More on Consent: Translation, Non-English Speaking Subjects, Types of ICFs (Addendum, Tissue Banking, Genetic Research) & Waiver of Consent

IRB Education Series
2006

Presentation may only be reused or reprinted with written permission from the Tufts-New England Medical Center/Tufts University IRB office.
Enrolling non-English Speaking subjects

*Exclusion* of non-English speaking subjects from research studies is prohibited unless there is a sufficient justification, e.g., lack of validated survey or when another language may confound the research results.

If the research study offers a potential for direct benefit that may only be available within the context of the study, the exclusion of non-English speaking subjects is ethically problematic.

Investigators are obliged to plan for the possible inclusion of non-English speaking subjects.
Enrolling non-English Speaking subjects

Tufts-NEMC Interpreter Services is available to assist during recruitment and with ongoing interactions with the subject.

Ad hoc verbal translation of the ICF must not be substituted for written translation.

The grant or clinical trial agreement should include a provision for the sponsor to cover translation of the study documents and Interpreter Services.
Translation Policy
翻譯政策
Política De la Traducción
 Политика Перевода
Politica Di Traduzione
번역 방침
Vertaal Beleid
Translation Policy

The Common Rule (45 CFR 46.116) states “the information that is given to the subject or representative should be in language understandable to the subject or the representative.”
Translation Policy

When the Investigator plans to regularly enroll non-English speaking subjects, documents should be prepared in the applicable native language.

These documents must be approved by the IRB.
Translation Policy

- The IRB will review & approve English version of the documents (ICF, ads, patient education, contact letters, questionnaires).
- IRB approved and validated English documents may then be translated into the subject’s primary language.
- The translated material should then be back translated into English to confirm the meaning has not changed.
Translation Policy

Submit the following to the IRB:

- Translated documents
- A copy of the approved English version
- The qualifications of the translator

Translated documents may not be used until they are approved and validated by the IRB
Translation Policy

Qualifications of Translators:

- Certification should be submitted when available.
- If no certification is available, a cover letter should be provided outlining the translator’s qualifications and their relationship to the study.
- Qualifications will be evaluated by the IRB on a case by case basis.
Translations

- The person who translates the approved IRB documents into the subject’s primary language may be a member of the research team.
- The person who back translates must not be involved with the study.
Short Form

Investigators cannot always anticipate the interest of a particular non-English speaking individual and provide him/her with a translated ICF translation of the approved English version in a timely manner. Under these circumstances, a translation of the "short form" (which attests that the elements of consent have been presented orally) can be used to document informed consent in writing.
Short Form

When a "short form" is used to document informed consent, the consent process must include oral presentation of the entire English version of the consent form in language understandable to the potential subject.
Short Form

- When this method is used, there shall be a **witness** to the oral presentation.
- Also, the IRB shall approve a **written summary** of what is to be said to the subject or the representative.
- Only the short form itself is to be signed by the subject or the representative.
- However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary.
- A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.
Short Form

- When the person obtaining consent is assisted by a translator, the translator may serve as the witness.
- The IRB must approve all foreign language versions of the short form document. Expedited review of these versions is acceptable if the protocol, the full English language ICF, and the English version of the short form document have already been approved by the convened IRB.
SAMPLE SHORT FORM WRITTEN CONSENT DOCUMENT FOR SUBJECTS WHO DO NOT SPEAK ENGLISH

THIS DOCUMENT MUST BE WRITTEN IN A LANGUAGE UNDERSTANDABLE TO THE SUBJECT

Consent to Participate in Research

You are being asked to participate in a research study.

Before you agree, the investigator must tell you about (i) the purposes, procedures, and duration of the research; (ii) any procedures which are experimental; (iii) any reasonably foreseeable risks, discomforts, and benefits of the research; (iv) any potentially beneficial alternative procedures or treatments; and (v) how confidentiality will be maintained.

Where applicable, the investigator must also tell you about (i) any available compensation or medical treatment if injury occurs; (ii) the possibility of unforeseeable risks; (iii) circumstances when the investigator may halt your participation; (iv) any added costs to you; (v) what happens if you decide to stop participating; (vi) when you will be told about new findings which might affect your willingness to participate; and (vii) how many people will be in the study.

If you agree to participate, you must be given a signed copy of this document and a written summary of the research.

You may contact ______name____ at ___phone number__ any time you have questions about the research.

You may contact ______name____ at ___phone number__ if you have questions about your rights as a research subject or what to do if you are injured.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.

