Title: CONSENTING PARTICIPANTS WHO DO NOT READ OR SPEAK ENGLISH

Version No.: 1.13

SOP No.: IC-704

Effective Date: January 20, 2026

1. Purpose

This policy describes the general requirements for obtaining and documenting informed consent and research authorization (RA) for research participants who do not read or speak English or whose understanding of the language is limited.

2. Policy

Federal regulations require that informed consent information be presented “in a language that is understandable to the subject.” As a result, consent forms should be prepared in the language understandable to potential participants and have MSK IRB approval. In cases when a non-English speaker is unexpectedly encountered, the consenting professional must use the short form consenting process outlined in section 3.2.

Discussions with participants about their participation in the trial should be conducted with an interpreter or consenting professional who is fluent in both English and the language of the participant. Interpreter services should be arranged ahead of time, if possible. The interpreter may not be a family member.

While the use of non-English speaking participants presents a unique set of challenges for the investigator, care must be taken to not exclude non-English speaking participants from any research that may have potential benefit.

For any protocol which is therapeutic or under an MSK-held IND or IDE, a fully translated consent must be provided to the participant unless an exception was granted by the IRB. The short form consenting process may be used to initially consent, enroll, and begin protocol activities.

If using the short form process, the request for the translated documents should be initiated within 2 business days of registering the participant fully eligible.

Once the fully translated consent is approved, the participant should be re-consented according to MSK IRB SOPs IC-704 and IC-706.

All translated consents and associated translated protocol documents (e.g., diaries, questionnaires, calendars, brochures, etc.) must be IRB approved before use by research participants.

Once non-English documents are created and IRB approved for a specific language, the expectation is that they are maintained if needed by the non-English speaking participant from this language group (e.g., if the IRB approves an updated English consent form for which written reconsent is required due to a new risk, the translated consent form must be updated). If a participant is enrolled onto a specific arm or cohort, only those relevant documents need to be translated.

The translated documents must be amended subsequent to amendments to the English language equivalent documents for the relevant arm of the study (i.e., all English-language documents must be IRB approved prior to submitting for translation); unless HRPP grants an exception to discontinuing the maintenance of the translation.

3. Specific Procedures

3.1 Translated Full Consent Documents

The MSK IRB strongly encourages the use of a translated full consent whenever possible. If the Principal Investigator (PI) plans on enrolling non-English speaking study participants, the entire consent document (and associated protocol documents: (e.g., diaries, calendars, questionnaires, injury letters, etc.) should be translated into a language understandable to the participants. The translated document must be approved by the IRB. The submission must include the translated document(s) plus the certificate of authenticity. This is done after the IRB has reviewed and approved a final English document. When a fully translated non-English consent is used, all requirements and documentation outlined in MSK IRB SOPs IC-701 and IC-706 should be followed. The consenting professional must provide an oral explanation of the study with the assistance of an interpreter if the consenting professional is not fluent in both languages. If the consenting professional is fluent in the participant's language, an interpreter is not needed as the consenting professional can have the discussion with the participant.

3.1.1 Interpreters

The role of the interpreter is to interpret between the consenting professional and the prospective participant. An interpreter fluent in the participant's language must be available during the consent process and throughout the research participant's participation in the study unless the consenting professional is fluent in the participant's language.

- Interpreter may include:
  - MSK Language Assistant Program (LAP) interpreter
  - Official Telephone Interpreter
- Interpreters may not include:
  - Participant family members, friends, or caregivers

3.1.2 Witnesses

A witness is not required and should not sign the consent form.

3.1.3 Signature Requirements

- Consenting Professional
- Participant or the legally authorized representative

3.1.4 Documentation

- The consent process must be documented in a progress note in the participant's medical/research record. The note should include the details of the discussion and that an interpreter assisted.
- Interpreter name or reference number must be documented on the consent form unless the consent form does not include an area to document interpreter name or reference number.
  - If the consent form does not include an area to document interpreter name or reference number, it must be documented in the participant's medical/research record.
- Copies of the full consent (in the participant's language) must be signed and stored in accordance with MSK IRB SOP IC-706.

