4. PROCEDURE

4.1. The principal investigator is responsible for assuring study subject informed consent. If permitted by the sponsor and IRB, the principal investigator may delegate the duty of obtaining informed consent to appropriate clinical site research personnel. The principal investigator is responsible for assuring that any such designated member of the team is knowledgeable about the specific research study and the process of informed consent. This delegation should be documented on the delegation of duty/Site responsibility log.

4.2. The principal investigator is responsible for assuring that the content of the consent form is in compliance with GCP regulations and IRB requirements. The principal investigator may delegate the development and processing of the consent form to appropriate clinical research personnel.

4.3. The principal investigator is responsible for assuring that the written consent form and any other written information to be provided to subjects is revised whenever important new information becomes available that may be relevant to the subject's willingness to participate. The principal investigator may delegate to appropriate clinical research personnel the development and processing of the revised consent form or any other written information to be provided to subjects. Any such revisions should receive IRB approval prior to use.

4.4. Informed consent will be obtained for each research subject prior to altering a subject's care for the purpose of research. The consent must be obtained according to sponsor, IRB and GCP requirements.

4.5. Upon identification of a potential study subject, the principal investigator or designee will be responsible for identifying who is legally authorized to give consent. If the subject is physically or mentally unable to provide consent, then the legally authorized representative may be approached to give consent. Careful attention should be given to reviewing the subject's medical history to alert the researcher to any potential impairment to informed consent.

4.6. If the subject or the subject's legally authorized representative is unable to read, then the IRB-approved consent form must be read in its entirety in the presence of an impartial witness. This should be documented directly onto the consent form and signed by the witness accordingly [ICH GCP 4.8.9]. An impartial witness can be anyone

who is not a member of the research team as listed on the site responsibility log/delegation of duties log.

4.7. If the subject or the subject's legally authorized representative is unable to speak or understand English, then the IRB-approved consent form must be translated verbally in its entirety and so documented in the subject's record and/or directly onto the consent form. The IRB shall determine whether or not the written consent form itself needs to be translated into any other language. Translators or sign language interpreters should be contacted for ongoing communication throughout the research study.

4.8. The principal investigator or designee will fully inform the subject or the subject's legally authorized representative of all pertinent aspects of the trial including the written information as approved by the IRB. The process includes:

4.8.1. Giving the subject adequate information concerning the clinical investigation in language that is as non-technical as possible
4.8.2. Providing ample time and opportunity for the subject or the subject's legally authorized representative to inquire about the details of the clinical trial and to decide whether or not to participate in the trial as well as to consider other available options, if any
4.8.3. Responding to subject's questions--all questions about the trial should be answered to the satisfaction of the subject or the subject's legally authorized representative
4.8.4. Ensuring that the subject has comprehended this information
4.8.5. Ensuring that the subject is under no undue influence or coercion. All monetary payments to patients shall be explained in writing in the informed consent document.
4.8.6. Obtaining the subject's voluntary consent

4.9. Informed consent will be documented by using the current written consent form as approved by the IRB. The written consent should be signed and personally dated by the subject or subject's legally authorized representative, and by the person who conducted the informed consent discussion [ICH GCP 4.8.8]. Other signatures must be provided as required by the sponsor and/or IRB if specified on the IRB-approved consent form. The informed consent process should be documented in each subjects chart.

4.10. The investigator or designee will file the original signed consent form with the subject's case report forms. A copy of the consent form will be provided to the person signing the form.

4.11. Prisoners may only be consented and enrolled in clinical trials if specific written approval is obtained from the IRB.

4.12. Children must give assent prior to enrollment into a study if so required by the IRB. In such cases, the written consent form shall provide appropriate information and signature line if required by the IRB. Assent from a child does not constitute legal consent. The subject's guardian or legally authorized representative must give consent.

4.13. The investigator or designee will document in the subject's case history that informed consent was obtained prior to participation in the investigation [21 CFR 312.62].

4.14. The investigator and all site personnel are responsible for continuing the informed consent process throughout the subject's participation in the study. The subject or the subject's legally authorized representative should be informed in a timely manner if new information becomes available that may be relevant to the subject's willingness to continue participation in the trial. The communication of this information should be documented [ICH GCP 4.8.2].

4.15. If the written consent form is revised during the course of a subject's participation in the trial, then the subject shall be re-consented by the principal investigator or designee with the revised IRB-approved consent form. The investigator or designee will file the newly obtained original signed consent form with the subject's case report forms. A copy of the consent form will be provided to the person signing the form.

4.16. If at any time it is noted that the subject was consented using an Incorrect ICF version, a note to file should be placed in the subjects file along with the original ,incorrect version stating such facts. The subject should be re-consented by the principal investigator or designee using the correct ICF version at the next regularly scheduled visit (or sooner if subject willing to make unscheduled visit) and the process should be documented. The investigator or designee will file the newly obtained original signed consent form with the subject's case report forms. A copy of the consent form will be provided to the person signing the form.

Do Not Write Between Bold Lines

Spectrum Medical, Inc.
Obtaining Informed Consent
SOP - 200.2.0

_x_ Original __ Amendment
__ Revision __ Addendum

Date Effective: 02MAY2016

Approved: April D. Marshall Date: 02MAY2016
Research Director RN, CCRC