Drexel University Human Research Protection Program

Use of Short Form Consenting Practices:
Guidance to Investigators for use of the Short Form Consent and enrollment of non-English speaking subjects

Enrollment of subjects in research protocols should allow for equitable access to participation for all subjects who meet criteria for inclusion in the research. Principal Investigators (PI) whose protocols intend to enroll non-English speaking subjects will provide the IRB with a consent document, and any research related materials to be shared with the subjects, in the language understood by the non-English speaking subjects. Investigators who do not speak the language of non-English speaking subjects should also assure that non-English speaking subjects have access to a process to communicate their questions, needs or concerns through a translator.

If an investigator has not planned in advance for the enrollment of non-English speaking subjects, an investigator can be prepared to offer enrollment to non-English speaking subjects through use of the Short Form Consent process. The Short Form Consent process is described below in a summary format using excerpts from Office for Human Research Protection (OHRP), Food and Drug Administration (FDA) and Drexel University SOPs.

An overview of the consenting process using the short form of consent is outlined below:

1. The consent process will be documented in writing with short form of consent documentation in conjunction with the summary of consent form (the summary is the IRB approved English consent form used for long form of consent documentation).
   a. An example of the short form, in English, is provided at the end of this document as HRP 507 “Template Consent Short Form.” HRP 507 Template may be found on the Human Research Protection website. http://drexel.edu/research/human-research/humanSubjects/irb/applications/

2. At the time of IRB application the PI will provide to the IRB a version of HRP 507 in the language understood by the subjects that the PI may encounter for enrollment.
   a. Versions of the HRP 507 in languages other than English may be found on the Human Research Protection website. Should a PI require an HRP 507 in a language not currently available from Human Research Protection, the PI may translate the HRP 507 Template Consent Short Form. Translated documents provided by the PI will include;
      1. A signed letter of attestation that identifies the translator of the specific translated documents and attests to the translator’s fluency and the accuracy of the translation from English to the target language.

   (The Human Research Protection website will be updated periodically to host Consent Short Forms in various languages.)
   b. Guidance to using the Short Form Consent and execution of this process is found in this document in HRP-317 “Short Form of Consent Documentation”.

3. Obtain the current IRB approved short consent form and summary.
4. Verify that you are using the most current IRB-approved version of the study specific short consent form and summary and that the short consent form is in a language understandable to the subject/representative.
5. Provide copies to the subject/representative. Whenever possible provide the short consent form and summary to the subject/representative in advance of the consent discussion.
6. Obtain the services of an interpreter fluent in both English and the language understood by the subject/representative.
The interpreter may be a member of the research team, family member, or friend of the subject/representative.

7. Obtain the services of an impartial witness who is fluent in both English and the language spoken by the subject/representative to be present during the entire consent discussion to attest that the information in the short consent form, summary, and any other information provided was accurately explained to, and apparently understood by, the subject/representative, and that consent was freely given.

The witness and the interpreter may be the same person.
The witness may not be a person involved in the design, conduct, or reporting of the research study.
The witness may be a family member or friend.

8. Have the interpreter translate the summary (not the short consent form) to the subject/representative.

9. Through the interpreter explain the details in such a way that the subject/representative understands what it would be like to take part in the research study. When necessary provide a different or simpler explanation to make the information understandable.

10. Have the subject/representative read the short consent form or have the interpreter read the short consent form to the subject/representative.

Additional guidance and support is available by contacting Human Research Protection at 215-762-3944.

Drexel University HRP Guidance Documents

The Drexel University HRP Guidance Documents listed below will provide guidance to investigators regarding the enrollment and consenting of non-English speaking subjects for participation in research.

Reference:
HRP 090 “Informed Written Consent Process for Research”
HRP 091 “Written Documentation of Consent”
HRP-317 "Short Form of Consent Documentation", and
HRP 507 “Template Consent Short Form”

HRP-317 “Short Form of Consent Documentation”

An investigator may use the worksheet HRP 317 to guide them in the use of Short Form Consent and the consent process. Each of the noted sections below is required.

1. The written consent document states that the elements of consent have been presented orally to the subject or the subject’s legally authorized representative (LAR).
2. There is a written summary of what is to be said to the subject or the legally authorized representative that embodies the required and appropriate additional elements in Section 7: ELEMENTS OF CONSENT DISCLOSURE in the WORKSHEET: Criteria for Approval and Additional Considerations (HRP-314).
3. The consent document and summary are accurate and complete.
4. An impartial witness is present during the entire consent discussion.
5. For subjects who do not speak English, the witness is conversant in both English and the language of the subject or the subject’s legally authorized representative.
6. The subject or the subject’s legally authorized representative will sign and date the short form consent document and the summary.
7. The witness will sign and date the short form consent document and the summary.
8. The person obtaining consent will sign and date the short form consent document and the summary.
9. When a subject or the subject’s legally authorized representative is unable to read: An impartial witness will be present during the entire consent discussion and the consent document notes that
the witness attests that the information in the consent document and any other information
provided was accurately explained to, and apparently understood by, the subject or the subject's
legally authorized representative, and that consent was freely given.
10. A copy of the signed and dated summary will be given to the person signing the document.
11. A copy of the signed and dated consent document will be given to the person signing the
document.
12. If there is a signature line for a legally authorized representative or parent, the IRB has approved
inclusion of adults unable to consent or children.

HRP 507 “Template Consent Short Form”

The bullet points below outline the contents of a Short Form Consent document. The PI will use
these bullet points to guide their discussion with a subject, or the subject’s LAR, to assure all the
necessary elements of consent have been addressed. The PI should provide this bullet point
summary to the subject, or their LAR, as the investigator reads the consent summary to the
subjects, or LAR, while in the presence of the witness who speaks the language of both the
subject and investigator.

You are being asked to take part in a research study.
Before you agree to take part, someone will explain to you:
• That the study involves research
• The purposes of the research
• How long you will be in the research
• What will happen to you
• What is experimental
• Risks or discomforts to you
• Benefits to you or others
• Other choices you might have
• Who will see your information
• You volunteer to be in a research study
• Whether or not you take part is up to you
• You can choose not to take part in the research study
• You can agree to take part now and later change your mind
• Whatever you decide it will not be held against you
• If you have questions, concerns, or complaints, or think the research has hurt you, you can talk to the
research team at [Insert contact information for the research team]

• This research has been reviewed and approved by an Institutional Review Board. You may talk to them
at (215) 762-3944 or HRPP@drexel.edu for any of the following:
  o Your questions, concerns, or complaints are not being answered by the research team
  o You cannot reach the research team
  o You want to talk to someone besides the research team
  o You have questions about your rights as a research subject
  o You want to get information or provide input about this research

When applicable, someone will explain to you:
• Whether you will get treated or paid if injury occurs
• The possibility of unknown risks
• When you may be taken off the research without your agreement
• Added costs from taking part
• What will happen if you stop taking part
• Steps to safely stop taking part
• When new information will be told to you
• The number of people expected to take part in the research
• That the Food and Drug Administration may inspect the records
• What happens to collected data if you stop taking part
• An explanation of www.ClinicalTrials.gov