IRB SOP 705
Translation and Interpretation

Purpose

This Standard Operating Procedure (SOP) document describes the policies and procedures affiliated with translation and interpretation in human subject eu5C /H2pJ 0 Tc 0 Tw 18 87nD eu5C 0 T

2.0 The USAIRB expects that translated documents will meet the following requirements. Researchers are required to inform the IRB how they will ensure that these translation requirements will be met. A qualified translator/interpreter should be able to ensure that the tone, meaning, and content of the translated documents remain consistent with the IRB-approved English version

2.1 Linguistically accurate;
2.2 At an appropriate reading level for the subject population; and
2.3 Culturally sensitive for the locale in which they will be used.

3.0 Signed Translation Certification fr4 (io)ensi.007 Tw 1.8 6 347. EMC /Lbl <</MCID 8 >>B13slats
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1.4 IRB review and approval of translated materials
It is unlikely that an IRB member will be proficient in the translated language. Therefore, the IRB's review focuses on whether the translation method is appropriate, based on consideration of the factors described in section 1.2 (above).

1.5 IRB review and approval of interpretation
The IRB evaluates the researcher's selection (or criteria for selection) of an interpreter. The IRB considers the factors described in section 1.2 (above).

1.5.1 Privacy, confidentiality, and accuracy of translation/interpretation should be considered if family members or friends will be asked to interpret.
1.5.2 How will the researcher and interpreter determine whether the subject truly understands the consent information?

1.6 The IRB has the authority to require revisions or additions to the consent process to ensure that non-English speaking subjects are adequately informed and are providing truly voluntary consent.

1.7 Stamping translated materials
The USAIRB will return any approved consent form (whether in English or translation) with the IRB approval stamp.

Regulated Documents
45 CFR 46.116; 21 CFR 50.20

University Related Documents
SOP 702: Consent Documentation

Related Forms:
Translation Certification Form (Located in IRBNet Forms and Templates)

History:
Effective Date:
Revisions: January, 2019

Responsible Office:
Office of Research Compliance and Assurance