Ascension Wisconsin IRB Guidance

Use of Contraception in Clinical Trials & Model Language for IRB Consent

The central mission of Ascension Wisconsin Institutional Review Board (IRB) is to protect the rights, privacy and safety of individuals who volunteer to participate in research studies. As an essential structure within our Catholic Healthcare Institution, the IRB complies with the *Ethical and Religious Directives for Catholic Health Care Services,* 5th ed. In this way the IRB ensures that human subjects research within Ascension Wisconsin aligns with the Catholic moral tradition in addition to satisfying applicable laws, federal regulations and additional ethical guidelines for human subject research. This same commitment applies to all research contracts or agreements.

Ethical and Religious Directives for Catholic Health Care Services ("ERDs" or "Directives")

The Directives cite a twofold purpose: "first, to reaffirm the ethical standards of behavior in health care that flow from the Church's teaching about the dignity of the human person; second, to provide authoritative guidance on certain moral issues that face Catholic health care today." The IRB relies on the Ascension Wisconsin Center for Excellence in Catholic Health Care Ethics, which includes, applying the Directives and Catholic Tradition to human subject research.

ERDs, Research and Pregnancy Issues

Ascension Wisconsin understands the value and importance of conducting research, ensuring the safety of research participants, and fully disclosing all possible risks to research participants. Sponsors of clinical drug trials 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 participation ended because they do not know the effects of the study procedures on the fetus, who is not part of the study, in most cases. 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 Ascension Wisconsin IRB template Consent form language is based on language developed by Ascension that addresses these concerns.

Informed Consent Template Language

The following five options contain language for use in IRB consent forms that:

- avoids (Implicit) Formal Cooperation on the part of Catholic health care facilities; and,
- should 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:
  - not specifying the particular means that should be used to avoid becoming pregnant;
  - appropriately allowing for the choice of means to be made by the participant in consultation with her/his physician; and/or,
  - 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.

The language below should be used in the consent form for clinical trials (primarily with investigational drug) where there is a possibility of known or unknown harm to the woman or the fetus if the participant or their partner becomes pregnant during study participation (or the timeframe specific to the drug being used).

Instructions:

- Select the option that is most appropriate for the study.
- The language must be used verbatim; the changes should only be made to add study specific information by modifying the red colored text as is applies to the specific study.
- Any other changes must be called out and approved by the IRB Chair or Director prior to submission for IRB review.

OPTION 1:

If you are pregnant or currently breast feeding, you cannot take part in this study. To check that you are not pregnant, you will need to agree to have a pregnancy test done [within the screening period and at baseline before starting the first dose of the drug. You will also have a blood or urine pregnancy test before each dose of study drug is given. If the urine test is positive, you will have a blood test done. If the blood test is positive, you will not receive any more doses of study drug.]

If you are sexually active, it is important that you not become pregnant or father a child because this drug 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 drug/ entire time you are in the study/ and for 3 months after your last dose of study drug].

If you [or your partner] do become pregnant during the study, you should tell the study doctor right away. [If this happens, you/ you or your pregnant partner will be asked to have medical follow-up through the course of your pregnancy up until the point of delivery, and allow the study doctor or staff to follow-up with the obstetrician.] 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.

OPTION 2:

The study drug or procedures performed during this study may include unknown risks to an unborn child 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.

If you are pregnant or currently breast feeding, you cannot be in this in this study. Women are able to be part of the study if they 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, or
- able to have children and agree to take actions to avoid becoming pregnant

To check that you are not pregnant, you will need to agree to have a pregnancy test done [within the screening period and before you start the first dose of the drug. You will also have a blood or urine pregnancy test before each dose of study drug is given. If the urine test is positive, you will have a blood test done. If the blood test is positive, you will not receive any more doses of study drug.]

If you are able to become pregnant [or father a child] you must agree to take precautions that are at least 99% effective in preventing pregnancy while you are in this study [and for 3 months after your last dose of study drug]. 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

You should discuss this matter thoroughly with your physician so that you are able to make an informed decision, and so you and your physician agree that you are taking appropriate precautions.

If you [or your partner] do become pregnant during the study, you should tell the study doctor right away. [If this happens, you/ you or your pregnant partner will be asked to have medical follow-up through the course of your pregnancy up until the point of delivery, and allow the study doctor or staff to follow-up with the obstetrician.] 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.

For additional information to about the ERDs related to human subject research, see:

- IRB policy: Ethical Principles/Regulations
- Ethical and Religious Directives for Catholic Health Care Services