_________________________________ signature of participant _______date
_________________________________ signature of witness _______date
Addendum ICF

*Example: Investigator has added an extra questionnaire to the study*

- The current ICF should be revised for potential subjects who have not yet been enrolled.
- An addendum ICF should be created for subjects who are in the study who must consent to this extra questionnaire.
- An addendum ICF may also be used for subjects who have completed the study and will be invited to complete the extra questionnaire.
Addendum ICF

Since technically, subjects do not “consent” to new risks, the IRB recommends that the Investigator develop an acknowledgement letter for the subject to sign when new risk information is provided to the subject.
Addendum ICF

The IRB recommends the consent process as well as any addendum consent process or new information be documented in the subject’s records.

All documents, addendum ICFs, acknowledgement letters, etc. must be reviewed, approved, and validated by the IRB prior to use.
Tissue Banking ICF

Elements

If genetic testing is being performed as part of the research, please detail:

- Must contain all elements of informed consent
- Specify the types of specimens that will be collected and stored
- Specify whether the collected specimens will be used for future research, and if so, what kind of research (e.g., research specified in the consent form, research conducted by the PI only, research conducted by other investigators, research related to specific diseases or conditions)
- How will the specimens be labeled? (which identifiers?)
- Whether specimens will be coded and the plans for maintaining confidentiality
- Will information from the subject’s medical record be linked to the specimen
- Where the specimens will be stored
Tissue Banking ICF

**Elements (Continued)**

If genetic testing is being performed as part of the research, please detail:

- Specify who will have access to the specimens (only the PI, only this institution, other researchers, other institutions)
- If the results will be shared with the subject and/or their personal physician
- The clinical significance of the results, if any
- What will ultimately happen to the samples (e.g., discarded at the conclusion of the study, used up in the analyses)
- Whether specimens will be sold or used for commercial purposes
- Will the specimen be used to generate a cell line or for genetic testing?
- Include how long the specimens will be stored
- How subjects can withdraw consent
- Will specimens and all links to clinical data be destroyed or removed from the bank upon the subject’s request
Tissue Banking ICF

- The IRB will generally require a separate optional tissue banking consent rather than an opt in / opt out check box in the main study ICF.
- Subjects enrolled as minors must consent to optional tissue banking when they turn 18 years of age.
Genetic Research ICF

**Elements**
If genetic testing is being performed as part of the research, please detail:

- The clinical significance of the results, if any (based on technology, etc., now vs. at a future point in time when new test may be available, etc.)

- What will ultimately happen to the samples (discarded at the conclusion of the study, banked, etc. If banked – information about where samples will be banked, who is responsible, etc.).
Genetic Research ICF

**Elements**  (Continued)

- The potential risks associated with the testing, including risks to employability, insurability, learning upsetting information, risks to family members, etc.
- Any potential benefits (e.g., early diagnosis, no benefit, unknown benefit at this time).
- If the results will be shared with the subject and/or their personal physician.
Genetic Research ICF

**Elements** (Continued)

- How to withdraw samples from analysis (now and in the future).
- Confidentiality measures.
- If applicable, information that the samples might be linked back to the subject if they are used in future research and are coded.
- If samples will be banked, how they might be used in the future and for what purpose(s).
Waiver & Alteration of Informed Consent

Informed consent is also one of the fundamental principles of ethical conduct in the use of human subjects.

There are circumstances when written consent may be waived or requirements of consent may be altered.

Only the IRB can make the determination to waive some (written) or all (written and verbal) consent requirements.
Waiver & Alteration of Informed Consent

The Common Rule allows the IRB to approve a waiver or an alteration of the requirement for informed consent to the research if the proposed protocol meets the following specific criteria found at 45 CFR § 46.116(d).
Waiver of Informed Consent

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
Example of Waiver of Informed Consent

A retrospective survey of 300 medical records. (It would be impracticable to obtain the consent of each patient.)
Waiver of Documentation of Informed Consent

(d) An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
Waiver of Documentation of Informed Consent

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.
Example of Waiver of Documentation of Informed Consent

You are doing interviews and you are concerned that knowledge of subjects’ participation in your study could jeopardize their position and potentially harm them socially and financially. You will prepare a consent form containing all the elements of consent, review it with participants prior to the interview, and subjects will consent verbally.
Helpful Links

- http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116
- http://www.hhs.gov/ohrp/humansubjects/assurance/consentckls.htm (Informed Consent Form Checklist)
- http://www.fda.gov/oc/ohrt/irbs/faqs.html#IRBOrg (FDA FAQ)
IRB Office Contacts

- IRB Main Office # 6-7512
- Jennifer A. Graf - IRB Administrative and Operations Manager
- Julie Morelli Novak – IRB Coordinator
- André Briola & Kelly J. Shipman – Continuing Review Coordinators
- Jennifer C. Coes – Administrative Assistant