HUMAN SUBJECT STUDIES
MATERIALS INTENDED FOR NON-ENGLISH SPEAKING/READING POPULATIONS

Recruitment materials, consent/assent documents, study instruments and other study related materials must be translated into the language understood by the participant group if all or part of the participant population is non-English speaking 45CFR46.116-117; FDA at 21CFR50.20.

The IRB requires that documents be translated in one of two ways:

*Single Back Translation:* The translator providing the back translation into English must be a person different from the person who provided the original translation. Each person providing translation service must complete and sign the Translation Certification Form.

*Double Translation:* Two people translate the same document and an arbitrator reviews both translated documents to determine any differences between the two translated documents. Both translators must complete and sign the Translation Certification Form.

The IRB encourages but does not require the use of a certified translator/interpreter. Written documentation of the qualification(s) of each translator must be submitted if the translator is not certified.

The IRB may, at its discretion, invite a consultant to review the translated materials to determine cultural appropriateness.

Submit the following documents to the IRB:

1. English and non-English versions of the documents
2. Signed translation certification and/or interpretation certification form(s) from all persons providing translation or interpretation services