Enrollment of non-English speaking participants in NIH research

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Session Objectives

Understand the ethical basis for presenting consent documents in the participant's preferred language

Understand the NIH IRP requirements for translating informed consents

Be able to identify resources at the NIH to facilitate enrollment and participation of non-English speaking persons in research

Become familiar with the CC Language Interpreters Program for those with Limited Language Proficiency (LEP) and how it is accessed

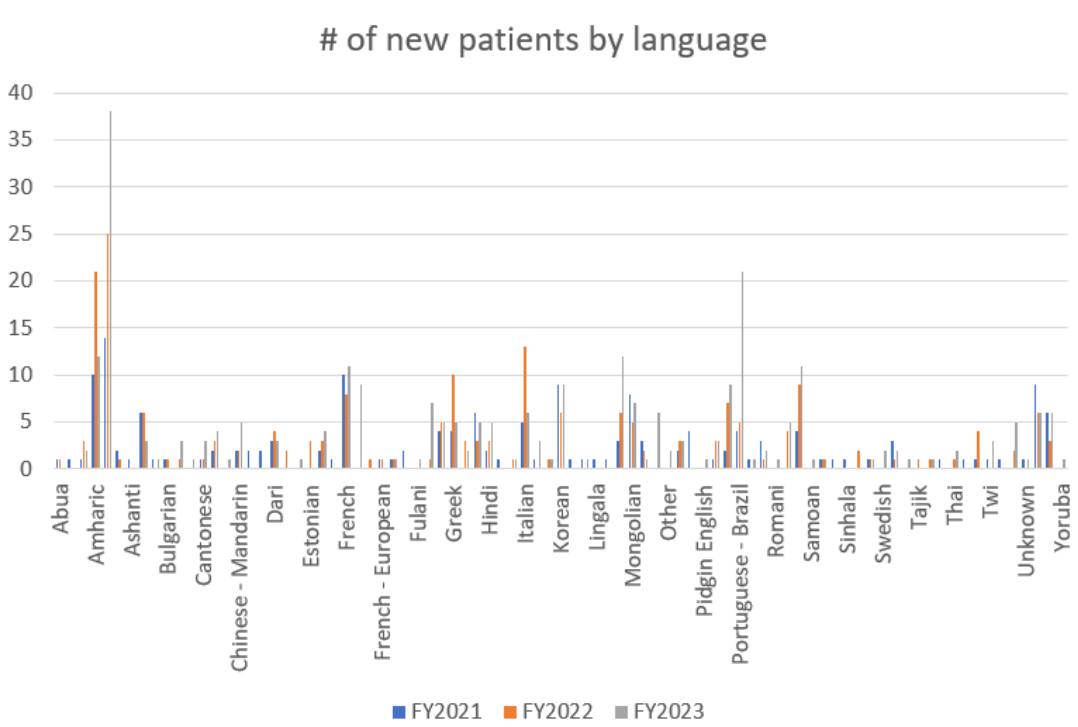
Recognize best practices for communicating with those with LEP

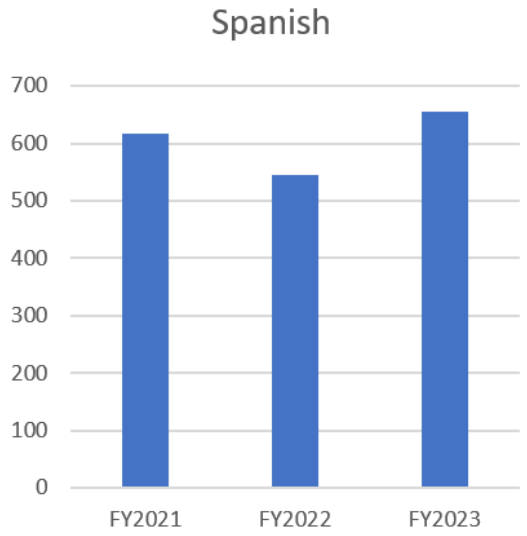
How many non-English speaking persons do we see?

