

Issuing Department: Human Subjects Protection Program
Policy Number: 2011-013.0
Policy Title: Translation Policy

Purpose

The purpose of this policy is to set forth acceptable means for translating documents and using translators for the consent process when non-English speaking subjects are expected to enroll in a research study.

Definitions

See policy 2011-007.0 for definitions of
Informed Consent Process | Informed Consent Form

Policy

When non-English speaking subjects are expected to enroll in a study, study related documents (e.g. the informed consent form, the HIPAA authorization, survey tools etc.) must be presented in a language understandable to the subject. Documents may be translated by a professional service or back-translated.

The informed consent process must also be conducted in a language understandable to the subject and may therefore require the use of a translator. The translator may be a family member or friend of the subject, an employee of the institution or may be hired by the principal investigator.

The PI is responsible for covering the cost of the translation. The cost of the translation will not be incurred by the subjects.

An investigator may elect to obtain approval of the English language version of documents first and then proceed with the translation of the documents, subsequently obtaining approval for those documents with a request for modification to the study.

Procedure

When documents are translated by a professional translation service, the service must attest to the accuracy of the translation and the principal investigator submits the attestation with the translated documents.

When documents are back-translated into English the following procedures are followed:

- the English version of the document is translated into the foreign language and the investigators provides the following documents to the IRB;
 - the original English version(s)
 - the translated document(s), and
 - the name and credentials of the individual who did the translation
- another individual who has not seen the English version of the document translates the foreign language document back into English and the investigator provides the following documents to the IRB;
 - the back-translated English document

- the name and credentials of the individual who did the translation
- a signed statement from the individual who did the translation that s/he has not seen the original English version of the form;
- the investigators submits the forms noted above concurrently to the IRB for review;
- the IRB reviewer compares both English versions of the documents
- if the IRB reviewer determines the translation is accurate the foreign language document will be approved for use.

Related Policies

2011-008.0 – Informed Consent – Forms
 2011-008.1 – Informed Consent - Process
 2011-008.4 - Informed Consent - Short Form

Basis

45 CFR 46.116
 21 CFR 50.20

Document Attribute

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Reviewed and Approved By:

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