CHRISTUS Health Standard Language for Pregnancy Prevention for Research Informed Consents and Assents

CHRISTUS Health
919 Hidden Ridge 6th Floor
Irving, Texas 75038

Version Date – 7-7-2017

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Introduction

Sponsors of clinical trials (sponsors) often require study subjects in their studies to avoid becoming pregnant (or, sometimes, in the case of male study subjects, to avoid fathering a child) while enrolled in the study and for a designated period of time after study subjects have withdrawn from the study or the study has ended. For this reason, sponsors usually include language in their informed consent documents that explicitly mandates the use of contraceptives. Language that explicitly mandates the use of contraceptives by study subjects presents a challenge for Catholic health care facilities and their Institutional Review Boards (IRBs). Including such language in an IRB consent form would constitute Formal Cooperation (or, at least, *Implicit* Formal Cooperation) with an act that is considered to be intrinsically immoral by Catholic Church teaching. Church teaching does not permit Formal Cooperation (implicit or otherwise) in immoral acts.

The following seven standard clauses contain language for use in clinical research consent forms that: 1) avoids (Implicit) Formal Cooperation on the part of Catholic health care facilities; and, 2) might be acceptable to sponsors of a clinical trial. Each of these standard clauses retains a mandate for study subjects to avoid becoming pregnant while actively participating in a clinical trial, but avoids Formal Cooperation on the part of the Catholic institution by: 1) not specifying the particular means that should be used to avoid becoming pregnant; 2) appropriately allowing for the choice of means to be made by the study subject in consultation with the study doctor; and, 3) emphasizing a means that is considered morally appropriate under Catholic Church teaching, namely, abstinence. In this way, these clauses are effective in obtaining appropriate informed consent, but allow IRBs acting on behalf of a Catholic health care facility to remain silent on the issue of which means should be used to avoid becoming pregnant. The morally significant language in the standard clauses below has been emphasized for illustration purposes only.

For Research Coordinators

1. If a study requires subjects to avoid becoming pregnant or fathering children, submit the clauses below to the study sponsor for consideration if applicable. For studies approved by an external IRB with whom CHRISTUS Health has a reciprocity agreement, submit the clauses to that IRB.
2. The study sponsor or external IRB may choose one of these paragraphs to replace the language in their consent form that discusses the requirements to use contraception. The sponsor or external IRB should **remove the previous language** that discusses contraception and **replace it entirely** with one of these standard clauses, verbatim.
3. Standard clauses 1 through 6 are the preferred options. Standard clause 7 should only be used if the study sponsor or external IRB refuse to use any of the first six clauses.
4. If the sponsor or external IRB will not agree to use any of these standard clauses, they may attempt to craft language similar to a standard clause that they do find acceptable.
    a. NOTE – **Alterations could delay implementation of a study** since the CHRISTUS Health IRB will refuse to acknowledge a consent form altered in this way that does not avoid Formal Cooperation with contraception. To avoid this possibility, it is recommended that the sponsor or external IRB follow step #3.
    b. If alterations are unavoidable, **to avoid delays**, they should only involve the following:
        i. Lengthening the amount of time a subject must avoid pregnancy after the study or study drug ends;
        ii. Removing references to becoming pregnant if the study involves only men;
        iii. Removing reference to fathering a child if the study involves only women;
        iv. Expanding or narrowing the exclusion criteria for being exempt from these methods such as post-menopausal, surgically sterilized, etc.;
        v. Removing or increasing the effectiveness mentioned in standard clause 7; or
        vi. Adding or removing specific methods of contraception in standard clause 7.
    c. If alterations are unavoidable, **to avoid delays**, make sure to remove any previous language that describes contraception as appropriate, recommended, or required. Phrases like "you should", "you must", need to be removed when referring to using contraception.
    d. The bolded language in the standard clauses has been carefully crafted to avoid Formal Cooperation with contraception. It does not need to remain bold in the consent form, but **to avoid delays** any alterations should leave this language intact.

5. If the study sponsor or external IRB refuse to accept any of the standard clauses even with alterations, please contact the CHRISTUS Institute for Innovation and Advanced Clinical Care (CIIACC). Please do not reject a study without first speaking to CIIACC.

Pregnancy Prevention - Standard Clauses

NOTE – Standard clauses 1 through 6 are preferred. Standard clause 7 should only be used if the study sponsor or external IRB will not accept any of the others.

Contraception - Standard Clause 1

"If you are pregnant or breastfeeding, you cannot take part in this study. You may be required to have a blood and/or urine test to see if you are pregnant before you begin this study. If you are sexually active, it is important that you not become pregnant because this drug may be harmful to your unborn child. **You must discuss your pregnancy plans with your study doctor before enrolling in this study; you must also agree to use the type and duration of precautions approved by your study doctor for the entire time you receive this study drug.** For women, if you become pregnant or have reason to believe you might be pregnant, please inform your study doctor immediately. Once you are no longer receiving this study drug, discuss with your study doctor when it might be safe to become pregnant. For men, if you have reason to believe your partner is pregnant, please inform your study doctor immediately. Once you are no longer receiving the study drug, discuss with your study doctor when it might be safe to become a new father."