	FY2021			FY2022			FY2023*			Total		
Preferred Language for Healthcare	# of New Patients	%	# of Unique Protocols	# of New Patients	%	# of Unique Protocols	# of New Patients	%	# of Unique Protocols	# of New Patients	%	# of Unique Protocols
Non-English	784	9.6%	158	746	8.8%	157	926	10.6%	185	2456	9.7%	287
English	7349	90.4%		7691	91.2%		7840	89.4%		22880	90.3%	
Total	8133			8437			8766			25336		

287 unique protocols over 3 years
87 languages
74% Spanish

Languages of participants





Ethical considerations in clinical research

Fiduciary relationship with patient-participant

Special vulnerability of sick people

Belmont principles

- Respect for persons
- Beneficence
- Justice

Ethical requirements for valid informed consent

Information

Comprehension

Voluntariness

Regulatory requirements for valid informed consent

Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative (45CFR46.116(a)(1), 21CFR50.20)

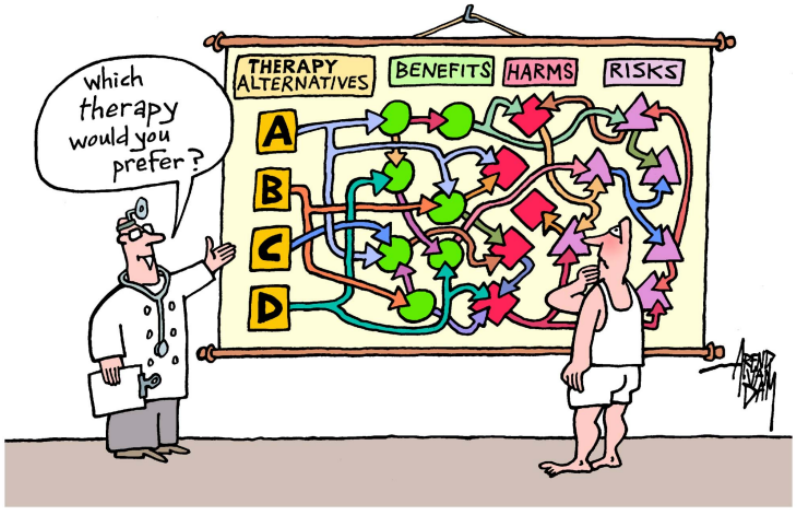
The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative. (45CFR46.116(a)(3), 21CFR50.20)

Documentation of written informed consent is generally required and may be either by the “long form” or “short form”.

How do participants use the informed consent document

Decision making aid at time of enrollment decision.

Source of reference during trial participation



informed consent

INSTITUTE/CENTER:

PRINCIPAL INVESTIGATOR:

STUDY NUMBER:

STUDY TITLE:

You are being asked to participate in a research study. Before you agree, you must first be provided with a summary of the research study. This summary must contain the key information to help you understand the reasons why you might or might not want to join the study.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

After presenting the summary, the study team will provide you with additional details about the study which must include:

1) the purposes, procedures, and duration of the research;
2) any procedures which are experimental;
3) any reasonably foreseeable risks, discomforts, and benefits of the research;
4) any potentially beneficial alternative procedures or treatments; and
5) how confidentiality will be maintained.

Where applicable, the study team must also tell you about:

1) any available compensation or medical treatment if injury occurs;
2) the possibility of unforeseeable risks;
3) circumstances when the investigator may halt your participation;
4) any added costs to you;
5) what happens if you decide to stop participating;
6) when you will be told about new findings which may affect your willingness to participate;
7) how many people will be in the study;
8) use of your biologic specimens for commercial profit;
9) whether you will be told about your research results;
10) whether the research might include whole genome sequencing; and
11) any future research use of your information or biologic specimens.
12) For clinical trials: A description of this clinical trial will be available on https://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

    Further, a description of this clinical trial may be available on https://www.clinicaltrials.gov consistent with NIH policy.

Short form consent

Does the short form process meet the needs of our patient participants, or the regulatory requirements for valid informed consent?

