FRANCISCAN
MISSIONARIES OF OUR LADY
UNIVERSITY

Informed Consent Checklist

Subject Name: _____

Study Title: _____

Principal Investigator: [Name, Title, Institutional Affiliation]

Co-Investigator(s) (if applicable): [Name, Title, Institutional Affiliation]

Faculty Advisor (required for all student projects): [Name, Title, Institutional Affiliation]

Subject ID Number (if applicable): _____

Date and Time of consent: _____

Please note: The first section of your consent form should highlight **five** key pieces of information:

1. An inviting statement indicating that participation is voluntary, and that participants may withdraw at any time with no penalty or loss of benefits.
2. A brief, simple, non-technical description of the project indicating what participants will experience in the study, and the time commitment.
3. Potential risks or discomforts, including loss of privacy or confidentiality, or that there will be no risks beyond what is experienced in normal, everyday activity.
4. The direct benefits of participation, or state that there are no direct benefits.
5. Add the following line under one of the following conditions only:
    a. If the project involves an intervention that might improve a condition or disease: There may be other ways of treating your condition if you do not want to be in this research study. Check with your health care provider to discuss other options. [Describe alternatives to participating in the research. These could include an intervention or treatment available outside the research context.]
    b. If the research participants are students who are being asked to participate in research as a course requirement: You are not required to participate in this research – you may instead choose a comparable, non-research activity, specified by your instructor, to fulfill your course requirement.

Please make sure that the potential Participant/Legally Authorized Representative (LAR):

- ☐ Is given time to read and consider the IRB-approved Informed Consent and the Study.
- ☐ Is asked privately if he/she had any questions regarding the Informed Consent.
- ☐ Is asked privately if he/she had any questions regarding the study.
- ☐ Has had all questions discussed and answered to Participant's/LAR's satisfaction.
- ☐ Is not pressured to waive any of his/her legal rights.
- ☐ Is not coerced to participate in the study.
- ☐ Has signed and dated in all places indicated, along with the person explaining the study and Informed Consent.
- ☐ Is given a copy of the signed Informed Consent to take home.
- ☐ Is obtained before any study-related activities occurred.

_____ _____

Signature of Person Obtaining Consent Date

_____ _____

Signature of Investigator (or designee) Date