

When Does Human Research Involve Pregnant Women?

Research involves pregnant women when the researcher is able to confirm that a woman is pregnant, either by self-disclosure by the subject, proof of missed menses, or a positive pregnancy test. These studies are not considered to involve pregnant women.

OHRP's current position is that an investigator does not have an obligation to ascertain whether any of the women involved in a research study are pregnant. Just because a project involves women who may become pregnant (also known as "women of childbearing potential"), it does not mean the project involves pregnant women. If the research does not require disclosure of pregnancy status, then the researcher is not obligated to determine whether a woman is or may be pregnant.

For example, a **federally-funded or supported research** survey of undergraduates would not require the investigator to ascertain whether any of the potential respondents is pregnant and exclude them in order to avoid having to comply with the Subpart B requirements. If the investigator does happen to know that a subject is pregnant, however, then the provisions of 45 CFR 46 subpart B apply, and the **biomedical** knowledge provision requirement is triggered where there is no prospect of direct benefit for the woman or fetus, as per [46.204\(b\)](#).

Requirements for Inclusion of Pregnant Women in Human Research

Investigators must provide protocol specific justification to the IRB, so that the IRB may make a determination that the enrollment of pregnant women in the research is justified.

Definitions ([45 CFR §46.202](#))

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.

Categories of Research Involving Pregnant Women

1. Federally funded minimal risk research or has prospect of direct benefit to the woman or the fetus ([45 CFR §46.204](#)).
2. 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 contact the HSPP office ([45 CFR §46.207](#)).

Expansion of Research Involving Pregnant Women

The University of Arizona has adopted flexible procedures for projects that are not federally funded, supported, or otherwise subject to the federal rules. Projects that meet the requirements of the Flexible Policy may be eligible for increased research activities involving pregnant women.

Social and behavioral research or medical research that does not involve greater than minimal risk are not required to meet the requirement of 'important biomedical knowledge'.