

OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH	CATEGORY	Clinical Research: Study Management
	SUBJECT	Obtaining Informed Consent
	SOP #	2.10
	EFFECTIVE DATE	August 6, 2008
	REVISION DATE	January 8, 2019

OBJECTIVE

Provide the steps in obtaining informed consent from subjects for a clinical research study. These procedures apply to all clinical research activities approved by the Office for Human Subjects Research conducted within the HCMC campus.

APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46 Protection of Human Subjects
21 CFR 50 Protection of Human Subjects
21 CFR 56 Institutional Review Boards
21 CFR 312 Investigational New Drug Application
21 CFR 812 Investigational Device Exemptions
FDA Information Sheet Guide to Informed Consent

REFERENCES TO RELATED SOPs

SOP 2.1
SOP 2.9
SOP 2.11
SOP 3.1
HSRC SOP 4
HSRC Attachment O – Informed Consent Guidelines
HSRC Attachment EEE – Prompt Reporting Guide
HSRC Attachment WWW – Research Subject Information Form – Short Form
HSRC Attachment YYY – Non-English Speaking Consent - Short Form

ATTACHMENTS

Non-English Speaking Subjects – Short Form Guidelines

1) Responsibilities

- a) The Principal Investigator is responsible for obtaining informed consent or delegating it to a designated trained employee. The PI is responsible for assuring that any such designee is knowledgeable about the specific research study and is trained in the process of obtaining informed consent.
- b) Ensure that the most recent Human Subjects Research Committee approved consent form is used.
- c) Researchers and research staff must recruit participants in a fair and equitable manner.
- d) Upon identification of a potential study subject, the appropriate member of the research team will be responsible for identifying who is legally authorized to give consent for the study.

- e) When the long form of consent documentation is used, researchers or research staff must follow the regulatory and HSRC requirements.
- f) When the short form of consent documentation is used, researchers or research staff must follow the regulatory and HSRC requirements.

2) General Informed Consent Requirements:

- a) Present the information to the subject or the subject's legally authorized representative (LAR) in a language that is understood.
 - Use a qualified interpreter; do not use a family member.
 - Have consent forms in the appropriate language if it is anticipated that recruitment will take place among non-English speaking individuals.
- b) Present the consent to the subject or LAR.
 - If feasible, have a physician initially broach the subject, preferably the PI or Sub-Investigator.
 - Present the study in a quiet and comfortable environment.
 - Read through the consent document together.
 - Discuss participation with the subject or LAR.
- c) Subjects must be provided with the information that a "reasonable person" would want to have in order to make an informed decision. Ensure that the following elements are discussed:
 - Concise and focused presentation of the "key information" to assist with the decision of why or why not to participate in research
 - Purpose
 - Procedures, conventional care and experimental
 - Investigator and subject responsibilities
 - Randomization (if applicable)
 - Time needed for study conduct on the part of the subject
 - Additional costs (if applicable)
 - Risks and benefits
 - Alternatives
 - Confidentiality
 - Conflict of interest (if applicable)
 - Compensation for research related injuries
 - Contact information for:
 - (1) The individual designated to answer research related questions.
 - (2) The Human Subject Research Committee, which is designated to answer research subjects', rights inquiries.
 - Voluntary nature of the research
 - Withdrawal procedures as applicable
- d) Give the subject or LAR a copy of the consent form.
 - Allow time for the subject to study the consent form (or to bring the consent form home if study timeline allows) and discuss with family, friends, and/or religious advisors.
 - Meet again at a pre-determined time to discuss participation.

