Informed Consent Process

1. Purpose

1.1 To establish the process for obtaining an informed consent from research subjects.

1.2 If an institutional procedure is in place for the informed consent process at a clinical site, it may be used in addition to or in place of this SOP as long as all of the same required elements are included.

2. Responsibilities

2.1 The informed consent process should be carried out by the principal investigator (PI) and/or any trained staff member delegated by the PI, which may include: sub-investigator, study coordinator, or research nurse.

2.2 Documentation of training on this procedure will be made on the Training Documentation form (CRF TD).

3. Procedure

3.1 A current Informed Consent Form (ICF) must be signed and dated by a potential research subject and/or legally authorized representative and investigator engaged in the informed consent process before initiating any study procedures.

3.2 The research staff person will give the potential research subject a copy of the current IRB approved ICF and review the details including, but not limited to:

3.2.1 Describe the study procedures and purpose of the study.

3.2.2 Explain the risks of the study, the subject's right to decide not to participate, and the subject's right to withdraw from the study anytime without fear of reprisal.

3.2.3 Educate the subject as to any costs associated with their participation and they may be given a schedule of study visits that they are expected to attend.

3.2.4 Explain that the subject's participation may be terminated for a number of reasons (many of which are beyond their control).

3.3 Subjects should decide to participate entirely by their own choosing and free will.

3.4 Members from the research staff will be available to answer questions, including the PI, if required.

3.5 Subjects will be given a private area to read and discuss the informed consent form.

3.6 Provide as much time as needed for the subject to read, understand and ask questions. Subjects should be encouraged to consult with friends, family and their family doctor or other medical providers. Ample time will be provided to the subject to make the decision to participate or not.

3.7 The informed consent process must be documented for each subject and the ICF must be signed by the subject or legally authorized representative and the person obtaining consent. The subject must also initial the ICF wherever required.

3.8 The signed ICF will be placed in the subject`s file and a copy given to the subject for their records.

3.9 A signed ICF will be sent to Sponsor along with the completed eligibility checklist (EC form) and other required documents for registering a new subject as described in the Patient Registration SOP.