

GUIDANCE DOCUMENT FOR ENROLLING SUBJECTS WHO DO NOT SPEAK ENGLISH

Aurora Health Care's Research Subject Protection Program (RSPP)

This guidance document will outline the proper procedures for obtaining and documenting informed consent/authorization from potential research subjects who do not speak and/or read English.

Federal regulations found at 45 CFR 46.116 and 46.117 (DHHS) and 21 CFR 50.20 (FDA) require investigators to present study information to a potential research subject in a language the subject can understand, and, in most cases, agreement to participate in research must be documented in writing. The Aurora IRB permits two methods for obtaining and documenting informed consent/authorization from subjects who do not speak or read English.

Method 1 (Preferred Method): Prospective translation of the IRB-approved consent/authorization and written materials

When a researcher anticipates enrolling non-English speakers in a research study, the best practice is to have the English language consent/authorization form and written subject materials translated and approved by the IRB in advance.

An IRB-approved translated consent/authorization **must** be available in advance when:

- the research study targets a population with a significant percentage of non-English speaking individuals (e.g., research involving recent immigrants, a study performed in a geographic area with a large population of non-English speakers, etc.); or
- the investigator routinely provides medical care for those who do not speak English.

Consent/authorization document

A qualified medical translator should prepare the translated documents, which must be reviewed and approved by the Aurora IRB before they are used.

1. Obtain IRB approval of the English language consent/authorization first.
2. Submit a modification to the IRB that includes the following:
 - a. Informed consent/authorization translated into the target language.
Note: do not translate the header, footer, and last page (risk/benefits/alternative signature page) of the ICF. These must remain in English.
 - b. Any subject materials (e.g., diary cards, study questionnaires, or other written study instructions), translated into the target language.
 - c. Statement or certification of translation. The statement must list the translator's name and qualifications, and must indicate the version date of the documents that were translated

Consent/authorization discussion

If the Person Obtaining Informed Consent is **NOT** a qualified interpreter per the Cross Cultural Services process (Aurora policy 170):

- A qualified interpreter must facilitate the informed consent/authorization discussion, either in person or by phone.
- An impartial witness must be present in person for the entire consent/authorization discussion. The witness must be someone who understands both English and the subject's language. In

order to ensure impartiality, the witness must not be the subject's family member or a member of the research team.

- The subject will sign the translated consent/authorization document acknowledging their consent for participation in the study as well as authorization for collection, use and disclosure of their PHI for research.
- The witness will sign the witness signature line of the translated consent/authorization document. By signing, the witness is attesting that the information in the consent/authorization form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally authorized representative, and that informed consent was freely given by the subject or the subject's legally authorized representative.
 - The interpreter may serve as the witness if s/he is willing to do so. This must be clarified with the interpreter *before* beginning the informed consent discussion.

If the Person Obtaining Informed Consent **IS** a qualified interpreter per the Cross Cultural Services process (Aurora Policy 170) and is familiar with the specifics of the research study, s/he may conduct the consent/authorization discussion without the need for an interpreter or an impartial witness. This situation is analogous to the situation where the consent discussion is conducted in English if the subject reads/speaks the English language.

It is recommended that a statement be included in the research record that the interpretation took place, along with the name of the interpreter, and the interpreter's belief that the subject understood the study information and had all of his/her questions answered.

If the research study involves additional visits, an interpreter must be present, in person or by phone, for each subsequent study visit. The interpreter will help ensure the subject's questions have been answered and the subject remains willing to continue participation in the research study. Document that this occurred in the research record.

Method 2: Use of an IRB-approved "short form"

Overview

For the occasional and unexpected non-English speaking subject, a "short form" consent may be used. However, Aurora Health Care and federal regulators strongly discourage the routine use of this method. It truncates and limits the informed consent process normally associated with research participation. Note that a valid, written (signed) HIPAA authorization, or a waiver of authorization/ elements of authorization from the Privacy Board for Research [Aurora IRB]) must be obtained in the Short Form process.

