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Standard Operating Procedure

SOP 12	SOP 12: Translation for Studies Conducted in a Language Other than English	Effective Date 1/1/2023

PURPOSE

SOP 12 defines the minimal requirements of using translated materials.

DEFINITIONS

SOP 1. Reference to SOP 1: Allowed and Banned Research.

SOP 9. Reference to SOP 9: Obtaining Informed Consent

SOP 10. Reference to SOP 10: Online Research Online Consent and Documenting Consent

POLICY

Studies may require the use of translated written consent forms, short forms, and related materials. Their use ensures that potential participants possess vital information required to provide informed consent. Hence, the IRB has established a policy on using translated materials. This policy may not supersede SOP 1, SOP 9, or SOP 10.

Obtaining IRB approvals for translated materials. Approvals depend on the level of risk associated with the study. Regardless of the level of risk, it is recommended that English versions of documents be approved before translating, minimizing the number of iterations of translations. Primary investigators should explain the utilization of translated materials via an addendum to their IRB application. However, as the IRB often requires researchers to revise project documents, translated documents should not be submitted to the IRB until the IRB indicates that the English version is acceptable.

Translation rules for at most minimal risk studies. For studies involving minimal risk to participants, the translator's qualifications should be provided (e.g., native speaker, academic degrees, certified translator) to the IRB as part of the IRB application and/or addendums, at the request of the IRB. Translated materials must remain consistent with the English version in form, content, and format. Translators must provide a letter indicating they have translated to the best of their ability.

Translation rules for more than minimal risk studies. For studies involving more than minimal risk to participants, the IRB requires the use of certified translators (with a letter of certification from the translator or translation service) or a *back-translation* by a different translator than the one who performed the original translation be provided. The back-translation

(*back into* English) ensures that the non-English version contains the critical elements of the English version. The translated documents (*forward* and *back*), as well as documentation of the qualifications of each translator, must be submitted to the IRB for final approval.

Use of translators during informed consent processes. The IRB requires the use of a *qualified* translator. The definition of *qualified* remains open to interpretation, so a case-by-case determination of whether the qualifications of the translator/verifier are sufficient. However, determinations oft involve determining whether the translator's background is congruent to the study, translated materials, and their role(s) in the informed consent process.

Primary investigators and translators must provide evidence of the translator's abilities and suitability for their proposed role(s) in the informed consent process.

The IRB may review the translated materials to determine sociocultural appropriateness.

RESPONSIBILITIES

IRB Chair and Reviewers are charged with ensuring SOP 12.

IO will monitor compliance and revise the SOP, as needed.

REGULATIONS

§ 46.116

§ 46.117

§ 50.20

CONTACT INFORMATION

Please direct questions or concerns about this policy to:

Contact	Title/Role
	Institutional Official
Brett Gordon	IRB Chair

DISCLAIMER

The University reserves the right to modify or amend sections of this SOP at its sole discretion.