

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: Women Who Are or May Become Pregnant; Fetuses; and Neonates	Date Effective April 19, 2005	Supercedes P&P dated October 22, 2004

Background

Pregnant women should be given the same opportunity as non-pregnant women to participate in, and share, the benefits and burdens of research. Pregnant women are, however, a vulnerable population and Federal regulations require that additional protections be provided for them when they take part in research. State and local laws may also require additional considerations for research that involves pregnant women. CHR reviews all research involving pregnant women, or women who may become pregnant, and includes among its members individuals who regularly work with pregnant women and/or neonates.

JHSPH Policy and Procedures

General Guidelines

- Pregnant women should be included in all research unless there are valid reasons for excluding them. Inclusion in research of women who are, or may become, pregnant is important so that research findings can be generalizable and of benefit to all persons at risk of the condition under study. Generally, pregnant women may be involved in research, but the risk to the fetus should be considered not greater than minimal.
- These regulations do not apply to research that is exempt from Federal regulations.
- Researchers conducting research involving pregnant women, fetuses or neonates must complete the checklist [Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research](#) and include it with the research application.

Pregnancy Testing

The following methods for determining that a woman is *not pregnant* are no longer acceptable:

- self-reporting by the subject, and
- relying on the subject's recent menstrual history.

The only acceptable method to determine that a woman is *not pregnant* is to perform a urine pregnancy test on the day the study commences and to exclude potential subjects whose tests are positive.

If a study involves a procedure or treatment that is contraindicated during pregnancy, the urine pregnancy test should be done each time the treatment is given or procedure carried out. Testing should be on the same day, but before the treatment or procedure.

Categories of Research Involving Women Who Are, or May Become, Pregnant

- *Studies in which pregnancy is coincidental to subject selection.* Any study that includes women of childbearing potential could by chance include women who are pregnant or become pregnant during the study. These subjects should be notified that a particular treatment or procedure "*may involve risks to the subject (or to the embryo or fetus if the subject is or becomes pregnant) that are currently unforeseeable.*"
- *Studies in which pregnancy is an exclusion criterion.* For studies in which pregnant women are to be excluded because of unacceptable risk to the woman or fetus, non-pregnant subjects of childbearing potential may need to be instructed on methods to avoid pregnancy while involved in, or following, the research. Testing to determine that a woman is not pregnant may be required before and during the study.
- *Studies directed primarily toward the health of pregnant women.* Research may be undertaken to explore how women's health is affected by pregnancy. In such research, a woman's needs generally take precedence over those of the fetus. CHR will, however, attempt to ensure that risks to the fetus are minimized.
- *Studies directed toward pregnancy.* Some studies examine the normal and abnormal processes of pregnancy, labor, and delivery. For these studies, CHR must determine that the risk to the fetus is no more than that from established procedures routinely used in an uncomplicated pregnancy or in a pregnancy with complications comparable to those being studied.

Specific guidelines for when CHR may approve research that involves pregnant women, fetuses and human fetal tissue are given below.

Research Involving Pregnant Women or Fetuses Prior to Delivery (45 CFR 46.204)

CHR may approve research involving pregnant women or fetuses prior to delivery if all of the following conditions are met:

- where appropriate, prior studies in animals and non-pregnant women provide a basis for assessing risks to pregnant women and fetuses, and the risks are the least possible for achieving the objectives;
- risk to the fetus is not greater than minimal risk and the risk is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus;