An interpreter relays the study information orally, while a "short form" consent in the target language summarizes the basic elements of informed consent in accordance with 45 CRF 46.117(b)(2). The use of a short form consent document helps to ensure access to research participation for all people, regardless of their ability to communicate in English.

Short forms in the following languages are available on the RSPP website (www.aurora.org/IRB):

- Hmong
- Russian
- Serbian/Bosnian/Croatian
- Spanish
- Vietnamese

If you need a short form in a language other than those listed above, the English short form must be translated into the target language, and the translation must be approved by the Aurora IRB before use. Please contact the RSPP office at (414) 219-7744.

Consent discussion

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- An impartial witness must be present in person for the entire consent/authorization discussion. The witness must be someone who understands both English and the subject's language. In order to ensure impartiality, the witness must not be the subject's family member or a member of the research team.

If the Person Obtaining Informed Consent **IS** a qualified interpreter per the Cross Cultural Services process (Aurora Policy 170) and is familiar with the specifics of the research study, s/he may conduct the consent/authorization discussion without the need for an interpreter or an impartial witness. This situation is analogous to the situation where the consent discussion is conducted in English if the subject reads/speaks the English language.

HIPAA authorization

In order for subject PHI to be collected, used and disclosed for purposes of the research, either a written (signed) HIPAA authorization must be obtained from the subject, or a waiver of authorization or elements of authorization (documentation) must be granted by the Privacy Board for Research [Aurora IRB]. It is noted that there are certain studies where a waiver of authorization/elements of authorization (documentation/signature of the subject) may be appropriate. For example, if you are conducting a phone consent process with a prospective subject – and you have already requested a waiver of documentation of consent – a waiver of documentation of authorization may also be appropriate. However, in instances where you are conducting in-person consent discussion with the potential research subject, a case for a waiver of authorization/elements of authorization would most often not be appropriate given that the practicability consideration necessary for the waiver approval would be difficult to argue.

If you are requesting a waiver of authorization/elements of authorization in the short form process, you must complete the 502A form. Note the Aurora IRB acting as the Privacy Board for Research will determine whether the waiver criteria are satisfied.

If you use choose to obtain written authorization from the subject, the Aurora IRB and the Aurora Privacy Officer have agreed upon the following:

- Because the elements of HIPAA authorization are not translated into a language that the subject understands, the elements of HIPAA authorization must be verbally presented to the prospective subject by a qualified interpreter in a language understood by the subject. Note that this requirement is fulfilled by the interpreter's verbal presentation of the Summary document to the prospective subject.
- In order to obtain written authorization, the subject must sign the English version of the summary document.

Process for using the Short Form process

1. Each use of the short form must be prospectively approved by the Aurora IRB. Complete **Step 1** of the form "Request for use of a short form consent", which can be found on the RSPP website (www.aurora.org/IRB). Sign and either send a hard copy to the IRB office or scan and email to IRB.Office@aurora.org.

