

**OFFICE OF RESEARCH AND DEVELOPMENT
VETERANS HEALTH ADMINISTRATION**

ORD Guidance on Conducting Research Involving Pregnant Women

Date: October 20, 2014

SCOPE: VA is authorized to care for Veterans and to conduct research that supports the mission of VHA and that enhances the quality of health care delivery to Veterans. Research involving women who are pregnant must be reviewed carefully by the IRB because of women's additional health concerns during pregnancy and because of the need to avoid unnecessary risk to the fetus. VA medical centers are expanding the capacity to care for pregnant Veterans, but not all facilities have the appropriate equipment or expertise to care for pregnant women should an emergency arise. Further, in the case of a pregnant woman, IRBs must determine when the informed consent of the father to the research is required. Special attention is justified because of the involvement of a third party (the fetus) who may be affected but cannot give consent.

This guidance is to assist IRBs, R&D Committees, and facility Directors in their review and approval of VA research that meets the definition of research involving pregnant women.

1. Under what circumstances can research involving pregnant women be conducted in VA?
2. What information should be provided in a research proposal and/or review materials that involve pregnant women in research?
3. What must the VA IRB of record review and document for approving research involving pregnant women?
4. What must the R&D Committee review and document for approving research involving pregnant women?
5. What are the requirements for the facility Director memo of approval?

1. Under what circumstances can research involving pregnant women be conducted in VA?

- The research is relevant to the health of Veterans, or
 - is directly relevant to its role as a health care provider in a period of local or national emergency, or
 - supports the mission of another federal agency through an interagency agreement or similar mechanism.
- The IRB reviewing the research has appropriate membership to represent pregnant women's interests and obstetric expertise.
- The IRB reviewing the research has specific SOPs regarding pregnant women in research.
- The research meets all requirements in 45 CFR 46, Subpart B, Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research, Sections 46.203 through 46.207 including the following ethical and scientific criteria:

- 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;
- the risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or fetus. If there is no such prospect of benefit, then 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;
- any risk is the least possible for achieving the objectives of the research.
- The VA facility Director certifies that the facility is able to respond to obstetric emergencies if the research involves an intervention greater than minimal risk in pregnant women at the VA facility.

2. What information should be provided in a research proposal and/or review materials that involve pregnant women in research?

- A description of the relevance of the study to the health of Veterans
- Justification for entering pregnant women into the study.
- A copy of the study protocol, the informed consent form and HIPAA authorization.
- Documentation of any additional safeguards that have been incorporated into the clinical site where pregnant women will be studied.
- Information on the funding source for the research.

3. What must the VA IRB of record review and document for approving research involving pregnant women?

- Review the research proposal and additional materials to determine that all criteria for IRB approval have been satisfied in accordance with VHA Handbook 1200.05.
- Review and approve consent documents in accordance with VHA Handbook 1200.05, or a waiver of consent or documentation of consent if these criteria are met.
- The study meets all requirements in 45 CFR 46, Subpart B, Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research, Sections 46.203 through 46.207.
- Document in the minutes the discussion regarding level of risk, the informed consent, the investigators' qualifications to conduct research involving pregnant women, and any additional safeguards incorporated into the protocol.
- If appropriate, the IRB must ensure that mechanisms are implemented to ensure appropriate management, reduction, or elimination of potential, actual, or perceived conflicts of interest related to all aspects of the research, including financial interests,

clinical roles (for example, investigator-patient relationships), and other professional, or personal roles.

4. What must the R&D Committee review and document for research involving pregnant women?

- The proposed research is relevant to the VA's mission and the care of Veterans.
- There is scientific merit to the research proposed.
- There are adequate protections for participating human subjects (including privacy and confidentiality), and adequate safety measures for research subjects and personnel engaged in the research.
- The required resources are available and the locations are appropriate where the research will be conducted.
- The research investigator and research team are qualified to conduct the study.
- All appropriate subcommittee approvals have been obtained.

5. What are the requirements for the facility Director memo of approval?

- The facility Director must review the minutes of the VA IRB and R&D Committee meeting at which the protocol was approved to ensure that all criteria in item #1 of this guidance were satisfied.
- If the study includes an intervention greater than minimal risk with pregnant women at the VA facility, the VA facility Director must certify that the facility is able to respond to obstetric emergencies.
- The memo documents for the record that the facility Director is aware of and approves the request for his/her facility to participate in the proposed research that includes pregnant women.

REGULATORY AND VHA POLICY REFERENCES:

38 CFR 16, Protections of Human Research Subjects

45 CFR 46.203 through 46.207, Additional Protections for Pregnant Women, Human Fetuses, and Neonates Involved in Research (Subpart B)

VHA Handbook 1200.01, Research and Development (R&D) Committee, June 16, 2009.

VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research, October 15, 2010.