



PREGNANCY DURING RESEARCH PARTICIPATION

Description

For some research protocols, women of childbearing age are advised to avoid pregnancy or nursing for a time during or following the research to protect the health and safety of the mother and/or child. Males must also be warned if there is a risk arising from the transfer of an medicinal-investigational product via semen. Participants need to be clearly warned regarding any known risks (e.g., birth defects) should pregnancy occur. Additionally, investigators must inform female participants of childbearing age that if she was to become pregnant, the particular treatment or procedure may involve risks to the embryo or fetus which are currently unforeseeable.

The University of Utah IRB requires that both male and female participants must be informed of the appropriate precautions to prevent pregnancy (see Points to Consider-IGS: Contraceptive Methods). 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.

This guidance is intended to clarify IRB requirements and what information should be provided to the IRB in order to ensure the protocol has a process for monitoring and managing pregnancy occurrences.

Follow-Up Guidelines

Information may only be collected on a research participant who becomes pregnant, a partner of a research participant who becomes pregnant and/or the newborn infant if the IRB-approved protocol, consent forms and data collection forms contain provisions for collection of information on the pregnancy and outcome.

Investigators may update the ERICA (Electronic Research Integrity and Compliance) application to include the vulnerable population(s) and any consent forms via amendment, should the need arise. Researchers should describe the rationale for collection of pregnancy information (e.g. discovery of any reproductive risks related to an investigational drug, etc.). Researchers should outline what data, if any, will be collected about the pregnancy, and the length of time data be collected (outcome of pregnancy only, infant at 3 months, infant at 6 months, etc.).

Research Participant

The research participant must provide consent for collection of follow-up pregnancy data in accordance with the IRB approved consent process and the ERICA application should be amended to include pregnant women as a vulnerable population. Information cannot be collected if the woman's participation is terminated or she has withdrawn.

Pregnant Partners

~~Researchers that plan to collect pregnancy outcome data from pregnant partners of research participants when data is being requested for research purposes (i.e. in order to document evidence of the effects of the study/drug/treatment on pregnancy), must obtain informed consent is required from the pregnant partner in addition to the trial subject, and amend the ERICA application to include pregnant women (see Points to Address below).~~ A pregnant partner informed consent document must adhere to the general requirements of informed consent (45 CFR 46.116; 21 CFR 50.25). Where HIPAA regulations apply, the pregnant partner must also sign an authorization for use of their protected health information (PHI). In cases where the pregnant partner is a minor (i.e. age 17 or younger), parental permission may also be required. Please see the Pregnant Partner Consent Template on the IRB website.

- ~~When data is being collected exclusively for clinical purposes (i.e. in order to ensure the safety of mother and child), a pregnant partner informed consent document is not required by the IRB.~~

Newborn Infant

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

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~~The investigator must not collect any information on the newborn infant unless the newborn infant becomes a research subject. Before collecting any information from the newborn infant, the investigator must include provisions for studying the newborn infant in the research protocol, the informed consent form, and data collection forms, obtain approval from the IRB, and then obtain appropriate parental permission informed consent from the newborn infant's parent or legal guardian. If the study is a VA study, a waiver from the CRADO, the VA facility director must approve participation of children in research prior be obtained to collection of data about enter the newborn infant following IRB review and approval into the study.~~

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Monitoring Pregnancy Occurrences

Investigators conducting research that advises participants to use an effective method of birth control to protect the health and safety of the mother and/or child must have a safety monitoring plan. The following information is required in either the Company Protocol or IRB Application to ensure that an adequate plan exists to report this safety information.

- Specify what data points will be sought from pregnant research participants or pregnant partners. Identify if follow-up information will be self-reported or if it will be acquired via chart review.
- The frequency and length of follow-up should be clearly defined.
- Describe the mechanism to track the mother's expected delivery date (and thus obtain follow-up data).
- Describe the plan to ensure the reporting of a pregnancy, an abnormal outcome for the fetus/child, or adverse reactions suspected in infants following exposure to breast milk -to the appropriate entities (IRB, sponsor, FDA, etc.) as applicable.
- In cases where it is necessary to monitor the pregnancy of a woman whose male partner is the trial participant, partner privacy may become an issue in follow-up for certain situations (e.g. cases where the pregnant partner is a minor, where the partner does not wish to be identified, where paternity is in question, etc.). The protocol should describe the process for monitoring and managing special circumstances with regard to partner privacy.

