The San Juan de Dios Institutional Review Board (SJDIRB) is dedicated to safeguarding the rights, privacy, and safety of all research participants within our Catholic institution. We uphold the Catholic moral tradition while adhering to all applicable laws and ethical standards in research, including clinical drug trials. This commitment is reflected in all research contracts and informed consent processes.

Site-Specific (SJDIRB) Language for Informed Consent Forms:

To ensure ethical integrity and avoid any implicit formal cooperation in practices that conflict with Catholic teaching, the SJDIRB provides the following guidance for informed consent forms:

1. **Avoidance of Pregnancy:** Language concerning the avoidance of pregnancy should be included in the informed consent form when appropriate, specifically in clinical drug trials where potential risks to a developing fetus are unknown or where a drug may pose risks to reproductive health. This language should:
    a. Clearly state the necessity of avoiding pregnancy during the study and for a specified period afterward.
    b. Emphasize that participants should consult with their personal physician or healthcare provider to determine the best method for avoiding pregnancy.
    c. Acknowledge that abstinence is a morally acceptable option within the Catholic tradition.
2. **Terminology:** Use the term "birth control" instead of "contraception."
3. **Specific Methods:** Do not list specific methods of birth control within the informed consent form.

Example Language:

"If you are a woman of childbearing potential, it is important to avoid pregnancy during this clinical trial and for [specified timeframe] after the study ends. Please discuss appropriate methods for avoiding pregnancy with your personal physician or healthcare provider. Abstinence is also a morally acceptable option."

> ***Para sa mga Babae:*** *"Kung ikaw ay isang babaeng may kakayahang magbuntis, mahalagang iwasan ang pagbubuntis habang isinasagawa ang clinical trial na ito at sa loob ng [tinukoy na tagal ng panahon] pagkatapos matapos ang pag-aaral. Mangyaring talakayin ang mga angkop na paraan upang maiwasan ang pagbubuntis sa iyong personal na doktor o tagapagbigay ng pangangalagang pangkalusugan. Ang pag-iwas sa pakikipagtalik (abstinence) ay isa ring katanggap-tanggap na opsyon sa moral."*

"If you are a man participating in this study, it is important to avoid fathering a child during the trial and for [specified timeframe] after the study ends. Please discuss appropriate methods to avoid conception with your personal physician or healthcare provider. Abstinence is also a morally acceptable option."

> ***Para sa mga Lalaki:*** *"Kung ikaw ay isang lalaking kalahok sa pag-aaral na ito, mahalagang iwasan ang pagkakaroon ng anak habang isinasagawa ang trial at sa*

loob ng [tinukoy na tagal ng panahon] pagkatapos matapos ang pag-aaral. Mangyaring talakayin ang mga angkop na paraan upang maiwasan ang paglilihi sa iyong personal na doktor o tagapagbigay ng pangangalagang pangkalusugan. Ang pag-iwas sa pakikipagtalik (abstinence) ay isa ring katanggap-tanggap na opsyon sa moral."

Guidance on Pregnancy and Paternity:

As a Catholic healthcare institution, the SJDIRB upholds the sanctity of life from conception and is therefore entrusted with the ethical responsibility of safeguarding the well-being of both research participants and any unborn children they may be carrying. By meticulously monitoring pregnancies that occur during clinical trials, the SJDIRB can assess potential risks to both mother and fetus, ensuring the provision of appropriate care and support. This data collection is essential to understand the impact of investigational drugs on fetal development and maternal health, generating invaluable knowledge that informs future research and clinical practice. Furthermore, maintaining open communication and transparent reporting practices fosters accountability and strengthens the ethical foundation of the research conducted under the SJDIRB's purview, reflecting the Catholic commitment to truth and the dignity of all human life.

Principal Investigator Responsibility: Principal investigators have a responsibility to:

1. Inform participants about the potential risks of pregnancy during the trial and the importance of reporting any suspected or confirmed pregnancies immediately.
2. Provide support and guidance to participants who experience a pregnancy during the trial, including referral to appropriate healthcare professionals.
3. Promptly report any pregnancy or paternity concern to the SJDIRB by completing the **Pregnancy Report Form (SJDIRB Form 17.1).**

Principal Investigator Acknowledgement:

I, the undersigned principal investigator, hereby acknowledge that I have read, understood, and agree to abide by the ethical guidelines and reporting requirements outlined in this agreement. I understand that failure to comply with these guidelines may result in further action by the SJDIRB.

Name of Principal Investigator	Signature & Date