



INCLUDING SPANISH-SPEAKING INDIVIDUALS IN RESEARCH

Definitions

- A. A **certified interpreter** is an individual who has passed a certification exam given by an accredited entity to verify his/her professional interpretation skills in a certain language.
- B. A **certified translator** is an individual who has passed a certification exam given by an accredited entity to verify his/her professional translation skills in a certain language.
- C. **Interpretation** is the spoken exchange of communication between two languages.
- D. A **person who speaks Spanish** is a person for whom a) Spanish is their native or only language spoken, and/or b) Spanish is their preferred language for communication.
- E. A **qualified interpreter** is a person who speaks English and Spanish and facilitates communication either through virtual, in-person or over the phone. NOTE: for the purposes of this guidance document, the interpreter will be a Spanish interpreter.
- F. A **qualified translator** is person who speaks and writes in both languages, English and Spanish, and converts a document into the target language. NOTE: for the purposes of this guidance document, the translator will be a Spanish translator.
- G. **Translation** is the change of written materials from one language into another.

Description

Spanish is the second-most common language spoken in the state of Utah. The principles of justice and equitable selection of participants compels the University of Utah IRB and research community to make adequate provisions for including Utahns who speak Spanish in research. **This policy is effective July 1, 2023.**

For all prospective research with participant interaction conducted by University of Utah researchers within the state of Utah, the University of Utah IRB requires each non-exempt study to have provisions for including people who speak Spanish. Provisions must include the following:

- a) Recruitment methods for people who speak Spanish, including translated recruitment materials and interpretation services if individuals would like to discuss the study.
- b) Consent processes for people who speak Spanish, including translated consent documents and interpretation services during the consent process and discussion.
- c) Methods for ongoing communication with and data collection from participants who speak Spanish, including translated study materials and interpretation services for ongoing communication.

It may be reasonable to modify study procedures for Spanish-speaking participants to facilitate efficient, effective communication and data collection. For example, English-speaking participants may be asked to record side effects they experience in writing, where Spanish-speaking participants may be asked to provide answers orally through an interpreter so that their responses can be recorded by the study team in English.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

Spanish Consent Methods

Studies may utilize either a full Spanish translation of the consent document or the Spanish Short Form consent process, depending on what is most reasonable for the study.

Researchers are encouraged to provide a full consent form translation at study initiation, and it may be required by the IRB as a condition of approval. It would be reasonable to expect a full consent form translation when the study population is likely to include a high number of people who speak Spanish or if the study is targeting Spanish-speaking populations. A full consent form translation would also be necessary if a consent process is self-led by the participants, e.g., an online survey study with e-consent, where there is no direct participant contact.

If the likelihood of enrolling a person who speaks Spanish is considered low at study initiation, the use of a Spanish Short Form is recommended by the IRB to conserve study and translation resources. Limits on continued use of the Spanish Short Form are considered according to the following guidelines:

- a) For studies that are greater than minimal risk, a Spanish Short Form may generally be used up to two (2) times at which point the IRB expects the full consent form to be translated and used for all subsequent Spanish-speaking participants who enroll.
- b) For studies that are minimal risk, a Spanish Short Form may be used to enroll all Spanish-speaking participants, at the discretion of the IRB. Limits may be set by the IRB on a study-specific basis, based on the following factors:
 - i. The complexity of the study procedures.
 - ii. The complexity of the consent process.
 - iii. The length of time participants are expected to be in the study.
 - iv. The number of Spanish-speaking participants expected to enroll or are observed to have been enrolled via ongoing reporting to the IRB.

Refer to the IRB’s [Short Form Instructions for Use](#) for details on how to document informed consent using a Short Form.

Who can Perform Translation and Interpretation?

To ensure that high-quality communication occurs between the study team and Spanish-speaking participants, the following standards must be met for those performing document translation and interpretation.

Who can serve as a qualified translator? This individual must read, speak, and write the native language (in this guidance, Spanish) and English. A translation certification must be submitted. For a sample translation certification letter, see the IRB website. See specific restrictions based on study risk in the following table.

	Exempt	Minimal Risk	Greater than Minimal Risk
Certified Translator	Yes	Yes	Yes
Native-Speaking Study Team Member	Yes	Yes	No
Native-Speaking Student Researcher	Yes	No	No
Fluent Study Team Member	No	No	No

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Who can serve as the qualified interpreter for the consent process and any re-consent processes?

This individual must read and speak the native language (in this guidance, Spanish) and English. See specific restrictions based on study risk in the following table.

	Exempt	Minimal Risk	Greater than Minimal Risk
Certified Interpreter	Yes	Yes	Yes
Native-Speaking Study Team Member	Yes	Yes	Yes
Native-Speaking Student Researcher	Yes	Yes	No
Fluent Study Team Member	Yes	No	No
Family Member of Participant¹	No	No	No

For recruitment conversations and study visits that involve complex discussion of study concepts, study procedures, risks, etc., interpretation must be performed by someone who is qualified to conduct the consent process as outlined above.

For recruitment conversations and study visits that do not require complex delivery of information, interpretation may be performed by a study team member who is proficient in speaking both the native language (in this guidance, Spanish) and English. Examples include study visit scheduling; study reminders; simple study instructions that do not involve substantial risk; and collecting data that would not expect a report of substantial risks experienced by the study participant.

