

Quick Guide: Research with Non-English Speaking/Reading Populations



Purpose

This guide has been drafted by the Saint Francis Hospital and Medical Center Research Development Office to use as a reference for conducting research with Non-English speaking/reading populations.

Per the IRB Policies & Procedures:

The Consent Process

Written consent documents must be in the subject's native language that is understandable to the subject. When the study subject population includes non-English speaking individuals, the consent interviews are to be conducted in the language understood by the subject, using a translator if necessary, and a translated consent form is prepared. When the study subject population includes illiterate persons who understand English, the form may be read to the subject or subject's legally authorized representative (when applicable) and the subject may "make their mark" on the consent. When this method is used, there shall be a witness to the oral presentation. A Short form may be used for blind or illiterate persons.

Use of a Short Form Written Consent Document for Non-English-Speaking Subjects

When this procedure is used with subjects who do not speak English, the oral presentation and the short form written documents should be in a language understandable to the subject. The IRB-approved English language informed consent document may serve as the summary. It is strongly recommended that the full English consent be translated into the participant's language. The translator/interpreter should be fluent in both English and the language of the subject. There must be a witness during the entire consenting procedures. Adequate time should be afforded to the subject, to make an informed decision regarding participation in the research. At the time of consent, the short form document must be signed and dated by the subject and the witness. The summary must be signed/dated by the person obtaining consent (as authorized under protocol) and the witness. The translator/interpreter may serve as the witness. A copy of the summary shall be given to the subject, in addition to a copy of the short form. If a member of the study staff speaks the subject's language, the staff member can act as the translator/interpreter and person obtaining consent but should not also act as a witness. Expedited review of all foreign language versions are acceptable if the protocol, the full English language informed consent document, and the English version of the short form document have already been approved by the convened IRB. It is the responsibility of the IRB to determine which of the procedures at 46.117(b) is appropriate for documenting informed consent in protocols that it reviews.

Non-English Speaking/Reading Populations

When some or all of the participants of a research protocol are likely to be non-English speaking/reading populations, the recruitment materials, consent documents, and other study documents (i.e. questionnaires) must be translated into the language understood by the targeted group (45CFR46.116-117 and 21CFR50.20). When non-English speaking/reading individuals are to be consented, an interpreter must be present to facilitate oral communication in more than one language. All documents translated from English to another language must receive IRB review and approval before use, to assure that the rights and welfare of research participants are adequately protected and the accuracy of the translation. The IRB does not provide translation or interpretation services. Investigators can contact Center for Health Equity for more information on translation and language services. The IRB recommends that document be translated in one of two ways: (a) Single Back Translation: The translated document is translated back into English. The translator providing the back translation into English must be different from the person who provided the original translation. Each person providing translation service must complete and sign the Translation Certification Form (b) Double Translation: Two individuals independently translate the same document from English into another language. An arbitrator reviews both translated documents to determine any differences between the two translated documents. Changes to documents will be made, if applicable. Both Translators must complete and sign the Translation Certification Form (c) The IRB encourages the

use of a certified translator. Written documentation of qualification of each translator must be submitted if they are not certified. The IRB may invite a consultant to review the translated materials to determine cultural appropriateness

Community Based Research:

Trinity Health Of New England promotes community-based research and inclusion of under-represented populations in research:

In partnership with the ministry's Center for Health Equity, the Trinity Health Of New England IRB and research staff have developed a process to expedite translation of approved research documents. The process leverages ministry language services resources and ensures immediate IRB review of certified translations. Moving forward, research training and education for investigators, study staff, and certified interpreters will be included. The Center for Health Equity also provides access to potential research participants through partnerships with the community and community organizations. On conjunction with organizational priorities around equity, the IRB is assisting the research development office develop a process to track enrollment of underrepresented groups in research. Per recent NIH guidelines, tracking will include all gender categories and older age.

Steps and Procedures

1. Submit Protocol and English version of the study documents to the Trinity Health Of New England IRB

- Using standard application submit study documents to the Trinity Health Of New England IRB via the iRIS/iMedris Electronic IRB system <https://stfrancis.imedris.net>.

