
Yale University Institutional Review Boards Procedure

330 PR.1 Inclusion of Pregnant Women or Women of Child Bearing Potential in Research

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Overview

During the course of a research study, pregnant women or women of childbearing potential may be recruited coincidentally as potential participants into research that is not designed to study conditions related to pregnancy and delivery or the fetal condition. Alternatively, pregnant women and fetuses may be the intended study population(s). This procedure describes the considerations to be made and the processes to be followed when pregnant women or women of childbearing potential participate in research.

Pregnant women are the intended study population

Pregnant women can participate in Department of Health and Human Services (DHHS)-funded biomedical and behavioral human research that meets specific regulatory requirements as described in Policy 330: Pregnant Women, Fetuses and Neonates in Research. Of key importance is the scientific aim of the research and the level of risk involved to the pregnant woman and/or to the embryo or fetus by participating in the research. Therefore, investigators should carefully consider the research procedures and associated conditions that contribute to the risk/benefit assessment that will be made by the IRB. If there is any risk to a fetus, the investigator should consider whether or not the information sought is judged to be important and whether it could be obtained by any other means. The IRB can approve research with pregnant women and fetuses generally if:

- The research is conducted to meet the health problems of a pregnant woman and holds the promise of directly benefiting the woman, even when the benefit to the woman is minimal and the risk to the embryo or fetus may be greater than minimal. An example would be administering an FDA-approved medication in an investigational manner to treat pre-eclampsia, a potentially life-threatening condition even though it may have unknown or greater than minimal risk for the fetus.
- The research does not hold the prospect of directly benefiting the woman or fetus. The research is allowed if the risk to the fetus is not greater than minimal and the purpose is the development of important biomedical knowledge that cannot be obtained by other means. Examples include obtaining samples of blood or amniotic fluid from clinically-indicated procedures, or completing surveys or questionnaires.
- The research is directed toward the fetus in utero and the purpose of the research is to meet the health needs of the fetus and is conducted in a way that will minimize risk.

Pregnant women are not the intended study population

If research targeting a wide population includes women of childbearing potential, there is the possibility of pregnant women becoming involved.

If there are special concerns with conducting research on pregnant women, the research protocol should define any conditions for inclusion or exclusion of pregnant women or women of childbearing potential who may be encountered during study enrollment.

The consent form for treatment and intervention studies should describe any known risks to the participant (or to the embryo or fetus if the participant is or becomes pregnant). If the risks are not known because there is little experience in pregnant women, the consent form should clearly say so.

For research that presents no additional risks to pregnant women or to women of childbearing potential, the research protocol should specifically state that there are no known or suspected risks to pregnant women who may coincidentally be enrolled.

(See Guidance 330 GD. 1 on Reproductive Risks and Contraception)

Pregnancy is an exclusion criterion

National Institutes of Health (NIH) policy requires the inclusion of women in research study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study [PHS Grant Application form 398, pp. 21-22]. If pregnant women are excluded from research, the principal investigator should, in the protocol/application, justify the exclusion for science or risk-based reasons, describe the risks that require exclusion or, if applicable, state that pregnancy is exclusionary due to a lack of knowledge of the risks. Screening measures and the frequency of pregnancy testing should be commensurate with the risks to participants should they become pregnant.

For research that poses an unacceptable risk to a pregnant woman or fetus, non-pregnant participants of childbearing potential should be informed via the consent form and consent process of the following:

- Methods to avoid pregnancy during and after the study. During the consent process the investigator should review with each woman her plans to avoid becoming pregnant. If, in the judgment of the investigator, the plans are inadequate, the woman should be advised as to how to make them adequate or she should be excluded from the study.
- Any information about pregnancy testing that may be required before and during the study.
- The obligation to notify the principal investigator promptly if she departs in any way from the plans she discussed at the outset with the investigator or if, in spite of adherence to these plans, she thinks she might be pregnant.

Children

Research with adolescents may involve young females of childbearing potential. For those studies in which procedures and/or investigational treatments pose an unacceptable risk to a pregnant female or fetus, pregnancy must be an exclusion criterion. Pregnancy testing and, where appropriate, requirements for contraception for adolescents require special considerations that respect individual privacy and autonomy, yet ensure that appropriate care and guidance is given to the adolescent who is found to be pregnant.

The research application/protocol and parental permission/adolescent assent forms must include language describing procedures for testing young females for pregnancy. Recommended language is as follows:

For application/protocol:

Females of childbearing potential will require pregnancy testing prior to enrollment in the protocol. Because full confidentiality regarding pregnancy cannot be entirely guaranteed, these testing requirements and the limited scope of confidentiality will be made known to all subjects during the consent procedure. In this manner, young women who would not be comfortable with pregnancy testing or having their parents infer that they are pregnant can “opt out” of the study at the time of the initial consent, without having to declare specific reasons.

For parental permission form:

Females of childbearing potential will require pregnancy testing prior to proceeding with the protocol. Only your daughter will be told the results. We will, of course, counsel your daughter to seek appropriate healthcare and the support of an adult if she is found to be pregnant. A positive pregnancy tests means that your daughter cannot participate in this study. Because she will be asked to leave the study, you may infer or find out that she is pregnant. If you or your daughter are uncomfortable with pregnancy testing, then we would recommend that you or she not participate.

For adolescent assent form:

We will ask you to have a pregnancy test before you start this study. Only you will be told the results. If you are pregnant, we will also advise you to get care for your pregnancy and get the support of an adult. You will be asked not to participate or you will be removed from the study if your pregnancy test is positive. You need to know that your parents may ask you why you cannot participate or why you were asked to leave the study. So if there is any chance that you are pregnant or you might become pregnant during the time of this study, we would recommend that you think really carefully about whether you should participate. It is okay if you decide that you do not want to participate or to stay in this study. You do not need to give a reason for not participating.

Studies which are not funded by DHHS or which are not biomedical or behavioral

The IRB may approve research that is not funded by the Department of Health and Human Services (DHHS) that involves interviews, surveys, oral histories and other social, behavioral, and educational research that generally does not, on the basis of their pregnancy, present increased risk to participants who are or may become pregnant. Unless the research is specifically targeted to pregnant women or women of childbearing potential or fetuses, minimal risk studies which are not biomedical, behavioral or funded by DHHS are not required to include information regarding pregnancy-related risks. Such studies are also not held to the regulatory requirement that they intend to develop important biomedical knowledge which cannot be obtained by other means. Investigators and the IRB should nonetheless consider the study in light of the potential for the inclusion of pregnant women or women of childbearing potential and conform to the requirements of IRB Policy 330, as applicable to the study.

References:

Institutional Review Board Guidebook, Chapter VI, Special Classes of Subjects
(http://www.hhs.gov/ohrp/irb/irb_chapter6.htm)

University of California, San Francisco: Human Research Protection Program, The Committee on Human Research, Guidance on Vulnerable Subject Populations
(http://www.research.ucsf.edu/CHR/Guide/chrG_SpFPL.asp)