Exceptions to this Requirement

Not all prospective studies will be well-suited to include people who speak Spanish. The investigator may request a study-specific exception to this requirement by providing adequate justification in the IRB application. Reasons for exception may include the following:

- a) The study population does not reasonably include people who speak Spanish. Examples include, but are not limited to:
 - i. University students who are expected to communicate in English as requirement of their admission are the target study population.
 - ii. The study population speaks a language other than English or Spanish.
- b) The study methodology cannot be reasonably modified to accommodate people who speak Spanish without a large expenditure of resources. Examples include:
 - i. The study uses validated surveys and questionnaires that are not available in Spanish.
 - ii. The study requires a large amount of self-reported, written data collection from participants and the options for translating responses back into English are not feasible.

¹ Based on the Interpretation Code of Ethics a family member or friend should not be used as an interpreter. <https://uoflhealth.org/articles/why-medical-interpreting-should-not-be-left-to-family-members/>
<https://minorityhealth.hhs.gov/omh/Content.aspx?ID=9119&lvl=2&lvlid=8>

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Additional Considerations

Language Services for Research

The [Office of Research Participant Advocacy](#) provides certified translation and interpretation services specifically for research. Contact them to discuss services for your study.

Study Locator Recruitment Listings in Spanish

The Office of Research Participant Advocacy provides no-cost Spanish translation of all recruitment listings on the University of Utah Study Locator website (<https://studiesforyou.utah.edu/>). To add a recruitment listing to Study Locator, select this option in the IRB application in the recruitment methods section. The listing will be posted in both English and Spanish automatically upon receipt of IRB approval for the listing text.

Veterans

If the primary study population involves veterans, an exception may be requested since veterans are expected to communicate in English as a requirement of their admission to the United States military.

Exempt Research

Studies that are determined to be exempt need not adhere to this policy but are encouraged to make provisions to include Spanish-speaking individuals.

Points to Address

- New Study Application:**
- 1. Study Information page, question 4a:** Consider the recruitment methods selected for recruitment in English and determine how these methods will apply to Spanish-speaking individuals.
 - a. You may select “Posting on the University of Utah's Study Locator Website” if you would like the study listed for recruitment in English and Spanish. Complete the Study Locator page that will follow.
 - 2. Study Information page, question 4b:** Provide a plan to translate recruitment materials (emails, flyers, brochures, ads, etc.) into Spanish. If an exception to this requirement is being requested, provide justification for the exception.
 - 3. Consent Process page, question 3:** Describe any interpretation services that may be utilized. For conversations that involve complex discussion of study concepts, procedures, risks, etc., clarify an appropriate interpreter for this study design as outlined in the IGS. Discuss methods for ongoing communication with participants who speak Spanish.
 - 4. Consent Process page, question 7:** Click “yes” to the question, “Will a language other than English be used to obtain consent?” and complete the questions that follow:
 - a. **Question 7a:** Indicate which consent form will be used (a translated consent document or a translated short form).

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- b. **Question 7b:** Describe the translation and interpretation services that will be used for the consent documents and process and how the communication will be conducted.
- 5. Documents and Attachments page:**
- a. If using a fully translated document, attach the translated document and a verification of translation.
 - b. If using a translated short form, you do not need to attach the translated short form if you use the IRB approved version. However, you should ensure that the English version of the long consent form has the qualified interpreter signature block.

References & Links

<i>Study Locator FAQ</i>	https://rpa.utah.edu/study-locator-faq.php
<i>Study Locator Website</i>	https://studylocator.utah.edu/
<i>Office of Research Participant Advocacy</i>	https://rpa.utah.edu/
<i>University of Utah IRB Short Form Instructions for Use</i>	https://irb.utah.edu/guidelines/investigator.php
<i>University of Utah IRB Translation Library</i>	https://irb.utah.edu/forms/translations-library.php

Appendix A: Frequently asked questions (FAQs) regarding the University of Utah IRB’s policy of the including Spanish speaking individuals in research

- 1. If my study was approved before July 1, 2023, and does not expire because IRB does not require continuing review, will my study have to adhere to this new policy?** No, but investigators are encouraged to make provision for the inclusion of Spanish-speakers and submit an amendment.
- 2. If my study is currently approved to use a Short Form consent process, do I need to continue to attach the translated versions in ERICA?** No.
- 3. Who can act as an interpreter?** The answer will vary depending upon the type of study and the type of conversations requiring interpretation. Please see the chart above for the details.
- 4. Can I use contracted hospital interpreters?** Yes.

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5. **How much should I budget for the translation of study materials?** The [Office of Research Participant Advocacy](#) provides certified translation and interpretation services specifically for research. Contact them to discuss services for your study.
6. **What if I have not budgeted for translation of study materials?** Contact the [Office of Research Participant Advocacy](#) to discuss.
7. **Do the same requirements and limits placed on use of the short form for people who speak Spanish apply to people who speak other languages?** While the IRB does not require all studies to make provisions to include other-language speakers, the IRB may set study-specific requirements and limits based on the context of the study.

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