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Subject: Reviews Requiring Special Consideration
Division: IRB
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IRB Policy 110.5: RESEARCH REQUIRING BIRTH CONTROL

Policy

The IRB will assess each study individually, and contraception will be required only on a case-by-case basis, where there is defined or truly unknown risk to the fetus.

Consent Form Requirements

When birth control is required for study participation the informed consent document should contain the following elements:

1. The section describing study procedures should include among the screening procedures any pregnancy testing done for study purposes.

2. The section on risks/discomforts should describe the risks to pregnant mothers, fetuses, and/or fertility of subjects as appropriate.

3. The consent form should list acceptable methods of birth control (i.e., birth control pills, birth control patches, Depo-Provera, Norplant, an IUD, a diaphragm or condom with spermicide, abstinence), and instruct participants when they should start using them and for how long.

4. The consent form should note if there is a possibility that the drug being studied may interact in a manner that makes the hormonal contraception less effective.

5. The consent form should note that there is a risk that a participant or a participant's partner could still become pregnant even if s/he is using/have used a reliable method of birth control.

6. The consent form should provide instructions for advising the PI if pregnancy is suspected.

7. The Institute of Medicine recommends that pregnancy termination options be discussed (in a neutral, nonjudgmental way) as a part of the consent process in clinical trials that have unknown or foreseeable risks to potential offspring.

The following is sample consent form language for requiring birth control (For Women):

> "If you are nursing an infant or you are pregnant now, you must not be in the study because we do not know how this drug could affect a fetus. Pregnancy tests will be done at screening, immediately prior to receiving the first dose of study drug, and every 4 weeks during your participation in this study. Pregnancy tests must be negative for you to enter and stay in the study.

If you are sexually active and are at risk of getting pregnant, you and your male partner(s) must use a method *(two methods)* of birth control that works *(work)* well, like birth control pills, birth control patches, Depo-Provera, Norplant, an IUD, a diaphragm or condom with spermicide, or abstinence. You will have to do this the whole time you are in this study. There is a risk that you could still become pregnant even if you are using/have used a reliable method of birth control.

If you become pregnant during the research study, please tell the investigator and your doctor immediately. If you are still receiving the study drug, you should stop taking it. We will still ask you to return for the rest of the evaluations, so that we can ask you information about your experiences with the drug."

The following is sample consent form language for requiring birth control (For Men):

If you are a sexually active male and at risk of causing a pregnancy, you must be sure that your female partner(s) are using a method of birth control that works well, like birth control pills, birth control patches, Depo-Provera, Norplant, an IUD, or a diaphragm with spermicide, or you must use a condom with spermicide during sexual intercourse, or abstinence. You must do this the whole time you are in this study. A vasectomy **[***is/is not***]** an acceptable method of birth control for this study. There is a risk that your partner could still become pregnant even if you are using/have used a reliable method of birth control. If a sexual partner becomes pregnant during the research study, please tell the investigator and ask your partner to tell her doctor immediately.

Applicable Regulations and Guidelines

OHRP IRB Guidebook
45 CFR 46.116 (b)(1)
21 CFR 50.25 (b)(1)