FDA 2023 guidance on Informed Consent

2023 FDA finalized guidance on informed consent. Includes 4 pages detailing expectations when enrolling non-English speaking persons.

Step 3 – Take Additional Actions Following Subject Enrollment

After the subject has been enrolled in the research, the investigator takes the following additional actions:

(1) If a subject was enrolled in the researc[h] [must] [f]orm to serve as the written summary, and if the investigator did n[ot] [p]erson (or designee) prior to enrollment of the subject who does not [speak] [i]nvestigator should promptly notify the IRB chairperson (or designe[e] [e]nrolled.

(2) The investigator must obtain a translated copy of the IRB-approved English version of the long form that served as the written summary, which should be done promptly. The investigator promptly submits it to the IRB for review and approval. Once the translated long form/written summary is approved by the IRB, the investigator must provide it to the subject or LAR and should do so as soon as possible. FDA considers this step essential to the requirement that informed consent be documented by the use of a written consent document and that the subject be provided a copy (21 CFR 50.27). Many of the clinical investigations regulated by FDA involve ongoing interventions and may involve long-term follow-up. For this reason, translation of the long form is critically important as a means of providing subjects or their LAR an ongoing source of information understandable to them.

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must

OHSRP current policy

h. Enrollment of non-English Speaking Subjects

I. When non-English speaking subjects are anticipated to enroll in the research:

i. The PI must submit a certified translated long form consent document in the language of the anticipated subjects to the IRB for approval.

ii. IRB approval of the certified translation must be obtained before the translated long form consent document is used.

II. When the NIH IRB is the reviewing IRB, report short-form consent use to the IRB at time of continuing review.

III. When a non-English speaking subject seeks to enroll unexpectedly and there is no IRB-approved long form consent document in the language of the subject:

i. The investigator must use ~~an IRB-approved short form consent document~~ in the language of the subject, if one is available, or

ii. If there is no IRB-approved short form consent document in the language of the subject, the NIH PI must submit to the IRB (before use), a certified translation of the short form consent in the language of the subject that meets the requirements of 45 CFR 46.116 and 46.117(b)(2), for approval by the IRB.

iii. At the discretion of the IRB, the PI may be directed to translate the English informed consent document into a foreign language.

New policy requirements

Effective March 1, 2024

For research determined by the IRB to be minimal risk

- If enrollment of non-English speaking individuals is anticipated, the consent must be translated into the anticipated languages.
- If a non-English speaking person is encountered that is eligible for enrollment and there is no translated consent document, the short form process may be used.
- The IRB must be notified by submission of an RNI for each use of the short form consent. In addition, if continuing review is required, the cumulative use of the short form must be reported at this time.
- If the short form process is used 3 times for a given language, the short form process may no longer be used for that language, and the consent must be translated for any future participants.

New policy requirements

Effective March 1, 2024

For research determined by the IRB to be greater than minimal risk

- If enrollment of non-English speaking individuals is anticipated, the consent must be translated into the languages of the persons the study team anticipates enrolling.
- If a non-English speaking person is encountered that is eligible for enrollment and there is no translated consent document available, enrollment of that individual should be delayed and an IRB approved translated consent obtained, UNLESS it is determined by the Principal Investigator that it is justified to proceed because it is in the prospective participant's best interest to enroll prior to the translation.
- The best interest of the subject means that it is necessary to ensure the rights, welfare, and safety of the prospective participant. For example:
  - A trial with therapeutic intent and there is insufficient time to obtain the translation due to the rapidity of disease progression or severity of the underlying disease.
  - Delaying consent would pose undue hardship on the prospective participant, for example due to travel distance, need for time off work or away from responsibilities at home, etc.
- The convenience of the study team or cost of translation does not constitute a sufficient justification.

New policy requirements

If the non-English speaking person has agreed to participate using the short form process, the consent must be promptly translated into the participant's language, submitted to the IRB along with the certificate of translation and, after IRB approval, be provided to the participant. Ideally, this should occur no later than 30 days following enrollment .

