

Appropriate Use of Interpretation and Translation Services in HIPAA Authorization Processes (Non-English-Speaking Participants)

The inclusion of non-English speaking research participants necessitates the use of HIPCO's standalone HIPAA Authorization Form in addition to the IRB Short Form. Note that this is a requirement that still applies if the combined HIPAA and Consent form is utilized for English speaking participants involved in the overall study. To meet this requirement, study teams have two available options*:

1. **Translated Documents:** Obtain the signature of the participant (or their authorized legal representative) on the [standalone HIPAA Authorization Form, translated into participants' first language](#), alongside the corresponding [translated Short Form](#).
or
2. **English Documents with Interpreter Assistance:** If participants' first language is not available on the HIPCO website, the English version of the standalone HIPAA Authorization Form can be used in conjunction with a certified and UMN-approved interpreter. In this scenario, obtain the participants' (or their authorized legal representatives') signature on the English standalone HIPAA Authorization Form, alongside the English short form. After the interpreter communicates the information of both forms to participants, they must also sign the HIPAA Authorization Form in the designated signature block for interpreters.

**Either of these approaches are acceptable as long as a UMN-approved interpreter and/or translator is being utilized.*

Additional instructions are as follows:

1. **Certified Translation and Interpretation:** A certified and UMN-approved translation and/or interpretation service must be utilized to facilitate HIPAA Authorization conversations with non-English speaking participants. It is not permitted for a study team member, or an unconfirmed third party, to undertake document translation without going through OIT and HIPCO approval processes.

2. **Reference Investigator Manual:** For information on current UMN-certified resources, please consult the *"What translation or certification services are acceptable or required?"* section in the Investigator Manual.
3. **Requesting Specific Services:** If study teams wish to utilize a particular translation/interpretation service not listed in the Investigator Manual, please initiate the vendor review process by emailing security@umn.edu. They will ensure the vendor is HIPAA compliant. If the vendor is approved, a Business Associate Agreement (BAA) will be required between UMN and the third-party vendor.
4. **Translating Optional Research Items:** To include optional research items in the HIPAA Authorization Form, study teams have two available options*:
 1. Add optional items, in English, to the form that is translated into participants' first language. These items must be interpreted during the consent and signature process.
or
 2. Add optional items, that have already been translated into participants' first language, to the corresponding non-English form being used.

**Either of these approaches are acceptable as long as a UMN-approved interpreter and/or translator is being utilized.*

Why is this guidance important?

At this time, the combined HIPAA/Consent Form (HRP-588) is exclusively available in English, and non-English speaking participants cannot consent to a document they cannot understand. When obtaining signatures from non-English speaking participants on HIPAA Authorization Forms, clear communication is crucial to ensure a compliant process.