

POLICIES AND PROCEDURES

SECTION: Research and Compliance			NUMBER: CLN-12.00	
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 4/14/2009	REV. B: 8/26/2010	REV. C:
TITLE: Obtaining and Documenting Informed Consent			Page 1 of 5	

1. PURPOSE

To outline activities and procedures for obtaining and documenting informed consent.

2. SCOPE

Applies to all personnel involved in the implementation and coordination of clinical investigations with human Study Participants (SPs).

Personnel responsible: Principal Investigator (PI) and, when delegated by the PI, additional Investigators, Study Coordinators (SCs), and other designated site personnel.

3. RESPONSIBILITIES

The PI is responsible for the informed consent process, which includes:

- ensuring that the Informed Consent Form (ICF) has all of the required and additional elements prescribed by the regulations of the Food and Drug Administration (FDA) and the Creighton University Institutional Review Board (IRB).
- ensuring the IC process is free from any coercive influence.
- ensuring that no study-specific procedures are performed prior to obtaining IC from the SP and/or his/her legally authorized representative.
- the training of study staff in how to explain the research process such that the SP is truly informed.

4. BACKGROUND

Informed consent is a dynamic process that provides the prospective subject or the subject's legally authorized representative with information pertaining to the research study and sufficient opportunity to consider whether or not to participate, thus minimizing the possibility of coercion or undue influence [21 CFR 50.20].

5. PROCEDURE

- 5.1. The PI is responsible for assuring SP informed consent. If permitted by the sponsor and IRB, the PI may delegate the duty of obtaining informed consent to appropriate clinical site research personnel and Investigators. This responsibility cannot be delegated to personnel who are not listed as Investigators on the IRB application and the ICF approved by the IRB. The PI is responsible for ensuring that any such designated member of the team is knowledgeable about the specific research study and the process of informed consent.
- 5.2. The PI is responsible for ensuring that the content of the ICF is in compliance with Good Clinical Practice (GCP) guidelines and IRB requirements. The PI may delegate the development and processing of the ICF to appropriate clinical research personnel.
- 5.3. The PI is responsible for ensuring that the written ICF and any other written information to be provided to subjects is revised whenever important new information

POLICIES AND PROCEDURES

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TITLE: Obtaining and Documenting Informed Consent			Page 2 of 5	

becomes available that may change the risk/benefit ratio or is relevant to the subject's willingness to participate. The PI may delegate to appropriate clinical research personnel the development and processing of the revised ICF or any other written information to be provided to subjects. Any such revisions should receive IRB approval prior to use.

- 5.4. Informed consent will be obtained for each research subject prior to performing any study procedures or altering a subject's care for the purpose of research. The consent must be obtained according to IRB requirements and applicable sponsor and GCP requirements.
- 5.5. Upon identification of a potential study subject, the PI 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.
 - 5.5.1. A legally authorized signator is defined as a person assigned by the courts to represent a person with diminished decision-making capability.
 - 5.5.2. If surrogate consent is required by the study protocol, the IRB must approve the protocol and the ICF for other types of surrogates to consent. See IRB Policy 118, "Informed Consent (Including Permission/Assent)," Section 2.7 (Surrogate Consent).
- 5.6. If the subject or the subject's legally authorized representative is unable to read, then the IRB-approved ICF must be read in its entirety in the presence of an impartial witness. This should be documented directly onto the ICF and signed by the witness accordingly [ICH GCP 4.8.9].
- 5.7. If the subject or the subject's legally authorized representative is unable to speak or understand English, then the IRB-approved ICF text must be translated in its entirety and so documented in the subject's record and/or directly onto the ICF.
 - 5.7.1. Informed consent must be obtained as outlined above by medical translators or sign language interpreters. Medical translators or sign language interpreters should be contacted for ongoing communication throughout the research study. Medical translators are available through some clinics and through Creighton University Medical Center.
- 5.8. The PI 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:

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TITLE: Obtaining and Documenting Informed Consent			Page 3 of 5	

