Guidance for obtaining consent to participate in research from non-English speaking participants.

Obtaining the informed consent for participation in research is perhaps the most fundamental ethical obligation in conducting human subjects research. It is one of the most important means by which individuals are able express their choice as to what will and will not happen to them and act in a manner consistent with their own, personal goals and values.

The Belmont Report identifies 3 key components to the consent process.

- Information: The prospective participant must be provided with sufficient information to allow them to make a considered choice whether, or not, they wish to participate in the research. The revised Common Rule specifies that the prospective participant "*must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information."* (45 CFR 46.116(a)(4))
- Comprehension: The information provided to the individual must be able to be understood by that person. There are many potential barriers to adequate comprehension. One important one, and the focus of this guidance, is the language in which the information is provided to the individual. Delivering information about research in a language that the individual is not able to understand does not meet the ethical obligation of respect for persons nor the regulatory requirement that *"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.* (45 CFR 46 (a)(3). (21 CFR 50.20)
- Voluntariness: Valid informed consent requires that the decision to participate be made voluntarily. Situations that present the possibility of coercion or undue influence may lead individuals to make decisions that are not truly consistent with their goals and values, and that might differ if they were presented with the choice in the absence of such pressures.

The decision to enroll in a clinical trial is often complex, with the need for the potential participant to consider and balance many factors. At NIH, many of the clinical trials are early-stage investigations, testing drugs and/or procedures for which there is little or no information on their effect in human beings. In addition, many trials are inextricably linked with complex "routine medical care" such as stem cell transplant protocols. Adding to the complexity of the decision making, individuals being approached to enroll in these trials are often suffering from serious or life-threatening conditions, making truly informed decisions both more important and simultaneously more difficult.

The need for individuals participating in research to have a full understanding of the trial is important to ensure participant safety. Many of the drugs that are being tested and procedures being performed come with significant toxicities and risks of harm to participants. The safety of the participant requires them to have an awareness and understanding of the potential adverse events they may experience so that they may take appropriate actions and report them to the investigator. The written informed consent document serves as an important reference document, providing study participants with information as to what to expect, and what do and whom to contact in certain situations. Many participants refer to this document throughout the trial as a source of important information.

The "short form" consent process

Both HHS and FDA regulations allow for consent to be documented using a process referred to as the "short form" process. (45 CFR 46.117(b)(2)) (21 CFR 50.27)(b)(2)). In brief, the short form process allows for an oral presentation of the information that is contained within the full written English consent document, and for written documentation of consent to be obtained by having the participant sign a form that lacks any study specific information (the short form). Typically, the short form has only generic headers that correspond to each of the required elements of consent, with no information about the actual study in which the person is enrolling.

Although the regulations do not specify under what circumstances the short form process can be used, it has been commonly used to enroll non-English speaking persons when there is no written consent document in the language of the participant. When used in this way, the participant receives no written study specific information in their own language. Therefore, they have no documentation to refer to as they decide whether or not to participate or, if they do enroll, to refer back to during the course of the study. Given the ethical and regulatory requirements for obtaining valid informed consent and ensuring the safety of subjects, in many if not most cases, the short form process falls short.

The intent of permitting the short form process has been to provide a mechanism for the *unanticipated or unexpected* enrollment of non-English speaking individuals when there is no IRB approved translated full consent document, **and** when it is clearly *in the participant's best interest* to enroll prior to obtaining a translated consent. Given the known inadequacies of the short form process, the expectation has always been that use of the short form would be infrequent.

When the short form process must be used, the limitations of this process can be mitigated in part by translating the consent promptly after enrollment and providing it to the individual that was consented using the short form. Recent FDA guidance on informed consent indicates that this is an expectation of the FDA any time a short form consent process is used.

Anticipating enrollment of non-English speaking participants

Unanticipated enrollment means that the study team could not have reasonably known that they might enroll a person that doesn't speak English. The Washington DC metropolitan area is home to a substantial population of non-English speaking persons, with Spanish being a common first (and only) language for many. At NIH, we frequently enroll persons from all over the world that speak a diverse array of languages. Study teams should prospectively consider whether it is likely that they will encounter persons who are not native English speakers. Based upon their knowledge and experience with the population typically enrolled, if it can be reasonably anticipated that for example, Spanish speaking persons will be enrolled, it is advisable to obtain a Spanish translation of the informed consent document and relevant study instruments ahead of time.

This does not mean that study teams are obligated at the initiation of any study to translate the consent document into every possible language that might be encountered. Typically, at the time a clinic appointment is made, the study team will be aware that a potential participant does not speak English and that an interpreter is needed. At this time, the study team should have the informed consent translated into the language of that person. The prospective participant's appointment may need to be delayed to obtain the translated document, unless it is clearly in the prospective participant's best interest to not delay and proceed with enrollment using the short form process.