2. Once you receive IRB approval of the English version of the study documents

- Request translation of the recruitment materials, consent documents, and other study documents (i.e. questionnaires) into the language understood by the anticipated study population.
- The IRB recommends that document be translated in one of two ways:
 - Single Back Translation: The translated document is translated back into English. The translator providing the back translation into English must be different from the person who provided the original translation. Each person providing translation service must complete and sign the Translation Certification Form
 - Double Translation: Two individuals independently translate the same document from English into another language. An arbitrator reviews both translated documents to determine any differences between the two translated documents. Changes to documents will be made, if applicable. Both Translators must complete and sign the Translation Certification Form

Note: The IRB encourages the use of a certified translator. Written documentation of qualification of each translator must be submitted if they are not certified. The IRB may invite a consultant to review the translated materials to determine cultural appropriateness

3. Submit the translated study documents to the IRB

- Using the amendment form submit the translated study documents to the Trinity Health Of New England IRB via the iRIS/iMedris Electronic IRB system <https://stfrancis.imedris.net>.
- Remember to include the translation certification with the submission

4. Only use IRB approved (stamped) translated study documents

- Study documents provided to participants (including but not limited to recruitment materials, consent documents, and questionnaires) should be stamped with an IRB number and approval date. Consent documents have an expiration date. Never use an expired consent document.

5. Consenting non-English speaking/reading populations

- When non-English speaking/reading individuals are to be consented, an interpreter must be present to facilitate oral communication in the language understood by the subject. The interpreter should be fluent in both English and the language of the subject. There must be a witness during the entire consenting procedures. Adequate time should be afforded to the subject, to make an informed decision regarding participation in the research. At the time of consent, the consent document must be signed and dated by the subject, the study staff member obtaining consent and the witness. The interpreter may serve as the witness. A copy of the consent document shall be given to the subject. If a member of the study staff speaks the subject's language, the staff member can act as the translator/interpreter and person obtaining consent but should not also act as a witness.

6. Use of a short form during the consenting process

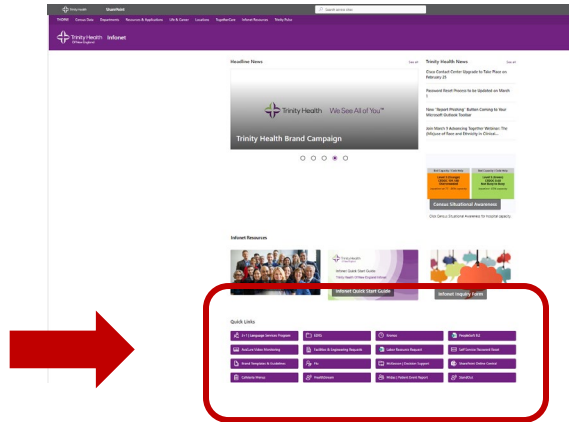
- When this procedure is used with subjects who do not speak English, the oral presentation and the short form written documents should be in a language understandable to the subject. The IRB-approved English language informed consent document may serve as the summary. The translator/interpreter should be fluent in both English and the language of the subject. There must be a witness during the entire consenting procedures. Adequate time should be afforded to the subject, to make an informed decision regarding participation in the research. At the time of consent, the short form document must be signed and dated by the subject and the witness. The summary must be signed/dated by the person obtaining consent (as authorized under protocol) and the witness. The translator/interpreter may serve as the witness. A copy of the summary shall be given to the subject, in addition to a copy of the short form. If a member of the study staff speaks the subject's language, the staff member can act as the translator/interpreter and person obtaining consent but should not also act as a witness.

7. Consenting illiterate persons

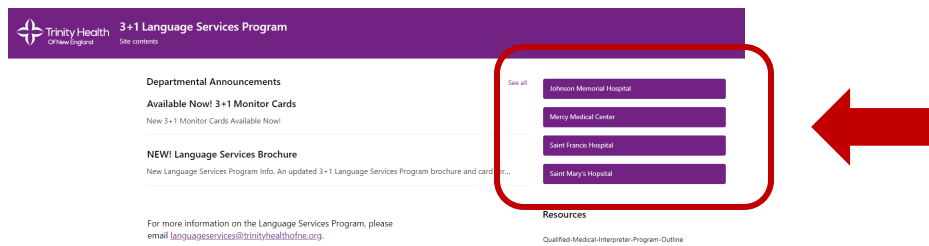
- When the study subject population includes illiterate persons, the consent form may be read to the subject -and the subject may "make their mark" on the consent. When this method is used, there shall be a witness to the oral presentation as well as sign the consent form as a witness.

