Guidance for Pregnancy Prevention, Reproductive Risk and Use of Contraception Language in Clinical Trials

OVERVIEW
The Ethical and Religious Directives (ERDs) for Catholic Health Care Services is the document that provides moral guidance on various aspects of health care delivery which is drawn from the Roman Catholic Church’s theological and moral teachings. These Directives place firm restrictions on research protocols requiring specific methods of birth control. As St. Joseph Health is a Catholic institution, its ministries are required to adhere to these Directives.

Sponsors of clinical trials often require female participants of child-bearing potential and men who may father a child while enrolled in the study, use one or more forms of birth control to ensure that pregnancy does not occur. Protocols that explicitly mandate the use of contraceptives by study participants present a challenge for St. Joseph Health ministries wishing to participate in these trials.

CRITERIA
Research protocols that satisfy the directives and inform participants of the gravity and nature of pregnancy-associated risks must adhere to the following guidelines:

- Use general terms without specifying the particular means that should be used to avoid becoming pregnant;
- Include abstinence as a means as it is considered morally appropriate under Catholic Church teaching and is the only means with 100% clinical effectiveness; and/or,
- Appropriately allow for the choice of means to be made by the participant in consultation with her/his physician.

These guidelines are effective in ensuring researchers obtain morally appropriate informed consent in accordance with the Catholic Directives.

PROTOCOLS THAT DO NOT ALLOW FOR ABSTINENCE
In cases where a sponsor’s protocol does not allow for abstinence as a stand-alone method of pregnancy prevention, SJH requests a signed memorandum or letter from the sponsor that recognizes the Ethical and Religious directives as part of the sponsor-approved investigational plan with one of the following statements:

- Abstinence is an effective method of avoiding pregnancy, and is an acceptable alternative to protocol language that requires the use of delineated birth control method.
- Two forms of contraception are required only for patients who are sexually active.
- If the patient and their partner are sexually active and capable of becoming pregnant or causing a pregnancy, they must agree to not to conceive a child during their participation in this study. Sexual abstinence is the only certain way a person does not become pregnant.

MODEL LANGUAGE EXAMPLES FOR INFORMED CONSENT

- Whether you are male or female, your participation in this protocol includes treatment which may present certain or unknown risks to a fetus or embryo. You must avoid becoming pregnant or avoid causing a pregnancy while you are participating in this study.
- You will be asked to use specific methods of birth control. You should discuss the alternatives available to you for pregnancy prevention with your study investigator. Further, if you are a female, you must submit to a pregnancy test to ascertain that you are not pregnant before enrolling in the study.

SPECIAL CIRCUMSTANCES
There may be scenarios not addressed in this guidance. When questions about such language arise, please consult with the SJH Center for Clinical Research (CCR). For matters that require additional input, the SJH CCR will consult with the Vice President of Theology and Ethics.