Contraception - Standard Clause 2

"If you are pregnant or breastfeeding, you cannot take part in this study. You may be required to have a blood and/or urine test to see if you are pregnant before you begin this study. If you are sexually active, it is important that you not become pregnant for this drug may be harmful to your unborn child. **You must discuss your pregnancy plans with your study doctor before enrolling in this study and agree that you will take the appropriate precautions not to become pregnant while enrolled in the study.** For women, if you become pregnant or have reason to believe you might be pregnant, please inform your study doctor immediately. Once you are no longer receiving this study drug, discuss with your study doctor when it might be safe to become pregnant. For men, if you have reason to believe your partner is pregnant, please inform your study doctor immediately. Once you are no longer receiving the study drug, discuss with your study doctor when it might be safe to become a new father."

Contraception - Standard Clause 3

"If I am a woman able to have children, I understand that I must not be pregnant when I enter the study. I also must not become pregnant during the study. This study could seriously harm my fetus if I am pregnant or become pregnant. **I understand I must use a birth regulation method or abstain from sexual relations throughout the study and** one week **after completing the study.** These methods should be used by both female study subjects of childbearing potential and by males who are partners of such females. **I understand that only abstinence is 100% effective in preventing pregnancy.** If I enter the study and then think I might be pregnant, I will tell my study doctor right away. I also understand that there might be risks to a fetus if I become pregnant after the study is done. These risks are unknown. If I do want to become pregnant when the study is done, I will talk about it with my study doctor."

Contraception - Standard Clause 4

"**If you are sexually active, your study doctor strongly recommends that you take precautions to avoid becoming pregnant or fathering a child** for one or two months **after discontinuing study drugs because it is not known how these drugs could affect an unborn child.** If you are a woman, you cannot take part in this study if you are pregnant or plan to become pregnant. You will take a urine test to see if you are pregnant before you start the study drug. Should pregnancy occur while you are receiving study drugs, you must tell your study doctor immediately."

Contraception - Standard Clause 5

"This study may be harmful to a nursing infant, pregnant woman, or an unborn child. Sufficient medical information is not available to determine whether the study drug administered to a pregnant woman causes significant risks to a nursing infant, pregnant woman, or fetus. You should not nurse your baby while on this study. If you are a woman able to have children and have not been surgically sterilized (tubal ligation or hysterectomy), you should have a pregnancy test before enrolling in this study. **You should not become pregnant while on this study. If you are unwilling to use adequate measures to prevent pregnancy,**

you should not participate in this study. If you should become pregnant while you are on this study, you must tell your study doctor immediately. **Ask about counseling and more information about preventing pregnancy.**"

Contraception - Standard Clause 6

"Some research drugs or procedures can cause birth defects or miscarriage. If you take part in a research study that includes a drug or medical procedure, you must be willing to have a pregnancy test done before your participation. If you are pregnant or nursing a child while taking the study drug or during the study procedure, there may be risks to you, the embryo, fetus, or the nursing child. **You must avoid becoming pregnant while you take part in the research study.** If you are pregnant, or become pregnant, you cannot take part in this research study. It is important that you let the research study doctor know if you are breast feeding. If you are pregnant or think you are pregnant, it is important for you to let the study doctor know immediately. **If you are sexually active during your participation in the research you and your partner must be willing to use effective measures (chosen in consultation with your health care provider) to avoid a pregnancy.**"

Contraception - Standard Clause 7

NOTES

1. Study sponsors or external IRBs may add or remove options to the list in the third paragraph. However, abstinence must be listed as an option and must be the first on the list. Again, this clause should only be used if the study sponsor or external IRB will not accept any of the first six clauses.
2. The language in the third paragraph about "two of the following methods…" is not required. If a sponsor or external IRB require that specific methods be listed out, doing so will not delay the implementation of a study.
3. The references to 99% in the third paragraph are not required and may be removed or kept as needed depending on the protocol.

"The study drug or procedures performed during this study may include unknown risks to the woman, embryo, or fetus if a woman is already pregnant or becomes pregnant during the study. Since the effects of the investigational drug on the female and male reproductive systems are still unknown**, you and your partner MUST take effective precautions to avoid becoming pregnant or fathering a child throughout the study until your follow-up visit.**

Women who are pregnant or breastfeeding may not participate in this study. Only women of child bearing potential who are willing to take precautions to avoid becoming pregnant and women who are post-menopausal for at least 1 year, or surgically sterile (had a hysterectomy or bilateral oophorectomy [removal of ovaries] for at least 3 months) may participate.

A subject in this study who is capable of becoming pregnant or fathering a child must agree to take precautions that are at least 99% **effective in preventing pregnancy throughout this study. The following methods have been identified in the medical literature as being** at least 99% **effective in preventing pregnancy: complete abstinence from sexual intercourse**; a sympto-thermal method of natural family planning; use of two of the following methods in combination (a+b or b+c or a+c): (a) condom or occlusive cap (diaphragm or occlusive/vault caps) with spermicide, (b) oral, injectable, or implanted hormonal contraceptives, (c) tubal ligation or vasectomy (surgical sterilization) or intrauterine device or intrauterine system.

The potential subject and study doctor should discuss this matter thoroughly so that the subject is able to make an informed decision and the study doctor and subject must agree that **the subject is taking appropriate precautions."**