Model Language for IRB Consent Clauses
Regarding the Use of Contraception in Clinical Drug Trials

Introduction
Sponsors of clinical drug trials (sponsors) often require participants in their studies to avoid becoming pregnant (or, sometimes, in the case of male participants, to avoid fathering a child) while enrolled in the study and for a designated period of time after participants have withdrawn from the study or the study has ended. For this reason, sponsors usually include language in their informed consent clauses that explicitly mandates the use of contraceptives. Language that explicitly mandates the use of contraceptives by study participants presents a challenge for Institutional Review Boards (IRBs) of Catholic health care facilities. 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. Formal Cooperation (implicit or otherwise) in intrinsically immoral acts by Catholic health care facilities is not permitted under Church teaching.

The following five sample clauses contain language for use in IRB 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 drug trial. Each of these sample clauses retains a mandate for study participants to avoid becoming pregnant while actively participating in a clinical drug 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 participant in consultation with her/his physician; and/or, 3) emphasizing a means that is considered morally appropriate under Catholic Church teaching, namely, abstinence. In this way, these clauses are effective in obtaining morally 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 sample clauses below has been emphasized for illustration purposes only.

Sample Clauses

1. “The study drug or procedures performed during this study may include unknown risks to the 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 appropriate 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 participant 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:

1. Complete abstinence from sexual intercourse
2. 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 participant and physician should discuss this matter thoroughly so that the participant is able to make an informed decision, and the physician and participant must agree that the participant is taking appropriate precautions.”

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 treatment. If you are sexually active, it is important that you not become pregnant because this medication may be harmful to your unborn child. You must discuss your pregnancy plans with your doctor before enrolling in this study; you must also agree to use the type and duration of precautions approved by your doctor for the entire time you receive this study treatment. For women, if you become pregnant or have reason to believe you might be pregnant, please inform your doctor immediately. Once you are no longer receiving this study treatment, discuss with your doctor when it might be safe to become pregnant or become a new father.”

3. “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 treatment. If you are sexually active, it is important that you not become pregnant for this medication may be harmful to your unborn child. You must discuss your pregnancy plans with your 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 doctor immediately. Once you are no longer receiving this study treatment, discuss with your doctor when it might be safe to become pregnant or become a new father.”

4. “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 participants 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 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 doctor.”

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

6. “This study may be harmful to a nursing infant or an unborn child. You should not nurse your baby while on this study. Sufficient medical information is not available to determine whether the study treatment administered to a pregnant woman causes significant risks to the fetus. 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 birth control 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.”

7. “Some research medications or procedures can cause severe birth defects, mental retardation to an unborn baby, or loss of the unborn baby. 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. 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 investigator 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.”