3+1 LANGUAGE SERVICES PROGRAM – Requesting Interpreter Services

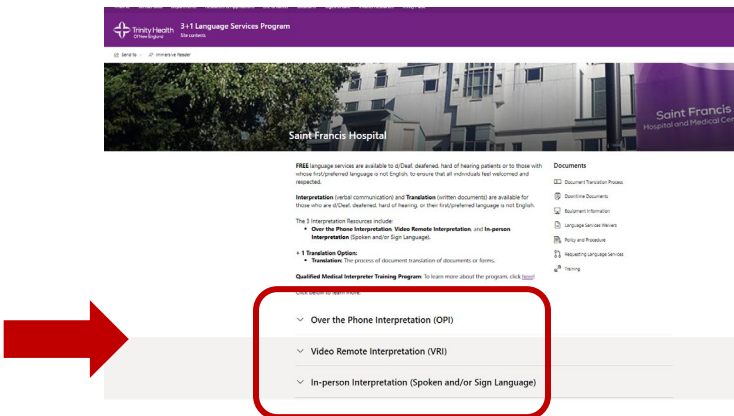
1. From the Trinity Health Of New England Infonet, click on the “3+1 Language Services Program” Quick Link



2. Choose the appropriate Hospital from the list of Hospitals



3. From the 3+1 Language Services Program Page



4. Choose the appropriate interpreter service

- Over the Phone Interpretation (OPI)
- Video Remote Interpretation (VRI)
- In-person Interpretation (Spoken and/or Sign Language)

REQUESTING TRANSLATION SERVICES

1. Click on the link [NEW! Document Translation Process.pdf](#) or see instructions below:



Interpreters and Translators, Inc.

How to request a quote for document translation

1. Go to ITI's portal at <https://login.ititranslates.com>
2. Enter your individual login credentials. If you do not have an individual login, please contact an ITI team member to receive one.
3. You can email us at – translations@ititranslates.com and we will get you login all set up.

Note: HIPAA requires individual logins for each requestor.

4. Click on the "Create a Request" button.

5. Enter the name of your project and any other pertinent information in the Description/Message area.
 - a. This should include your name, email, and requesting department.
 - b. Please include relevant billing information if applicable: such as cost center, PO#, billing address, department supervisor.
 - c. Enter your requested delivery date if you need the document returned by a certain day.

232 Williams Street East, Glastonbury, CT 06033

Phone: 860.647.0686

Toll Free: 1.800.648.0686

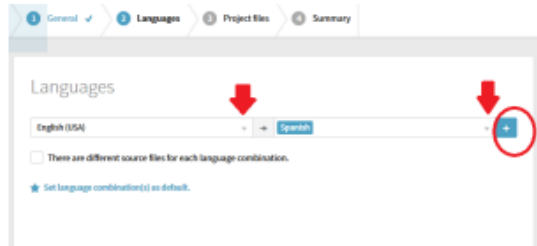
Fax: 860.646.3590

www.ititranslates.com

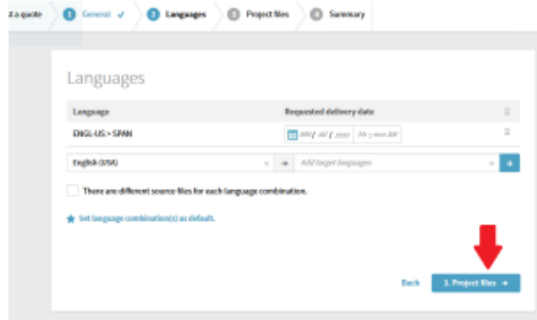


Interpreters and Translators, Inc.

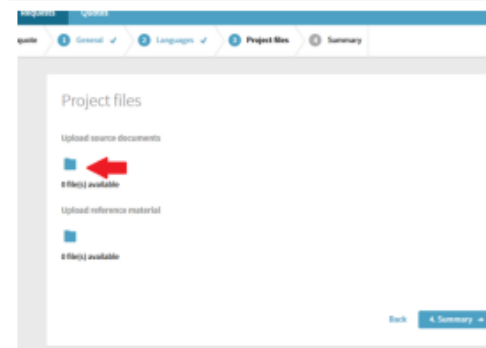
- 6. Click "2. Languages" to move to step 2.
- 7. Add language pairs for your documents. Once you have your language selected, be sure to press the "+" button to add to the project. You can add multiple languages at once.