Step by Step instructions for enrolling non-English speaking individuals.

For research determined by the IRB to be minimal risk

1. If enrollment of non-English speaking individuals is anticipated, the consent must be translated into the anticipated languages.
2. 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.
3. Inform the IRB of the use of the short form within 7 calendar days by submission of a Reportable New Information (RNI) form in PROTECT. This should be done for each use of the short form. For those studies which require continuing review, cumulative short form use must be provided at that time.
    a. Select "Short Form Use" on the RNI form.
    b. Provide the justification for using the short form consent process in the description of the event.
    c. Inform the IRB if the translated consent will be provided to the participant.
4. 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 translated for any future participants that speak that language.

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

(See **Figure: Enrollment of non-English speaking persons in a greater than minimal risk study.**)

1. 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.
2. 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.
    a. The best interest of the subject means that it is necessary to ensure the rights, welfare, and safety of the prospective participant. For example:
        i. 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.
        ii. 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.
    b. The convenience of the study team or cost of translation <u>are not</u> sufficient justification.
3. If the Principal Investigator determines it to be justified to proceed with informed consent prior to translating the consent, this determination and the reasons for it must be documented in the research record and/or CRIS as part of the consent note.
4. If the determination is made to proceed prior to translation of the consent, informed consent should be obtained and documented using the short form process.

5. 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 within 7 calendar days by submitting a Reportable New Information (RNI) form in PROTECT.
    a. Select "Short Form Use" on the RNI form.
    b. Provide the justification for using the short form consent process in the description of the event.
    c. Indicate when it is expected that the translated consent will be provided to the participant.
    a. Inform the IRB that the translated consent was provided to the participant (this will typically be by responding to a clarification request in PROTECT).
6. 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.
    a. 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.

What about modifications to the consent document?

If there are modifications to the consent document that might affect the willingness of a participant to remain in the study, and the IRB has determined that reconsent is required, non-English speaking persons must be provided this information in their own language. In some cases, this may be accomplished by creating a translated consent addendum that addresses the changes, and providing this addendum to the non-English speaking participant, rather than incurring the expense of translating the entire document. However, if the changes are extensive, it may be that the full modified consent document must be translated. Consult with the IRB Office for guidance.

What about previously enrolled participants?

Individuals enrolled using the short form process prior to the implementation date of this policy change do not need to have the informed consent document translated and provided to them. The new requirements apply only to participants moving forward. However, should a study team translate a consent document in order to enroll a new participant, it would be considerate and respectful of prior participants to provide them with this translated document.

What about study documents other than the informed consent?

Documents or study instruments that are necessary to ensure the safety and welfare of participants, or the scientific integrity of the study, should be translated into the language of the subject. For example, emergency contact cards, documents identifying medications or foods to avoid due to safety considerations, or participant facing study instruments important for outcome measures, should all be translated into the participant's language.

When should the short form process NOT be used?

There are some circumstances in which it is difficult to ethically justify the use of the short form process.

- Enrollment of healthy volunteers in a greater than minimal risk study

- When there is sufficient time to obtain a translated consent document

What about multi-site research or research reviewed by a non-NIH IRB??

This policy applies to all research conducted by NIH investigators, whether or not the NIH IRB is the reviewing IRB. In other words, NIH researchers must follow this policy even if the reviewing IRBs is an external (non-NIH) IRB and that IRBs policies do not require translation. NIH investigators must report short form use to the NIH IRB, even if the reviewing IRBs policies do not require reporting.

This policy does not apply to non-NIH sites for which the NIH IRB is the reviewing IRB. The non-NIH sites should follow their institutional policies for translation. OHSRP will not reimburse for the translation of consents to be used at a non-NIH site.

Resources for obtaining translated consent forms.

The NIH Library provides translation services for NIH researchers. OHSRP and NIH Library leadership have been working together to assess the anticipated increased need for translation services and to ensure that sufficient resources are in place at the time this policy goes in effect.

The Office of Intramural Research (OIR) believes that this policy is an important part of our overall commitment to enhance diversity in clinical trial enrollment and to promote equity. OIR has agreed to defray the initial cost over the first year by paying 50% of the cost of each informed consent translation when the NIH Library services are utilized. This applies only to the initial translation of the consent into a new language, not subsequent modifications. OIR cannot reimburse for translations performed by other mechanisms.

Figure: Enrollment of non-English speaking persons in a greater than minimal risk study