Clinical Research Enterprise (CRE)

Standard Operating Procedures

Informed Consent Process

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Revision History:	**Version**	**Effective Date**	**Description**

Purpose

The purpose of this SOP is to explain the process of obtaining a patient's informed consent for study participation.

Scope

This SOP applies to all CRE research and support staff that obtain informed consent.

Procedures

I. Administration of Informed Consent

a. All materials used for obtaining consent and verbal discussions are in a language understood by the participant.

b. Unless the IRB has granted a 24 hour waiver, potential participants are provided with a consent form at least 24 hours prior to signing the consent form. Ample time is allocated to address any questions or concerns.

c. The most recent IRB approved informed consent form will be used to obtain informed consent from potential research subjects.

d. Discuss with the participant, information including but not limited to: possible discomforts, risks and benefits, responsibilities of the participant/family, required procedures which the participant may have to undergo, participant's right including termination from the study, the Institution's responsibilities and liability, alternative treatments available, and any cost to the participant.

e. Each protocol will specify if the study allows the use of a Legally Authorized Representative (LAR). In such instances, LARs can sign on behalf of the patient to participate and space will be provided for the LAR to sign. The LAR and the impartial witness are not to be confused with each other. The impartial witness' signature is required irrespective of whether a LAR is used.

f. Once the informed consent has been explained to the patient, the physician is responsible for ascertaining that the patient understands what has been disclosed.

A great period of time is expended in questions and answers about the study.

g. After the participant signs the ICF, the research staff should ensure that all aspects of the consent process have been implemented correctly.

h. A copy of the signed ICF is given to the participant and the original is kept on file in the participant's research chart.

i. Participants will be re-consented when there are any revisions that may affect their willingness to stay in the study (i.e. procedures will be changed; additional risks/emergent safety information has been identified). The informed consent process will continue even after the participant has completed all research-related activities but is being followed per protocol.

II. Documentation of the Process

a. Research staff who obtain informed consent should document the process on a study specific consent checklist source document. Documentation includes:

1. The name of the person obtaining the consent
2. A statement indicating that all questions were answered and the participant has verbalized understanding of all protocol requirements.
3. A statement indicating that the participant received a copy of the signed ICF.
4. Section to document the version date and/or expiration date.

Training

a. Each staff member receives or has direct access to applicable Standard Operating Procedures (SOPs).

b. Each staff member reviews the applicable SOP annually.