

Nova Southeastern University – Institutional Review Board Standard Operating Procedures		
SOP #4-2 Version #1	TITLE: Translations for Studies conducted in a Language other than English	
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OBJECTIVE

To describe policies and procedures for the translation of study documents into a language other than English.

GENERAL DESCRIPTION

Regulations require that all study documents be understandable to participants. When a study enrolls a particular participant population that does not speak or read English, recruitment or other study materials and informed consent documents must be translated into the language understood by those participants. Nova Southeastern University (NSU) policy requires that all documents to be translated or interpreted from English to another language must receive Institutional Review Board (IRB) review and approval prior to translation. Depending on the level of IRB review, investigators will be required to submit either the Translation Verification Form or documentation of a certified translation.

RESPONSIBILITY

Execution of SOP: Principal Investigator (PI)/Research Personnel, IRB Office Staff, IRB Members, IRB Chairs

PROCEDURES

A. Investigators Responsibilities

1. Investigators must indicate in their protocol submission that they will be conducting a portion or all of their study in a language other than English.
2. English versions of all documents that will need to be translated must be attached in the appropriate sections within the protocol submission. **Do not** attached translated versions of documents. Documents should not be translated into the target language until after the investigator has received official IRB approval of the English versions of study documents.
3. After receiving final approval of their protocol submission, investigators must submit translated versions of approved English documents for review by the IRB via an amendment.

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4. For exempt or expedited level of review, investigators must submit a completed Translation Verification Form with their amendment. The Translation Verification Form can be found on the IRB website. This form is completed and signed by the person(s) translating the documents attesting to the accuracy of their translation. All documents that are translated must be listed along with the target language.

5. For full level of review, investigators must submit a certified translation to the IRB for review with their amendment form. A certified translator is a professional translator who has passed an exam and received certification from an organization like the American Translators Association.

6. Research activities involving non-English speaking participants may not begin until an amendment has been submitted and approved by the IRB.

7. The IRB Office will send investigator an official approval memo and stamped copies of translation documents.

8. The consent process in languages other than English must be conducted in accordance with the policies and procedures outlined in the Informed Consent SOP.

REFERENCES

None