

Standard Operating Procedures for Clinical Research at USF Health Morsani CRC



INFORMED CONSENT PROCESS

SOP#: 402

Effective Date: 06/01/2016

Version: 1.0

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PURPOSE: This SOP describes the processes followed for informed consent generation, review and documentation, including requests to waive the informed consent process or informed consent documentation based on federal criteria. This SOP ensures that adequate and legal informed consent has been properly obtained and documented for each study subject participating in a clinical study at the CRC.

SCOPE: This SOP applies to the Principal Investigator (PI) and all key research personnel who obtain informed consent for human subjects' research at the CRC.

RESPONSIBILITY: The PI retains overall responsibility for the development, implementation and evaluation of the informed consent process. Key research personnel are responsible for implementation of this SOP in accordance with Federal, State and local IRB requirements.

DEFINITIONS:

Coercion: Pertaining to unacceptable participant recruitment methods which involve duress, undue inducement or indirect pressure. One example of an environment conducive to coercion involves the recruitment of employees by their employer for human participant research.

Health Insurance Portability and Accountability Act of 1996 (HIPAA): This Act requires, among other things, under the Administrative Simplification subtitle, the adoption of standards, including standards for protecting the privacy of individually identifiable health information.

Key Personnel: Individuals who are directly involved in conducting research with human participants, or are directly involved with handling identifiable private information related to those participants in the course of a research project, regardless of the source of research funding. Students who are directly involved in either aspect of research involving human subjects are considered key personnel.

Informed Consent: A process by which a subject voluntarily confirms his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. The Informed Consent Form (ICF) may also be referred to as Informed Consent Document (ICD) or Patient Consent Form (PCF).

Assent: A child's affirmative agreement to participate in research. Assent of children and permission of parents or legal guardians as determined by the IRB is required as per provisions of 45 CFR 46. State and local laws where the research is taking place define the age of a minor.

Legally Authorized Representative (LAR): An individual, or judicial or other body, authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

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Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Voluntary: Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

PROCEDURE:

1. The regulatory or study coordinator will obtain an informed consent template from the USF IRB, USF relied-upon IRB, or the sponsor, if provided.
2. The regulatory or study coordinator will perform the following activities in compliance with Federal, State and local regulations:
 - 2.1 Add the required USF IRB or external IRBs ICF elements into the clean version of informed consent template using lay language relevant to the study.
 - 2.2 Include a specific statement for applicable clinical trials that refers to the trial's description on www.clinicaltrials.gov.
 - 2.3 Ensure that all key research personnel listed on the informed consent form have current approved Human Subjects Research Protection Training.
 - 2.4 Prepare the informed consent form, final protocol, Investigator's Brochure (IB), and all subject materials including a written copy of verbal script or short form presented to subject or LAR summarizing informed consent process, questionnaires, flyers and other recruitment materials for critical review by the PI prior to IRB submission.
 - 2.5 Submit the informed consent form with supporting documents referenced above for IRB review after PI approval is obtained.
 - 2.6 Ensure that the informed consent form is not used prior to IRB approval.
 - 2.7 Ensure that the IRB approved informed consent form is documented with a valid USF IRB watermark and date on it.
 - 2.8 Retain a master copy of the IRB approval letter for the protocol and the approved IRB stamped informed consent form in the study regulatory file.
3. The PI and/or other key personnel obtaining informed consent will :
 - 3.1 Possess current USF IRB-approved Human Subjects Research protection training. The PI must be listed on the informed consent form, however other research staff may be involved and can act on behalf of the PI.
 - 3.2 Ascertain that the most current IRB stamped informed consent form is used prior to discussion with the potential subject.

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PROCEDURE (cont.):

- 3.3 Ensure that the informed consent process is conducted in a quiet, comfortable and private setting.
- 3.4 Properly discuss/inform potential subjects regarding study events, risks/benefits, and other information detailed in elements of the informed consent form to ensure that he/she understands the content and meaning of the research related information.
- 3.5 Ensure that the subject can provide voluntary consent free from coercion or other undue influence.
- 3.6 Provide the potential subject sufficient time to consider all options. Allow him/her ample time to read, review, ask questions and, if applicable, take home the informed consent document to discuss the research with family, friends, and/or others.
- 3.7 Ensure that the potential subject signs and dates the form in ink using legal name prior to initiation of any study related activities.
- 3.8 Ensure that the PI and/or key research personnel obtaining consent signs and dates the form in ink as soon as possible after the study participant has signed.
- 3.9 Note in the source document that the subject signed the consent form.
- 3.10 Provide the study subject with a copy of the signed consent form. File the original signed informed consent form in the study subject's source documents or in a separate binder where it will be available upon IRB request.
- 3.11 Ensure that amended informed consent forms are signed by all study subjects, if applicable per the sponsor or IRB. Copies of these forms are to be treated as the original informed consent and should be filed with the original form.
4. An IRB waiver of informed consent for non-FDA studies may be obtained provided the research satisfies all of the required criteria from 45 CFR 46.116(d):
 - 4.1 The research involves no more than minimal risk to the subjects.
 - 4.2 The waiver or alteration will not adversely affect the rights and welfare of the subjects.
 - 4.3 The research could not practicably be carried out without the waiver or alteration.
 - 4.4 Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
 - 4.5 For more information on determining whether a research study qualifies for a waiver or partial waiver of the authorization requirement, refer to the USF Division of Research Integrity & Compliance Standard Operating Procedure for Evaluating a Research Study for HIPAA Compliance on the USF Division of Research Integrity & Compliance Website.

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PROCEDURE (cont.):

- 4.6 For external IRBs, complete the HIPAA waiver forms available on their respective websites.
5. A short form may be used as a substitute for the long form consent document when non-English and or non-Spanish speaking subjects are expectantly enrolled in the research and translating the consent document into the language spoken by the subject will not be feasible.
6. Since the informed consent process continues throughout the subject's participation in the study, consent should be informally verified on an ongoing basis through verbal communication.
7. Significant new information must be given to the subject and continuing consent documented in some way; for example, new risk information presented to the subject in an addendum to be signed by subjects who agree to continue to participate.

REFERENCES:	21 CFR 50.25 Elements of Informed Consent 21 CFR 56.109 IRB Review of Research 21 CFR 312.60 General Responsibilities of Investigators 45 CFR 46.116 General Requirements for Informed Consent 45 CFR 46.117 Documentation of informed consent 45 CFR 164.512(i) AHRQ Informed Consent and Authorization Toolkit for Minimal Risk Research	
RELATED POLICIES:	USF Office of Research Integrity and Compliance Manual of Operation	
APPENDICES:	Appendix Z: Consent Process work sheet	
REVISION HISTORY: Keep a running history of all revision dates.		
Approval Date	Effective Date	Review/Revision Date
01/01/2015	01/01/2015	06/01/2016