3.2 Short Form Consent Process

Principal Investigators may not be able to anticipate the enrollment of non-English speaking participants and therefore may not be able to obtain a specific IRB-approved translated full consent document in a timely manner. In these instances when a non-English speaker is unexpectedly encountered and the translation and IRB approval of a full consent document is not

feasible, the regulations permit the use of a "short form." The short form should not be used as a way to circumvent translation of the full consent form.

The short from is written in a language understandable to the participant and outlines what the participant must be told by the consenting professional during their discussion about participation in the trial. The MSK IRB has approved short forms available in multiple languages on the HRPP website; this is the only source of short forms. Relying sites are permitted to use their own short forms only if reviewed and approved by the MSK IRB.

If an English consent form contains embedded questions and there is not enough time to prepare a fully translated consent document, the participant can answer the questions through the short form process. The interpreter should ask the participant the questions and convey their responses to the consenting professional. The consenting professional indicates the participant's response on the English consent form. This process must be documented in the medical record.

The consenting professional must provide an oral explanation of the study with the assistance of an interpreter if the consenting professional is not fluent in both languages. If the consenting professional is fluent in the participant's language, an interpreter is not needed as the consenting professional can have the discussion with the participant.

When utilizing the "short form" method, the following procedures must be followed:

3.2.1 Short Form
Obtain the MSK IRB approved short form in a language understandable to the research participant from the HRPP website. Use of non-IRB approved short forms is not permitted. If a language is not available in a short-form, please contact the HRPP Office for guidance.

3.2.2 Written Summary
The short form must be accompanied by a written summary of what is presented orally. The MSK IRB-approved English language consent document is used as the written summary.

3.2.3 Use of Interpreter
The role of the interpreter is to interpret between the consenting professional and the prospective participant. An interpreter fluent in the participant's language must be available during the consent process and throughout the research participant's participation in the study unless the consenting professional is fluent in the participant's language.

- Interpreter may include:
  - MSK Language Assistant Program (LAP) interpreter
  - Official Telephone Interpreter
- Interpreter may not include:
  - Participant family members, friends, or caregivers

3.2.4 Use of Witness
A witness to the oral presentation is required. The role of the witness is to document that "an oral presentation" of the long form English consent document has occurred. The witness must sign both the short form written informed consent document and the English consent/RA. The interpreter may serve as the witness. The Consenting Professional may not be the witness. The witness must be fluent in the participant's language and English and be present during the consent discussion.

- A witness may include:

- MSK Language Assistant Program (LAP) interpreter
- Participant family member or caregiver
- Impartial MSK staff

- A witness may not include:
  - Consenting Professional
  - Study Investigator
  - Study Research Staff

3.2.5 Signature Requirements

- Short Form (in participant's language and MSK IRB approved):
  - Participant or the legally authorized representative
  - Witness name and signature
- English Consent/RA: (the long form; i.e., English Summary)
  - Consenting Professional name and signature
  - Witness name and signature

3.2.6 Documentation

a) The interpreter name or reference number must be documented on the short form and English consent form unless the forms do not include an area to document interpreter name or reference number.
   - If the forms do not include an area to document interpreter name or reference number, it must be documented in the participant's medical/research record.

b) The consent process must be documented in a progress note in the participant's medical/research record. The note should include the details of the discussion, that an interpreter assisted, and that a witness was present.

c) Copies of the short form and English consent must be signed as indicated in MSK IRB SOP IC-706.

d) Participants (or legally authorized representatives) must receive a signed copy of the short form and English Summary.

e) Both the signed short form and signed English Summary should be sent to the medical record.

f) For therapeutic protocols or those under a MSK-held IND/IDE - a fully translated consent must be completed unless an exception was granted by the HRPP Office. Participants must be re-consented following MSK IRB SOPs IC-704 and IC-706.

3.3 Translation Process

All documents (e.g. diaries, calendars, non-validated questionnaires, brochures, advertisements, etc.) requiring translation must adhere to the step-by-step guidelines available on the HRPP website. Documents must be IRB-approved in English before translation into other languages including at the time of amendment unless an exception was granted by the HRPP Office. The IRB requires (1) translated documents and (2) Certificate of Authenticity.