- This is not considered a reconsent, so therefore the participant does not have to re-sign. However, it is expected that any questions that may arise after the participant reviews the translated consent will be answered.

In addition to reporting short form consent use at time of Continuing Review (CR), the IRB must be informed of the use of the short form in real time by submitting a Reportable New Information (RNI) form in PROTECT.

- Select “Short Form Use” on the RNI form
- Provide the justification for using the short form consent process in the description of the event.
- Indicate when it is expected that the translated consent will be provided to the participant.
- Inform the IRB that the translated consent was provided to the participant.

Short form consent

Short form consent is not permissible in the following circumstances:

- Enrollment of healthy volunteers in greater than minimal risk research.
- When there is sufficient time to translate the consent document.

What about assent?

There is no short form process for assent.

If written assent is required by the protocol

- Best practice is to translate assent
- If no translated assent available, use verbal assent process and document in consent note
- Older children can read and document assent on the translated long form.

No one should sign a form they cannot read.

Anticipated concerns

Cost

- Cost range $0.14 - $0.34 per word depending on language
- “average” consent ~ 10,000 words
- Anticipated cost of an average consent $1,400 - $3,400

Access to timely translations

- Extensive discussion with NIH library in preparation

Cost calculations

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200 translations of a 10,000 word consent

70% Spanish @ 0.14/word

30% other @ 0.34/word

Spanish: 140 x 10,000 x 0.14 = $196,000

Other: 60 x 10,000 x 0.34 = $204,000

Total Estimated cost/year = $400,000

OIR will contribute $200,000 for the first year

Pay 50% of cost of initial translations of consent documents when done by the NIH library.

Some Q and A

Effective date is March 1, 2024

- That means that you must follow this policy for any potential participant that from whom you will obtain consent or reconsent on or after March 1.

What about modifications that require reconsenting of participants after March 1, 2024

- If the participant you are reconsenting does not speak English, then the consent must be translated consistent with this policy.

What about “screening consents” vs “protocol consent” if the screening is only minimal risk interventions.

- The determination of minimal risk vs greater than minimal risk is for the study not the consent. All consents within any given study are subject to the same policy requirements, based on the risk level of the study.

Why do this?

Promote truly informed decision making

Promote safety

Promote equity

Resource links

FDA 2023 guidance on informed consent

NIH HRPP policy 301-Informed Consent

National Institutes of Health
Office of Management

NIH Library Translations Service

Nancy Muir, MLS
Director

February 1, 2024

Office of Research Services
National Institutes of Health
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

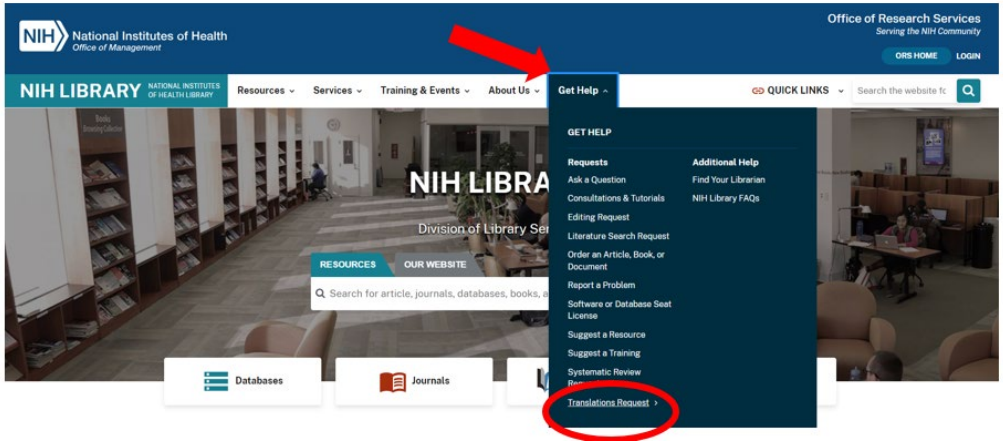
1. Use the NIH Library web site to make a request: https://custserv.nihlibrary.ors.nih.gov/Translations/

2. NIH Library staff will email a quote and the estimated turnaround time from the translation vendor.

   Researcher must approve 50% of the cost of the full quote (IRP covering the other 50%). CAN number provided on original request must be confirmed.

