SECTION: Research and Compliance				NUMBER: CLN-23.00
CHAPTER: Clinical Research Standard Operating Procedures	ISSUED: 7/28/2008	REV. A: 5/4/2009	REV. B: 8/27/2010	REV. C:
TITLE: General Requirements of Informed Consent			Page 1 of 3	

1. PURPOSE

To outline the general requirements for developing the Informed Consent Form (ICF).

2. SCOPE

Applies to all personnel involved in the review and implementation of clinical investigations.

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 all aspects of the conduct of clinical research, including the contents of the ICF. The PI may delegate the authoring of the ICF to the Regulatory Document Specialist (RDS) or SC, but must be fully aware of its contents and the accuracy of the contents.

4. BACKGROUND

Informed consent is an ongoing, dynamic process that provides the prospective Study Participant (SP) or the SP's legally authorized representative with information pertaining to the research study. The prospective SP or the legally authorized representative must be provided sufficient opportunity to consider whether or not to participate as a research volunteer, thus minimizing the possibility of coercion or undue influence. The ICF must be written in language that is readable and understandable to the subject or his/her legally authorized representative

5. PROCEDURE

5.1. The PI is responsible for ensuring that the content of the ICF is in compliance with ICH-Good Clinical Practice (ICH-GCP) regulations and Institutional Review Board (IRB) and sponsor requirements. The PI may delegate the development and processing of the ICF to appropriate clinical site research personnel.

5.2. The PI or designee will ensure that the ICF document contains all the required elements in compliance with the Code of Federal Regulations (CFR) and ICH-GCP regulations.

5.3. The PI or designee will assess the adequacy of the information to be provided to the potential subjects in light of the risks and benefits of the proposed research procedures. The determination of whether or not the information is adequate should be based on the following:

5.3.1. The PI or designee will determine the way the information is provided and the impression being conveyed (i.e., it is clear that a procedure is to be done for research purposes).

5.3.2. The PI or designee will view the information disclosed during the informed consent process from the subject's perspective (i.e., what facts will the subject need to know before deciding whether or not to participate in the research).

5.3.3. The PI or designee will ensure that the information is presented to prospective SPs in a language they can understand. If English is not the subject population's primary language, the oral presentations and written ICFs should be translated into the subjects' native language. Medical terms, complex sentences, and technical terms should be explained or replaced with ordinary language (layman's terms).

5.3.4. The PI or designee will ensure that the ICF or consent process does not involve the use of exculpatory language that waives the SP's legal rights and/or releases or appears to release the Investigator, sponsor, and/or institution from liability or negligence [21 CFR 50.20; 45 CFR 46.116].

5.4. 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 becomes available that may be relevant to the subject's consent. The PI may delegate the development and processing of the revised ICF or any other written information to be provided to subjects to appropriate clinical site research personnel.

5.4.1. Children from age 7-18 must give assent prior to enrollment into a study unless waived by the IRB. In such cases, the written assent form shall provide age-appropriate information and a signature line, as required by the Creighton University IRB. Assent from a child does not constitute legal consent. The child's guardian or legally authorized representative must provide written informed consent in addition to the child's signed assent.

5.4.2. The PI or designee will be responsible for submitting the ICF documents to the IRB for review. Only IRB-approved versions of the ICF can be provided to subjects to review during the informed consent process and used to document the subject's willingness to participate in the clinical trial.

5.4.3. If the written ICF is revised during the course of a subject's participation in the trial, then the subject shall be re-consented by the PI or designee with the revised IRB-approved ICF.

5.4.4. The written ICF must contain elements as described in Section 4 of the Creighton University Institutional Review Board Policy 118, "Informed Consent." See also the IRB Consents and Authorization Templates web site.

6. TERMS & ABBREVIATIONS

CFR Code of Federal Regulations
FDA Food and Drug Administration
GCP Good Clinical Practice
ICH International Conference on Harmonisation
IRB Institutional Review Board
RDS Regulatory Document Specialist
SC Study Coordinator

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

8. ATTACHMENTS

None