Non-English validated questionnaires must be obtained from the copyright source. Certificates of authenticity are not required at the time of IRB review.

4. Applicable Regulations and References

- 21 CFR 50.25
- 21 CFR 50.27(b)(2).
- 45 CFR 46.116 and §46.117
- FDA: A Guide to Informed Consent, Non-English Speaking Subjects
- OHRP: Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English
- Translation Documents for Non-English Speaking Participants:
    - First Time/Amended Translations on an Industrial Sponsored Protocol
    - First Time/Amended Translation on a Non-Industrial Sponsored Protocol
- MSK IRB SOPs IC-701, IC-704, IC-706

Revision History

Revision	Effective Date	Reason for Change
1.0	6/15/09	NEW
1.1	8/14/09	In section 3.2 clarifies who may serve as a witness
1.2	4/12/10	Revisions to 3.1 and 3.2: updated distinction and role of interpreters, translators and witnesses. Clarification on the process for consents which include yes/no indication from participants.
1.3	8/23/10	Clarification to section 3.2.
1.4	6/4/12	Updated with new translation requirements
1.5	9/10/12	Updated that when using an interpreter, signature is not required, only name or ID number. Witness signature is still required.
1.6	2/29/16	• Updated Signature page, MSK branding, formatting. • 2. Clarified that translations are only required on a specific arm of the study and translated documents must be maintained for the life of the study unless granted exception by the IRB. • 3.2.6 Clarified that participants or LARs must receive signed copies and signed copies of both short form and English summary must be sent to the medical record. • 3.1.4/3.2.6 Moved requirement for interpreter name and reference number from Signature to Documentation subsections. • 3.3 Removed injury letters.
1.7	5/10/18	• 2/3.2.6f Clarified allowances for therapeutic protocols or those under a MSK-held IND/IDE
1.8	5/11/20	• 3.1 and 3.3 Removed back translation requirement • 3.1.2 Clarified that a witness should not sign the consent form • 3.1.4 and 3.2.6a Clarified that the interpreter name or reference number must be documented either on the consent form or in the participant's medical/research record • 3.2.3 Updated interpreters to interpreter throughout this section • 3.2.4 Updated witnesses to witness throughout this section
1.9	1/31/22	• Removed gendered language throughout SOP

		• 3.2 Updated the short form process to allow non-English speaking participants answer questions embedded within the English consent form during the short form consent process. • 3.2.3 and 3.2.4 Added MSK to the LAP bullet • 3.3 Added "non-validated" • 4 Updated to include all MSK IRB SOPs referenced in this SOP
1.10	1/23/23	• Editorial changes made throughout • 2 Clarified that once non-English documents are IRB approved for a specific language, the expectation is that they are maintained for future participants from this language group; Added "If a participant is enrolled onto a specific arm or cohort, only those relevant documents need to be translated and maintained for future participants…"; Changed IRB to HRPP for whom grants exceptions to discontinuing the maintenance of translation • 3.3 Added statement that non-English validated questionnaires must be obtained from the copyright source and that certificates are not required at the time of IRB review
1.11	2/5/24	• 2 Clarified that a consenting professional fluent in both English and the language of the participant can have the discussion; removed "member of the study team" as one who have be an interpreter. • 3.1, 3.2: Added language to clarify that, if the consenting professional is fluent in the participant's language, an interpreter is not needed as the consenting professional can have the discussion with the participant. • 3.1.1, 3.2.3 Aligned language in both sections to state that the role of the interpreter is to interpret between the consenting professional and the prospective participant; clarified that the interpreter must, not should, be fluent in the participant's language; removed "MSK staff including consenting professionals fluent in the participant's language" from the list of interpreters as CPs are able to converse, not interpret, with the participant if they are fluent in the language.
1.12	6/2/25	• 2 Removed requirement to maintain all non-English documents for future participants; Replaced with new requirement [Once non-English documents are created and IRB approved for a specific language, the expectation is that they are maintained if needed by the non-English speaking participant from this language group (e.g., if the IRB approves an updated English consent form for which written reconsent is required due to a new risk, the translated consent form must be updated)].
1.13	1/20/26	• 3.2.4 Added "RA" • 3.2.6 Replaced English Form with English Consent/RA