Request for Waiver of Informed Consent or Documentation of Informed Consent [45CFR46.117(c)]

According to the Office of Human Research Protections (OHRP), there are certain conditions under which the requirements for informed consent and/or the documentation of informed consent may be waived in a research study. It is the researcher's responsibility to request a waiver by filling out this form. The IRB at Franciscan Missionaries of Our Lady University is authorized to grant this waiver.

For more information on the OHRP policy on Informed Consent, please go to the following web site:

https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.116

Name of the Project:

Principal Investigator:

Other Researchers:

Waiver of Informed Consent

1. Will the research involve no more than minimal risk to subjects?
   ☐ Yes ☐ No
   Please describe:

2. Will the waiver of informed consent adversely affect the rights and welfare of the subjects?
   ☐ Yes ☐ No
   Please describe:

3. Is it practical to conduct the research without the waiver of informed consent?
   ☐ Yes ☐ No
   Please describe:

4. Whenever appropriate, will the subjects be provided with additional pertinent information after participation?

☐Yes ☐ No

Please describe:

When a waiver of Documentation of Informed Consent is requested: Please select ONE of the following and provide information relative to the specific procedures in the protocol.

☐45 CFR 46.117(c)(1): That the only record linking the subject to the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subjects wishes will govern.

Describe the potential harms/risks:

OR

☐45CFR46117(c)(2): That the research presents no more that minimal risk to subjects and involves no procedures for which a written consent is normally required outside of the research context.

Describe Procedures:

*The test of practicability may be met, for example by:

1) The need for a large number of subjects.
2) A presumed or demonstrated inability to contact individuals for whom contact information may not be accurate.
3) The fact that many subjects may be deceased.
4) The fact that a lack of data from a few subjects may make the number of subjects available for the study too small for make the study reliable and valid.