Center for Clinical and Translational Research Standard Operating Procedure

Section **Clinical Research Center** Date Created: **November 1st, 2010**

Title: **Informed Consent** Date Reviewed/Modified: **October 4, 2021**

SOP Number: **SOP-14** Version Number: **5**

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 and approved by the IRB-- 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.

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.

The process of consent will include the following:

- 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 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 an example of a smart phrase that can be used:

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"
- "What do I need to know before being in a research study?"
- 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 # 5.0 Informed Consent , JUL2021

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
Nurse Manager, Clinical Research Center
Research Nurse Coordinators, Clinical Research Center

Department Approval

Signed LuAnn Larson Date: Oct 5, 2021
Director of Clinical Research Operations

Signed Matt Lunning Date: Oct 5, 2021
Medical Director for Clinical Research Center

SOP-14 Informed Consent

Final Audit Report 2021-10-05

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