PURPOSE: This standard operating procedure (SOP) describes the steps taken by the Clinical Research Center (CRC) personnel in addition to the process of informed consent outlined by the UNMC Institutional Review Board (IRB).

SCOPE: This SOP applies to all study personnel involved in any part of the consent process and/or ensuring documentation of the process is complete and accurate.

PERSONNEL RESPONSIBLE: Principal Investigator—and when delegated by the principal investigator—Sub-investigators, Study Coordinator and/or other pertinent staff.

DEFINITIONS:
- **Informed consent** - A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.
- **Institutional Review Board (IRB)** - An independent group made up of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by reviewing and approving the clinical protocol, informed consent forms, and the methods and materials used in the trial.

PROCEDURES:

Consent Process

All CRC personnel will follow the approved policies and procedures for the consent process as outlined by the UNMC IRB. See [IRB Policy and procedures 5.1, 5.4, and 5.6](#).

Documentation of Informed Consent in the Research and Medical Records

The Clinical Research Center (CRC) will document the process of consent in the electronic medical record within the Patient Research Enrollment section of patient’s electronic chart.

A copy of the signed and dated informed consent form will be provided to the subject/the subject’s legal representative. The original signed and dated informed consent will be scanned to NM health information management (HIM) to be uploaded to the electronic medical record. The original signed and dated informed consent will be kept in the subject’s study binder.
• A description of the process of consent, including date, time and location where consent was obtained (provides verification that the consent was obtained prior to active participation in the study.)
• Identification of the individuals present during the time of consent.
• A brief summary of questions the subject asked and if these questions were adequately addressed.
• Other relevant information, including: determination of subject competency for informed consent and, where applicable, identification of individuals providing proxy consent.
• An indication that the subject received a copy of the signed consent form prior to participation in the research study.
• See below for the smart phrase to be utilized:

One Chart Medical Record smart phrase CRCCONSENTPROCESSDOCUMENTATION:

IRB: ***
Short Title: ***
Subject ID: ***
Participation in the above research study was discussed with ***. Subject was accompanied by ***.
Details of the study were explained, including but not limited to: study purpose, procedures, treatments, risks/benefits, alternatives, confidentiality and subject rights.
*** had the following questions: ***
All questions were addressed to satisfaction.
*** verbalized understanding and agreement to be a voluntary participant in this trial.
Informed Consent version *** and approval date ***.
Informed Consent signed by
  Subject or LAR: ***
  Investigator: ***
  Date: ***
  Time: ***
  Location: ***
Research staff provided copies of the following:
- Signed copy of informed consent
- “Rights of Research Subjects”
- Emergency contact information

Research staff spent *** minutes face to face for consent. Study procedures initiated after signed informed consent obtained. A copy of the Informed Consent was scanned to HIM for upload into subject’s EMR.

All procedures in compliance with Good Clinical Practice.

RESOURCES:
21 CRF 50.25
21CRF 50.27
UNMC IRB policy # 5.1 Obtaining Informed Consent from Research Subjects, 5FEB2016
UNMC IRB policy #5.4 Use of a Telephone Consent Process in Clinical and Non-Clinical Research, 12JAN2016
UNMC IRB policy #5.6 Use of the Short Form Consent Document, 5FEB2016

Staff Accountability:

Developed By: Director of Clinical Research Operations, Clinical Research Center
Associate Vice Chancellor for Clinical Research

Reviewed By: Director of Clinical Research Operations, Clinical Research Center
Lead Research Nurse Coordinator, Clinical Research Center
Research Nurse Coordinators, Clinical Research Center

Department Approval

Signed [Signature]
Director of Clinical Research Operations

Signed [Signature]
Medical Director for Clinical Research Center