SJDIRB's main goal is safeguarding the rights, privacy, and safety of research participants within our Catholic Institution. Operating in line with the Catholic moral tradition and complying with relevant laws and ethical standards, this commitment extends to all research contracts. Specifically, it includes guidance for clinical drug trials, where participants are advised to avoid pregnancy (or fathering a child) during and for a defined period after the study due to uncertainties about the study's impact on the unborn child.

Site-Specific (SJDIRB) Language

The provided options present language suitable for IRB consent forms that:

1. Avoid any implicit formal cooperation from the San Juan de Dios Educational Foundation Inc. Community; and,
2. Should be acceptable to sponsors of clinical drug trials. Each sample clause emphasizes the necessity for study participants to avoid pregnancy during active participation in a clinical drug trial while avoiding formal cooperation on the part of the Catholic institution by:
    a. Not specifying particular methods for preventing pregnancy,
    b. Allowing participants to choose the means in consultation with their physician, and/or
    c. Emphasizing abstinence as a morally legitimate option according to Catholic Church doctrine.

These provisions successfully ensure that informed consent aligns with the moral principles of a Catholic Institution. The highlighted morally relevant language in the example clauses is included solely for illustrative purposes, emphasizing the commitment to transparent communication and ethical considerations in the consent process. The goal is to underscore the adherence to moral standards while providing a clear representation of the language used for illustrative purposes.

The following wording is intended for use in the consent form for clinical trials, particularly those involving investigational drugs, where there exists a potential for known or unknown harm to both the woman and the unborn child if the participant or their partner becomes pregnant during the study participation period (or the specified timeframe associated with the drug being utilized).

Example Language:

"If you are a person of childbearing ability: you and the study doctor must agree on a method of birth control to use throughout the study."

"If you are a man, you and the study doctor should agree on a method of birth control to use throughout the study."

Please note that, the informed consent form must reference "birth control" and not "contraception," and may not list specific forms of birth control.

Ideal contents of SJDIRB Site-Specific Informed Consent (Mark all that is applicable)

1. **Study Title:**
2. **Investigator:**
3. **SJDIRB Approval Code:**

Section 1: Introduction and Study Overview
- Clear and concise introduction explaining the purpose of the study.
- Overview of the study design, procedures, and duration.

Section 2: Participant Eligibility Criteria
- Detailed criteria outlining who is eligible to participate in the study.
- Inclusion and exclusion criteria clearly defined.

Section 3: Study Procedures
- Comprehensive explanation of all study-related procedures.
- A clear timeline of participant involvement in the study.

Section 4: Risks and Benefits
- Thorough description of potential risks associated with participation.
- Explanation of anticipated benefits for participants and society.

Section 5: Confidentiality and Privacy
- Detailed information on how participant data will be handled.
- Measures to ensure participant confidentiality and privacy.

Section 6: Voluntary Participation and Withdrawal
- Statement emphasizing voluntary participation without coercion.
- Clear instructions on the process of participant withdrawal.

Section 7: Compensation and Costs (If Applicable)
- Explanation of any compensation or reimbursement provided.
- Clarification of any costs or expenses participants may incur.

Section 8: Contacts and Resources
- Contact information for the principal investigator and research team.
- Emergency contact details and resources available to participants.

Section 9: Informed Consent
- Inclusion of a statement emphasizing informed and voluntary consent.
- Space for participant signature and date.

Section 10: Site-Specific Language *(take Note of the considerations listed in this document)*
- Incorporation of any site-specific language required by the IRB.
- Verification that the site-specific language aligns with ethical standards.

Section 11: Ethical Clearance
- Confirmation of IRB approval.
- Date of IRB approval.

Principal Investigator	Signature