1. Policy

The ethical conduct of clinical investigations is based on the voluntary consent of the subject, who has been appropriately informed about a study's risks and benefits, and is designed to protect the rights, safety and wellbeing of human subjects. It is the responsibility of the investigator to ensure compliance with all ethical standards, guidelines and federal and state regulations have been met through the language of the informed consent document, and that informed consent itself has been properly obtained from the subject or the subject's legal representative. Documentation of the informed consent process is required to establish that the subject was accurately and adequately informed and that no study-related procedures were initiated prior to obtaining informed consent.

2. Scope

This SOP describes the steps for fulfilling the regulatory and ethical requirements for developing the informed consent document and for appropriately obtaining the subject's informed consent.

3. Responsibility

Responsibilities for implementing this SOP are indicated as follows:

General administration: See Attachment GA 101-A: List of Key Personnel and Responsibilities at <<Site>>.

Specific studies: See Attachment GA 101-B: Delegation of Authority <<Protocol>>

4. Applicable Regulations and Guidelines

FDA 21 CFR 50.20—General Requirements for Informed Consents

50.25(a)(b)—Elements of informed consent

56.00—Additional Safeguards for Children in Clinical Investigations of FDA-Regulated Products

56.109—IRB review of research

56.111—Criteria for IRB approval of research

312.54—Emergency research under §50.24 of this chapter

312.60—General responsibilities of investigators

312.62—Investigator recordkeeping and record retention

812.100—General responsibilities of investigators

812.110(a)—Awaiting approval

812.140(a) (3) (i)—Documents evidencing informed consent

HHS 45 CFR 46.116—General requirements for informed consent

FDA Internal Compliance Program Guidance Manual, 2008; 7348.811: Clinical Investigators

Information Sheets for IRBs and Investigators, October 2012

Frequently Asked Questions—Informed Consent Process

Informed Consent Document Content

A Guide to Informed Consent—Information Sheet, August 2011, http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm#content

ICH E6: Harmonized Tripartite Guideline for GCP; 4.8—Informed Consent of Trial Subjects

<<Applicable state requirements for age of assent and specific requirements>>

5. SOP Attachments

SM 402-A: Informed Consent Form Template & Checklist

SM 402-B: Informed Consent Process & Checklist

SM 402-C: Informed Consent Form Elements Checklist

6. Process Overview

A. Writing the Consent Document

B. Process for Informing Potential Subjects

C. Additional Processes for Exceptional Research

i) Emergency Research (21 CFR 50.53 and 54)

ii) Children

iii) Cognitively Impaired

iv) Terminally Ill

v) Other

7. Specific Procedures

A. Writing the Consent/Assent Document

#	*Who*	*Task*	*Attachments*	*Related SOPs*
A-1	<<Designee>>	Generally a sponsor or CRO will provide an informed consent/assent template with protocol-specific information. If the IRB, sponsor/CRO or cooperative group has a template, sample consent or requires specific information, refer to the information provided. If staff is developing the consent /assent documents, based on the protocol and investigator's brochure, prepare a draft consent /assent form.	SM 402-B, C	
A-2		If the sponsor or cooperative group provides a consent/assent form, adapt the language to meet <<Site>> requirements. Consult with the sponsor/CRO or cooperative group, if needed, to reconcile local requirements with central requirements. Verify that all required and additional elements of the informed consent form are incorporated by using the Informed Consent Checklist and inserting the appropriate language as required by the IRB. Ensure the document also meets all state and local requirements.		
A-3		If changes are implemented, submit to sponsor for approval prior to submitting to the IRB.		
A-4		If approved by sponsor, submit the draft informed consent form to the IRB for review and approval along with the other IRB-required documents.		
A-5		In consultation with the sponsor/CRO or cooperative		