- e) Ensure that informed consent is obtained prior to initiating any study related procedures.
 - f) Assess subject understanding by using open-ended questions and nondirective questions.
 - g) If the subject or LAR is willing, have him/her sign and date the informed consent document.
 - The person conducting the consent process must also sign the informed consent document as the “person obtaining consent”.
 - h) Document in the subject’s source record that consent was obtained for the (NAME) study, what was discussed including risks and benefits, who signed it, date it was signed, and time it was signed.
 - i) Provide a copy (preferably a signed copy) of the informed consent to the subject or LAR.
 - j) A signed copy is sent to Medical Records to be uploaded to the subject’s HCMC Electronic Health Record (EPIC) if applicable. Use the blue HIM interoffice mailing envelopes to assure confidentiality.
 - k) The investigative site retains the original, signed informed consent document.
- 3) Special Circumstances or needs:
- a) Informed consent information is required to be presented “in a language that is understandable to the subject”. Discussions with subjects about their participation in the trial should be conducted with an interpreter who is fluent in both English and the language of the subject. The interpreter may be a member of the study team. Family members should not serve as the interpreter.
 - b) There are currently two accepted procedures for obtaining informed consent from non-English speaking subjects:
 1. Ensure that both the subject (or the legal representative) and an impartial witness (can be the interpreter) sign and date the informed consent document that has been translated into the language of the subject and approved by the IRB.
 2. Investigators cannot always anticipate the interest of a non-English speaking individual and therefore may not be able to obtain an IRB-approved translated consent document in a timely manner. In such cases, the regulations do permit the use of a “short form”. The short form is written in a language understandable to the subject and sets out the basic requirements for informed consent. See attachment “Non-English Speaking Subject – Short Form Guidelines” for further details.
 - c) Subjects that cannot read may have the informed consent document read to them unless prohibited by the protocol.

Non-English Speaking Subjects - Short Form Guidelines

- 1) A short form consent document attests that the elements of informed consent, as required by DHHS (Common Rule) and the FDA, have been presented orally to either the participant or the participant's legally authorized representative.
- 2) Short form consent templates are available on the HHRI website (hhrinstitute.org) in several languages. If the language you need is not available, you must have the English short form translated into the appropriate language and submitted to the IRB for approval prior to use. (HSRC Attachment WWW)
- 3) The short form process may be used three times for a particular language in a study. After the second use of the short form consent process, the site must begin the process to have the full informed consent document translated into that particular language as it can be anticipated you will encounter additional potential participants that understand that language.
- 4) Use of the short form must be reported to the IRB. Please see HSRC Attachment EEE - Prompt Reporting Guidelines and HSRC Attachment YYY – Prompt Reporting Form – Non-English Speaking Consent – Short Form.

Please follow these guidelines when utilizing the "short form" method:

- The role of the interpreter is to interpret between the individual obtaining consent and the prospective subject.
- The short form must be accompanied by a written summary of what is presented orally (the IRB-approved English language consent document may serve as the written summary). The written summary embodies the basic and required additional elements of disclosure. The subject should be given copies of both documents.
- The interpreter signs as a witness that "an oral presentation" of the long form English consent document was conducted. When the person obtaining consent is assisted by an interpreter, the interpreter may serve as the witness.
- Signature Requirements:
 - Short Form (in subject's language):
 - Signature of subject or legally authorized representative (required by OHRP/FDA)
 - Signature of witness (required by OHRP/FDA)
 - English Informed Consent Document:
 - Signature of person obtaining consent (OHRP)
 - Signature of witness/interpreter (required by OHRP/FDA)

- 5) **Responsibilities after enrollment of a non-English speaking subject/participant:**
Once the participant is enrolled, the investigator is expected to adhere to the IRB's standard requirements for non-English speaking participants. This includes reporting the use of the short form within 10 days of consent and providing the IRB with the following in a timely fashion:

- Certified translations of all documents the participant will be required to complete (such as surveys and questionnaires);
- Certified translations of the modified consent document in a language understandable to the non-English speaking participant if the English version of the approved consent document undergoes subsequent modification;
- The plan for ensuring that ongoing communication with the participant is in a language understandable to the participant

6) **How to submit to the IRB:**

- Short form consent templates are available on the HHRI website (hhrinstitute.org) in several languages. Within 10 days of using one of those templates, the use of the short form consent process must be reported to the IRB. The communication must contain a plan on how research personnel are going to implement the requirements previously described above in “Responsibilities after enrollment of a non-English speaking subject/participant”. See also HSRC Attachment EEE – Prompt Reporting Guidelines and HSRC Attachment YYY – Prompt Reporting Form – Non-English Speaking Consent – Short Form.

OR

- If not using a translated short form from the HHRI website, the short form consent process cannot take place prior to IRB review. Communication should be submitted to the IRB containing the translated short form, certificate of translation, and the documents and confirmations previously described above. Once the IRB has given approval, the short form consent process can then be carried out.