Reporting Guidelines

Although pregnancy itself is not considered an adverse event or a serious adverse event, the pregnant participant or the partner of a male participant should be followed until termination or to term to ensure absence of congenital anomaly or birth defect that may have resulted from maternal exposure or transmission of the study drug via semen following paternal exposure.

Investigators conducting research that advises participants to use an effective method of birth control to protect the health and safety of the mother and/or child must report the pregnancy of a participant or a participant's partner to the University of Utah IRB. The following are reporting guidelines for the University of Utah IRB. Reports should be submitted using the Report Form in ~~the Electronic Research Integrity and Compliance (ERICA) system:~~

- Pregnancy should be reported as "Information" (not as an "Adverse Event" or "Other Problem or Event").
- Pregnancy does NOT have to be reported to the IRB if the subject is receiving follow-up only, and conception occurred outside of the time period that the study protocol requires contraception (e.g. protocol specifies that contraception is required for 6 months after the last dose of the study drug and the pregnancy occurred after that time).
- Subsequent reports containing follow-up information regarding a pregnancy is not required unless the pregnancy results in a congenital anomaly. The congenital anomaly should be promptly reported as an Adverse Event on the Report Form in ERICA.
- *NOTE: If you suspect that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child, it must be reported to the FDA.*

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Points to Address

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

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Application:

1. **Participants page, question 3:** Please select "Pregnant Women and Fetuses" as a vulnerable population. If data will be collected on infants, please also select "Children" as a vulnerable population. On the subsequent page (the Vulnerable Populations page) complete all questions justifying the inclusion of pregnant women and fetuses (and children, if applicable) as participants in the study.

2. Study information page:

a. Methods for ensuring participants are not pregnant prior to participation in the study should be described. Description of procedures should include the type of test being administered; when the test will be administered (e.g. prior to enrollment in the study, before the administration of the first study procedure, etc.); and who the results of the test will be given to (e.g. participant only, participant and partner, participant and parent(s), etc.).

b. If the protocol requires participants to use an effective method of birth control to protect the health and safety of the mother and/or child, describe any follow-up that will occur and clearly state whether data will be collected for research purposes or for clinical purposes.

3. **Safety Monitoring Plan page:** If the protocol requires participants to use an effective method of birth control to protect the health and safety of the mother and/or child, describe the safety monitoring plan with specific attention to the collection of follow-up data (see above).

Consent Document:

1. **Study Procedures:** If a pregnancy test will be administered prior to the beginning of the study, please explain the procedures involved. Explain what will happen if unexpected pregnancy occurs (i.e. follow-up of pregnancy outcome, withdrawal from the study, etc.).

2. **Risks:** State any risks to the fetus if a pregnancy occurs. Also, if there is any defined or unknown risk of congenital abnormalities arising from the use of the medicinal product by transfer via semen, it should be clearly documented.

3. **Unforeseeable Risks:** Include a statement that there may be risks involved in this study/procedure to an unborn child or fetus that are currently unknown.

Pregnant Partner Consent:

1. **Risks:** If there is a defined or unknown risk of congenital abnormalities arising from a medicinal product by transfer via semen, this needs to be clearly documented.

2. **Costs:** Clarify who is responsible for costs associated with follow up by the study and for pre-natal care outside of the research study.

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References & Links

Pregnancy Follow-Up Consent and Release of Information Authorization <http://irb.utah.edu/forms/health-sciences.php>

Pregnancy and VA Research: Guidance on Collecting Data on Pregnancy and Outcomes of Pregnancy from VA Research Subjects and Pregnant Partners of VA Research Subjects for Safety Monitoring

<https://www.research.va.gov/resources/policies/guidance/pregnancy.pdf>
<http://www.research.va.gov/resources/policies/guidance/pregnancy-and-research.pdf>

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