guidance Series: Transplantation of Fetal Tissue.

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If information associated with the dead fetuses or fetal material is recorded in such a way that living individuals can be identified through the research, these living individuals are considered research participants and the researchers must abide by all regulations that apply to this group.

Points to Address

New Study Application:

1. **Subjects section:** Please select “Pregnant Women and Fetuses”. The “Vulnerable Populations” page will populate next. While pregnant women are no longer named as a group vulnerable to coercion in the revised Common Rule, answering questions on the subsequent page (the Vulnerable Populations page) assists our reviewers in justifying the inclusion of pregnant women and fetuses as participants in the study and ensuring that additional protections are provided

2. **Risks and Benefits section:** Describe all potential risks and benefits to pregnant women and fetuses.

Consent Document:

1. Describe the risks and benefits to the pregnant women and fetuses. State that there may also be unforeseeable risks to an embryo or fetus for a particular treatment or procedure.

References & Links

*Additional Protections for
Pregnant Women, Human
Fetuses and Neonates*

*Involved in Research (OHRP):
45 CFR 46, Subpart B*

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb>

*Investigator Guidance Series:
Pregnancy During Research
Participation*

To be updated

*Investigator Guidance Series:
Transplantation of Fetal
Tissue*

To be updated

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