Translation of Study Documents

NC State University IRB Guidance and Form

This guidance conveys the NC State University IRB's expectations and requirements for translation of participant-facing research study documents such as recruitment, consent, and data collection tools, as well as study related documents. At the end of this guidance is a translation verification form that must be completed and submitted with the IRB application along with the translations and other supporting documentation.

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Definition of Terms

- **Certified Translator**: a professional translator who has successfully completed a certification program or exam providing them with certified translator credentials
- **Interpreter**: person who accompanies researchers, in real time, to convey verbal information to another person in their native language
- **Medical Interpreter**: an interpreter who is familiar with medical terminology
- **Non-English speaking**: unable to comprehend English language
- **Translator**: person who converts written materials from English to another language

When Translations Are Required

- Translations of study documents are required for expedited and convened full board studies.
- Translations of study documents are not required for studies that are determined to be exempt.
- The IRB may choose to require a certified translation, to have an independent back translation, or to have a review of the translated documents by an IRB member or other person who is fluent in that language.

Expectations for Translations

- Electronic translation applications (such as Google Translate) are not allowed for any document translations.
- Translated documents provided to subjects must be approved by the IRB prior to use.

- The translated versions must mirror the materials (e.g., consent, recruitment, data collection measures) that are in English.
- Translated documents should not have a reading comprehension level greater than 6th grade (i.e., understandable to 11–12-year-old pre-teens).
- Study-related information given to a participant or a participant's legally authorized representative must be in a language understandable to them or their representative.
- Language should be culturally sensitive to the population(s) to whom the documents are being presented.
- For studies ineligible for exemption, translations must be provided with all other study materials to the context reviewer.
    - Local context review (Word document) is a review by a subject matter expert in the culture of people being studied – including fluency of language proposal –who evaluates the protocol as part of the IRB review process.

Timing of Translations in the IRB Review and Approval Process

- For new studies enrolling only non-English speakers, study approval will not be granted until the translated documents are reviewed and approved by the IRB.
- To ease administrative burden, the research team can choose when to submit the translations with a completed translation verification form.
    - Some provide the translations and form with the initial IRB submission.
    - Others provide the translations and form once IRB pre-review determines that the study materials written in English are ready for final review but before a local context review is conducted.
- The research team can translate the documents after IRB approval is completed and then submit the translated documents and translation verification form as an amendment only if English speakers will also enroll in the study AND no research procedures (including recruitment) will occur with non-English speakers until after the protocol amendment is approved.

What Must Be Translated

All Participant-Facing Materials

- Recruitment materials (if applicable)
- Consent, parental permission, and minor assent materials
    - Verbal scripts
    - Written documents
    - Research information sheets
- Data collection measures, such as:
    - Survey(s)
    - Interview guide and questions
    - Focus group protocol
    - Observation protocol
    - Instructional materials
    - Intervention materials
- Other documents as requested at the discretion of the IRB

Regulatory and Policy Materials

- Site permission documentation (if applicable and written in a language other than English)

- Ethics committee approval documentation (if applicable and written in a language other than English)
- All communications from foreign entities and regulatory bodies (if written in a language other than English)
- Other documents as requested at the discretion of the IRB

What Must Be Provided to the IRB for Review

- All participant-facing materials in English and in translation
- Ethics committee approval documentation in English or with a translation (if applicable)
- All communications from foreign entities and regulatory bodies in English or with a translation (if applicable)
- Completed and signed Translation Verification Form
- Translator's Translation Certification of Study Documents (if applicable)
- Other documents as requested at the discretion of the IRB

Verification of Foreign Language Translation Form

Instructions: The principal investigator is responsible for ensuring that IRB approved participant facing study documents, e.g., recruitment and consent materials, data collection measures, are accurately translated into a language understandable to study participants.

If any study documents will be administered in languages other than English, the principal investigator must submit this form either:

- with the IRB application as part of the initial review process (i.e., the study has never been approved before) OR
- as part of a study amendment if there is a request to add new study documents that are translated

Note: All translated documents must be approved by the NC State IRB before use with participants. This includes recruitment.

Protocol Information:

IRB Study Number:
Study Title:
Principal Investigator:
Submission Type: ☐ Initial Submission ☐ Amendment Submission

Translated Document(s)

Document(s) Name:
Translated Language(s):
Name of Person Preparing Translation(s):
Preparer's Credentials:
Preparer's Role:

- ☐ NC State University PI
- ☐ Local Investigator
- ☐ Certified Translator
- ☐ Other, Specify

General Comments Regarding Translations:

Certification by Principal Investigator and Translator

By signing this form physically or electronically, I certify that I am fulfilling my responsibility as principal investigator by ensuring that IRB approved study documents, e.g., recruitment materials and consent forms, were accurately translated in a language understandable to study participants.

_____
Principal Investigator's Signature Date

By signing this form physically or electronically, I confirm that translations of the documents listed above are accurate and complete.

_____
Translator's Signature Date