- 5.8.1. Ensuring that the SP is able to distinguish between patient care and research, and understand that he/she is participating in a research study. The SP should be able to understand the study's purpose, potential benefits, and potential risk(s) of participation. He/she should understand that there are no promises that a medical condition will be treated successfully or that the study medication or device will be safe and effective.
 - 5.8.2. Giving the subject adequate information concerning the clinical investigation in language that is as non-technical as possible.
 - 5.8.3. 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.
 - 5.8.4. Answering all questions about the trial to the satisfaction of the subject or the subject's legally authorized representative.
 - 5.8.5. Requesting permission to inform the subject's primary care provider, if applicable, about the subject's participation in the clinical trial. A participant has the right to refuse to disclosure his or her protected health information (PHI). If the subject agrees to this disclosure, the primary care provider will be added to the HIPAA authorization under the recipient section.
 - 5.8.6. Ensuring that the subject has comprehended this information.
 - 5.8.7. Obtaining the subject's voluntary consent.
- 5.9. 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 (the PI or designated investigator) [ICH GCP 4.8.8].
- 5.9.1. The most current ICF is indicated by the date stamp on the form.
- 5.10. The PI or designee will file the original signed consent form with the subject's Case Report Forms (CRFs). A copy of the ICF will be provided to the person signing the form at the time of consent.
- 5.11. Prisoners or SPs incarcerated while participating in a research study may only be consented and enrolled in clinical trials if specific written approval is obtained from the IRB. SPs who are temporarily incarcerated while enrolled in a research study, but the incarceration does not impact study procedures or scheduled visits, are not considered prisoners. See IRB Policy 117, "[Prisoners in Research](#)."
- 5.12. Children between the age of 7 and 18, inclusively, must give assent prior to enrollment. The assent 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 permission. Children age 6 or younger

POLICIES AND PROCEDURES

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TITLE: Obtaining and Documenting Informed Consent			Page 4 of 5	

need not sign an assent form; however, their guardian or legally authorized representative must give full permission. Once a minor SP turns 19 years of age (per Nebraska law), the PI must re-consent the SP using the most recently approved ICF.

- 5.13. The PI or designee will document in the subject's source documents that informed consent was obtained prior to participation in the investigation and prior to any medication changes required for the particular study. [21 CFR 312.62].
- 5.14. The PI 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].
- 5.14.1. SPs must be advised of any changes by the PI or designee by written notice, letter, or documented discussion, unless otherwise required by the study sponsor.
- 5.15. If the written ICF is revised during the course of a subject's participation in the trial and the revisions constitute re-consent, then the subject shall be re-consented by the PI or designee with the revised IRB-approved ICF. The PI or designee will file the newly obtained original signed ICF with the subject's research file. A copy of the ICF will be provided to the person signing the form at the time of consent. Another copy will be filed in the subject's research chart (source documents) and medical record (if applicable).
- 5.15.1. Requirements to communicate changes to SPs are detailed in IRB Policy 118, ["Informed Consent \(Including Permission/Assent\)."](#)

6. TERMS & ABBREVIATIONS

FDA	Food and Drug Administration
GCP	Good Clinical Practice
IB	Investigators Brochure
ICF	Informed Consent Form
IRB	Institutional Review Board
PI	Principal Investigator
SP	Study Participant

7. REFERENCES

- 7.1. Title 21 CFR 50.20 - General Requirements for Informed Consent
- 7.2. Title 21 CFR 50.23 - Exception from General Requirements
- 7.3. Title 21 CFR 50.25 - Elements of Informed Consent

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TITLE: Obtaining and Documenting Informed Consent			Page 5 of 5	

- 7.4. Title 21 CFR 50.27 - Documentation of Informed Consent Title 21 CFR 50.40, 50.42, 50.44, 50.46, 50.48 - Protections Pertaining to Investigators Involving Prisoners as Subjects.
- 7.5. Title 45 CFR 46.116 - General Requirements for Informed Consent (when applicable)
- 7.6. Title 45 CFR 46.117 - Documentation of Informed Consent (when applicable)
- 7.7. Title 45 CFR 46.408 - Requirements for Permission by Parents or Guardians and for Assent by Children (when applicable)
- 7.8. ICH GCP Consolidated Guideline - Part 4.8 Informed Consent of Trial Subjects
- 7.9. Clinical Research Site SOP 200.1.0 - Documenting Delegation of Authority
- 7.10. The Declaration of Helsinki
- 7.11. Creighton University Institutional Review Board Policies and Procedures
- 7.12. Creighton University Institutional Review Board Policy 118, "Informed Consent (Including Permission/Assent"

8. ATTACHMENTS

- 8.1. Study Participant Bill of Rights
- 8.2. Informed Consent Process Progress Note