- Document on the Request form whether you are obtaining a valid written (signed) authorization from the subject or if you are requesting a waiver of authorization/elements of authorization.
 - If you are requesting a waiver of authorization/elements of authorization in the short form process, you must complete a 502A form focusing on the questions in section V (waiver criteria). Note the Aurora IRB acting as the Privacy Board for Research will determine if the conditions of the waiver of authorization/elements of authorization are satisfied.
 - If you are going to obtain a valid written (signed) authorization from the subject, the elements of the authorization **must** be incorporated into the required Summary document that is presented verbally to the prospective subject. There are two options that can be used for the Summary document:
 - The Aurora IRB **preferred** option: The English language version of the most current IRB approved consent/authorization document is used as the Summary document. (If the consent/authorization document is to be used as the Summary document, you do not need to attach it to the request, since it has already been approved by the IRB.)
 - A new written (English) summary of the study information may also be created. Per DHHS regulations and AAHRPP accreditation standards (II.3.F), this summary must “embody the basic and required additional elements of consent”, including a summary of the study procedures. In addition to the consent elements, this document **must** also include the elements of a valid HIPAA authorization. As this document does not have IRB approval, this Summary document must be attached to the Request form. The Aurora IRB must provide approval of this document before it is used to enroll the research subject.
- When quick turnaround is needed:
 - The IRB will make every effort to review the request in advance of the anticipated consent date listed in Step 1. However, for requests needing same-day approval, please call the office (414-219-7744) as soon as you know you will be making the request to let us know the situation.
 - If you encounter a situation outside of business hours where you need approval immediately, please page the IRB manager at 414-222-4792 for verbal approval. Submit the form as soon as possible. Indicate on the form that verbal approval was already given.
- 2. The IRB chair or designee will review the Step 1 request and complete **Step 2** (short form use approved/denied). The form will be returned to you with the determination marked and signed.
- 3. Once you have received the approval of the Aurora IRB to use the short form consent process:
 - a. , download the correct version of the short form from the RSPP website and insert the Aurora IRB number in the header (*Note: do not change the version date*) and fill in the blue highlighted areas of the consent with the investigator’s contact information. This translated short form document should be provided to the prospective subject during the consent discussion.
 - b. The Summary document (including the elements of HIPAA authorization) must be verbally presented to the prospective subject by a qualified interpreter (per Aurora Policy 170) in a language that the subject understands. The Summary document is used to guide the consent/authorization discussion about study participation.
- 4. After conducting the consent/authorization discussion with the subject, complete **Step 3** of the Request form, notifying the IRB of the outcome of the process. If the subject agreed to participate, attach a copy of the signed short form with personal identifiers redacted and answer the questions in the form.

5. The IRB chair or designee will assess the study based on several factors (risk level, study duration, etc.) to determine whether a translation is required, and will complete **Step 4** of the Request form to notify the site of the determination.
6. If translation is required:
 - a. The consent/authorization document and any written materials to be provided to the subject during the study must be translated as soon as possible.
 - b. The translated documents must be submitted to the IRB as a modification. If a sponsor's translation of their informed consent template is submitted, please also include an English version of the document for reference.
 - c. Translated materials must be provided to the subject as soon as possible once they are approved. The subject does not need to sign the translated consent/authorization document. If there will be a significant gap in time before the subject's next visit, it is acceptable to send the documents to the subject via certified mail. Note the date sent and the date of confirmed receipt in the research records.
 - d. For future revisions, ICFs must only be translated when a site is expecting to enroll additional non-English speakers or when there is a current, active subject who is impacted by the change(s). It is not necessarily to continually update a translated ICF when there are no subjects currently active who speak that language, and none expected to enroll.

Documentation of Consent/Authorization

Once the subject has agreed to participate:

- The subject must sign and date the translated short form consent document as well as the English Summary document.
- The witness must sign and date the translated short form consent document and the English Summary document.
- The Person Obtaining Informed Consent must sign and date the English Summary document..
- Give copies of the signed short form consent document and the English Summary document to the subject.
- Retain the originals of the documents in the investigator's study research records.
- File copies of the documents in the subject's medical record, in accordance with Aurora policy.
- It is recommended that a statement be included in the research record that the interpretation took place, along with the name of the interpreter, and the interpreter's belief that the subject understood the study information and had all of his/her questions answered.

Future research visits

If the research study involves additional visits, an interpreter must be available, in person or by phone, for each subsequent study visit. The interpreter will help ensure the subject's questions have been answered and the subject remains willing to continue participation in the research study. Document this in the research record. If an interpreter is not available for a particular visit due to unforeseeable problems, reschedule the visit, if possible. If the visit cannot be rescheduled, make every attempt to have someone present who can speak the subject's language. Document the situation in the research record and report it to the IRB as a minor violation at the time of continuing review.

For more information:

FDA guidance: *A Guide to Informed Consent* (see Non-English Speaking Subjects section):
<http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm>

OHRP guidance: *Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English*
<http://www.hhs.gov/ohrp/policy/ic-non-e.html>