- 8. Click "3. Project files" to move to step 3.



- 9. Now you can upload your files. Click on the folder icon under "Upload source documents".



- 10. You can drag & drop your file(s) to the field, or you can manually search for the files you need. After placing the files, you need to click the "Upload" button on this window.



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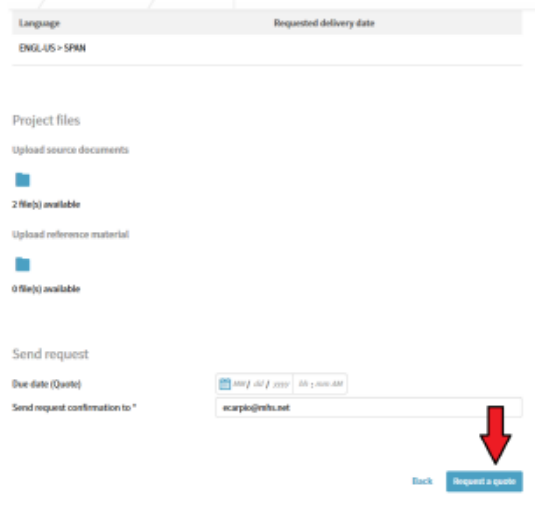
Interpreters and Translators, Inc.

- 11. Your files will now be visible below the folder icon.

- 12. Click on the "4. Summary" button to review and edit your request. This is an important step as you will see a field that says "SEND REQUEST CONFIRMATION TO". Please enter your email address here so ITI knows whom to send the quote to.



- 13. Click "Request a Quote" and logout of the system. After logging out, ITI is sent a notification that you have uploaded your files and will get back to you shortly with a quote.



Note: For any reason if you need to reach the time before a quote is received, please email your Account Manager, or the Translations Department directly at translations@ititranslates.com.

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Email Process

You can also email your documents to translations@ititranslates.com

Below is the information to provide the vendor:



1. Email document that requires translation to translations@ititranslates.com
2. An iTi Project Manager will confirm receipt and will send a quote including price and turnaround time
3. iTi will begin upon approval of quote
4. Certificates of Accuracy are available at no additional cost
5. Final translation will be emailed securely back to requestor
6. Source language – Target language (Ex. English → Spanish)
7. Expected project delivery time

Please note that iTi has a minimum fee of \$100. Most one-page documents will fall under this minimum. We will bundle projects together unless you have approval from the Language Services Department.

If your document/form is an INTER-departmental form, the Language Services Program will incur the cost of the translation. However, if it is an INTRAdepartmental form, iTi will bill your department directly. Payments can be made to them in several ways

If you have any questions, please email iTi's Main Office -
Phone:860.647.0686
Toll-Free:800.648.0686
Fax:860.646.3590
Email: Inquiry@ititranslates.com

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REQUESTING TRANSLATION SERVICES - Continued

2. Departmental responsibility for Translation Services

The translation of informed consents may be covered by the Language Services Department for unfunded research only. When requesting a quote indicate that the consent document is an interdepartmental form and submit the invoice to trinityhealthinvoices@prod.sourcehov.com per the [Invoice Submission Instructions](#)

The Language Services Department will only cover the cost of translating the informed consent, your Department is responsible for covering the cost of any other documents which require translation.

Trinity Health Of New England Institutional Review Board (IRB) Research Translation Study Documents Requirements for Non-English Speakers Checklist

1. English version of study-related documents must be submitted and approved by the IRB before submitting translated documents
2. Once the IRB approves English versions of study-related documents, submit the documents to the certified translator
3. Submit an amendment to the IRB and include:
 - A clean and tracked version of translated documents
 - Certification of translations
4. Investigators are obligated to have a plan on how they will manage non-English speaking participants during the study; this includes that the interpreter is a certificated translator

Please contact the IRB Office at (860) 714-4068 or ecordero@trinityhealthofne.org for additional guidance.