   If actual cost comes back higher than estimated, researcher must approve new cost.

3. NIH Library Translation Service manages the translation project from the vendor and sends the document(s) to the requestor with the certification of accuracy.



https://www.nihlibrary.nih.gov/

Turnaround Times

- Depends on availability of translators for the language requested
- Normally 1 week for a 15–20 page informed consent from English to Spanish

Estimated Costs Based on GSA Pricing

Language	Approximate cost per word	Estimate for 10,000 word protocol total cost
Spanish	$0.1820	$1.820.00
Amharic	$0.2489	$2,489.00
Arabic	$0.2297	$2,297.00
Chinese	$0.2016	$2,016.00
French	$0.1804	$1,804.00
Italian	$0.2040	$2,040.00
Korean	$0.2295	$2,295.00
Portuguese	$0.1870	$1,870.00
Russian	$0.2106	$2,106.00
Ukrainian	$0.2297	$2,297.00

***Rush Rates** are an **additional 30%** if needed in less than 3 business days*

Contact Information

Translations Service Team Leader

Mónica Valencia

Email: monica.valencia2@nih.gov

By phone: 301-827-4075

Contact the Library

Website: nihlibrary.nih.gov

Email: nihlibrary@nih.gov

Phone: 301-496-1080

In Person: Building 10

LANGUAGE ACCESS AT THE NIH CLINICAL CENTER BEST PRACTICES

Brenda Robles, BA, Certified Medical Interpreter
Language Interpreter Program Manager

NIH Clinical Center
America's Research Hospital

LIMITED ENGLISH PROFICIENCY

The Impact of LEP on Health Care

LEP patients…

- Less frequently access preventative & primary care services
- Are more likely to be non-adherent
- Are more likely to be dissatisfied with their care
- Are more likely to use the ED for primary care
- Are more likely to be confused about their medications

NIH Clinical Center
America's Research Hospital

PATIENT SAFETY

Miscommunication can become a liability

- Don’t settle for “getting by”
- Don’t use a family member (or minors) as Interpreters
- Communication is a patient safety issue
- Linguistic Access is a patient right
- Title VI Compliance

NIH Clinical Center
America’s Research Hospital

THE LANGUAGE INTERPRETER PROGRAM

Promotes the mission of the Clinical Center by providing comprehensive interpreting services to CC patients and their families facilitating their participation in biomedical research. The program exists to eliminate healthcare disparities.

Social Work/Language Interpreters:

- ✓ Are Certified Healthcare Interpreters
- ✓ Maintain Licensure Requirements
- ✓ Well versed in all interpreting modalities
- ✓ Interdisciplinary Partners
- ✓ Participate in Random Supervisory Quality Assessments

ASL Services are provided through The Office of Research Services (ORS):
https://www.ors.od.nih.gov/pes/dats/interpret/Pages/index.aspx

NIH Clinical Center
America's Research Hospital

INFORMED CONSENT BEST PRACTICE

Requirements for LEP

- When a prospective participant does not speak English a translated long-form consent in the native language of the participant should be utilized
- Short form consents should not be utilized in lieu of long forms on a regular basis
- Please use Interpreters for the consent process
- When the short form is used, there must be a witness to the consent process (Interpreters can serve as the witnesses)

COMMUNICATION BEST PRACTICE

Bilingual Fluency Testing at the CC

M23-2 Language Access in the Clinical Center
approved by MEC on 1/3/2023

- Measures competence of bilingual staff to perform their duties in a secondary language (scope of work restricted)
- Does not promote staff having dual roles
- Passing the test does not qualify staff to be interpreters
- Complies with Best Practices for promoting patient safety

To coordinate testing:
Email: CC-SWDLanguageInterpreterService@mail.nih.gov

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