

Process for Obtaining Informed Consent

Protocol Title and/or Number:

It is the Ethical Review Committee's policy that all sites must provide their process for obtaining informed consent. In the event that a site does not have Standard Operating Procedures for obtaining informed consent, the following consenting procedures may be used.

1. The research study and informed consent form are explained to the potential subject by the principal investigator or his/her designee in a quiet and private environment. This information is provided to the potential subject in the language, which they are fluent.
2. The potential subject is made aware of the course of action involved, the risks of the action, as well as the potential benefits, and the potential subject's responsibilities during the study. In addition, the potential subject is informed of the confidentiality of their medical records, and will be given emergency and Institutional Review Board (IRB) contact information.
3. After thorough explanation by the principal investigator or his/her designee, the potential subject is encouraged to ask any questions they have concerning the study. By the potential subject's request, a copy of the informed consent form may be provided for he/she to take home for review.
4. When the potential subject has decided to participate, any remaining questions must be answered in their spoken language before the informed consent form is signed. Once all questions have been answered to the potential subject's satisfaction, the subject and/or the subject's legally-authorized representative then signs, initials, and dates the informed consent form.
5. A signed and dated copy of the informed consent form is given to the subject, while the original is filed within the subject's chart by either the principal investigator or by his/her designee.
6. Once all signatures are obtained the study procedures may commence.

****NOTE**** When re-consenting a subject with an IRB approved amended informed consent form, the principal investigator or his/her designee will follow the same process. The subject will be shown and educated on the changes that have occurred within the amended study procedures and informed consent form, as well as any information that may affect their willingness to participate.

Documentation of the Consenting Process

International Conference of Harmonization guidelines require the following documentation of the consent process as follows:

1. Subject was given the informed consent form to read.
2. Subject was given the opportunity to ask questions and have them answered in their spoken language.
3. Subject and/or the subject's legally-authorized representative signed, initialed, and dated the informed consent form.
4. A signed, initialed, and dated copy of the informed consent form was given to the subject.
5. The original signed, initialed, and dated informed consent form was filed in the subject's chart.

By signing this form I, the undersigned, hereby state that I agree to use the above informed consent process to consent volunteer subjects into this study.

Principal Investigator Original Signature

_____/_____/_____
Date

Type or Print Name