- any risk is the least possible for achieving the objectives of the research;
- investigators will have no part in decisions regarding ending the pregnancy or in determining the viability of a fetus;
- no inducements, monetary or otherwise, will be offered to terminate a pregnancy;
- the consent document includes a clear explanation regarding the reasonably foreseeable impact of the research on the fetus or neonate; and
- consent will be obtained as follows:
 - the informed consent of the pregnant woman or her LAR will be obtained if:
 - the research holds out the prospect of a direct benefit to the pregnant woman, or
 - the research holds out the prospect of a direct benefit both to the pregnant woman and the fetus; or
 - the research does not hold out the prospect of direct benefit for the woman or the fetus, but the 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.
 - the informed consent of the pregnant woman and the father will be obtained if the research holds out the prospect of a direct benefit solely to the fetus unless the father is not reasonably available, is incompetent or temporarily incapacitated, or the pregnancy resulted from rape or incest. In cases where the father is not reasonably available, a statement to this effect must be signed by the mother.
 - for minors who are pregnant, the assent of the minor and permission of parents must be obtained. State and local laws for parental permission and assent by the minor may also apply. If, however, the research provides direct medical benefit concerning the pregnancy, the consent of the minor in Maryland is sufficient. (See [Research That Involves Children](#) and [Parental Permission/Child Assent](#))

Research Involving Neonates (45 CFR 46.205)

Neonates of Uncertain Viability

CHR may approve research involving neonates of uncertain viability if all of the following conditions are met:

- where scientifically appropriate, preclinical and clinical studies have been conducted which provide data for assessing potential risks to neonates;
- the research holds the prospect of enhancing survival of the neonate to the point of viability and any risk is the least possible for reaching that objective, or the purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means and the research does not create added risk for the neonate;
- investigators will have no part in decisions regarding ending the pregnancy or in determining the viability of a neonate; and
- the informed consent of at least one parent is obtained.

Nonviable Neonates

CHR may approve research involving nonviable neonates if all of the following conditions are met:

- vital functions of the neonate will not be artificially maintained;
- the research will not terminate the neonate's heartbeat or respiration;
- there will be no added risk to the neonate resulting from the research;
- the research seeks important biomedical knowledge that cannot be obtained by other means;
- investigators will have no part in decisions regarding ending the pregnancy or in determining the viability of a neonate; and
- the informed consent of both parents will be obtained, however the father's informed consent need not be obtained if he is not reasonably available, he is incompetent or temporarily incapacitated, or the pregnancy resulted from rape or incest. In cases where the father is not reasonably available, a statement to this effect must be signed by the mother. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice.

Viabile Neonates

Research on viable neonates is considered to be research on children (see [Research That Involves Children](#)).

Research Involving Human Fetal Tissue, the Placenta or Post Delivery Fetal Material (45 CFR 46.206)

- Some State and local laws, and certain cultures, ban or limit research that involves, after delivery, the placenta, the dead fetus, macerated fetal material, or cells, tissue, or organs excised from a dead fetus. Such research must be conducted in accord with all applicable Federal, State, or local laws and regulations regarding these activities.
- Research that involves human fetal tissue obtained after delivery (placenta, tissue from an induced or spontaneous abortion, or from a still birth) is evaluated by CHR as research on tissue specimens (see [Research Involving Human Biological Materials](#)). If the tissue or specimen is linked directly or indirectly through identifiers to living individuals, those persons must be considered human research subjects (See [What Needs Review](#)). Research conducted on tissue or specimens from deceased individuals is *not* Human Subjects Research.

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Research Not Otherwise Approvable Which Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem Affecting the Health or Welfare of Pregnant Women, Fetuses, or Neonates. (45 CFR 46.207)

The Secretary, DHHS will conduct or fund research CHR does not believe meets the above requirements only if:

- CHR finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, and neonates; and

- The Secretary after consulting with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comments, including a public meeting announced in the Federal Register, has determined that:
 1. the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates; and
 2. the research will be conducted in accord with sound ethical principles; and
 3. informed consent will be obtained as described in the sections above.

Definitions

Fetus: The product of conception from implantation until delivery.

Neonate: A living newborn infant.

Viable neonate: A newborn that, after delivery, is assessed as able (given the benefit of available medical therapy) to survive to the point of independently maintaining heartbeat and respiration.

Non-viable neonate: a newborn that, although living after delivery, is assessed as unable to survive (given the benefits of available medical therapy) to the point of independently maintaining heartbeat and respiration.

RESOURCES & REFERENCES

45 CFR 46.204

45 CFR 46.205

45 CFR 46.206

45 CFR 46.207