AAH RSPP GUIDANCE
ENROLLMENT OF SUBJECTS WITH LIMITED ENGLISH PROFICIENCY

PURPOSE

The purposes of this guidance document is to outline the procedures for obtaining and documenting informed consent/authorization from potential research subjects or their legally authorized representative (LAR) who are defined as individuals with Limited English Proficiency (LEP) by institutional policy [AAH system policy 62918: *AAH Assistance for Persons with Communication Needs (Language Services)*]. Individuals designated as LEP are individuals who "cannot speak, read, write, or understand the English language at a level that permits them to interact effectively with service providers".

Individuals with LEP are not prohibited from being included in human subject research (HSR) studies conducted at AAH. However special/regulatorily-required measures (outlined below) must be taken to ensure that such individuals understand the study, their rights, and voluntarily agree to participate in the research. It is the responsibility of the study PI to ensure that an individual with LEP is appropriately enrolled.

Individuals with LEP are also not prohibited from being included in research studies conducted at AAH but overseen by an external IRB – ceded research (see below). However, it is the position of the AAH RSPP that the inclusion of such individuals in a research study ceded to an external IRB is the decision of the IRB of Record. Processes outlined below or those similar to these, as directed by the IRB of Record, should be used to ensure that a subject with LEP is appropriately enrolled in the study.

The information in this guidance document is directed at research under the oversight of the Advocate/Aurora IRB. Note that this same guidance applies to the use of LAR with LEP. In your reading of this document, replace 'subject' with 'LAR'.

Definitions of *Italicized words* can be found in the AAH RSPP Glossary.

GUIDANCE

Why is it important to include subjects with LEP into research?

Enrollment of subjects with LEP into a research study can pose challenges for researchers, but this does not mean that they should be excluded from participation in research. Enrollment of subjects with LEP into a research study is a one way to increase diversity and ensure that investigational products are safe and effective for a diverse population. AAH does not prohibit the inclusion of such individuals as long as they are allowed by the sponsor.

FDA and OHRP regulations encourage inclusion of non-English speaking subjects in research as a way to ensure that subject selection is equitable. Unfortunately, federal regulations on inclusion of non-English speaking subjects focus mainly on informed consent requirements. The regulations note that information must be **presented to subjects in a language that is understandable to them** (45 CFR 46.116 and 46.117 (DHHS) and 21 CFR 50.20 (FDA)). Regulations also require that the subject voluntarily agree to participate and that documentation of this agreement be made in writing (except when a waiver of this requirement is allowed). All HSR regulations are required even in situations where the potential subject cannot speak or read English.

The informed consent document is only one piece of the informed consent discussion/process. It is important to include individuals in the consent discussion/process that can communicate with non-English speaking subjects in a language that is understandable to the subject. This may require the use of an interpreter or certified bilingual team member. AAH policy 62918dictates who can serve in the role of a qualified interpreter for medical treatment or as a certified bilingual team member. The RSPP uses this same policy in defining who may serve in these roles for human subject research.

What about inclusion of individuals with LEP in studies ceded to an external IRB?

For studies ceded to an external IRB, it is the position of the AAH RSPP to allow the inclusion of individuals with LEP as long as federal regulations are followed, and the IRB of record is agreeable and approves of their inclusion in the research study. When an external IRB is the IRB of Record for AAH, the policies of that IRB must be followed when enrolling individuals with LEP. However, AAH RSPP guidance must be followed with regard to: 1) use of a qualified medical interpreter and who may serve in this capacity; 2) use of an impartial witness and who may serve in this capacity; 3) the use of in-person or video/telepresence technology for the consent discussion/process; 4) presentation of elements of a valid research authorization to the prospective subject/LAR; and 5) proper storage of the executed consent and authorization.

When using the short form process to enroll an AAH patient with LEP into the research study, an AAH translated short form research consent should be used. However, an exception to this requirement may be made if the research short form consent document is not translated into the needed language and one exists with the IRB of Record. Contact the RSPP Office for more information should this occur.

- If the neither the IRB of record nor AAH RSPP has a translated short form consent in the needed language, the study team will need to ensure that the AAH English short form research consent document is translated into the needed language. This translated document will require the approval of the AAH IRB before it can be used to enroll the patient with LEP into the research study. The cost of the translation is the responsibility of the PI or study sponsor.

When using a fully translated research consent/authorization document to enroll an AAH patient with LEP into the research study, the IRB of Record must approve this document before it is used.

What are the methods used to enroll individuals with LEP into a research study?

Regulations and the AAH RSPP allow two methods for obtaining and documenting informed consent/authorization from individuals who have LEP.

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

When a researcher anticipates enrolling individuals with LEP in a research study, the English language consent/authorization form and written subject materials must be translated and approved by the AAH IRB in advance of subject enrollment.

An IRB-approved translated consent/authorization **must** be available 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.

OR

Method 2: Use of an IRB-approved "short form" when unexpectedly encountering a prospective subject with LEP [see more information later in this document]

The occasional and unexpected enrollment of a prospective subject with LEP may be conducted using a "short form" process. Federal regulations and AAH strongly prefer the use of a translated long form consent – Method 1 – but understand that a translated version of the English IRB approved consent may not always be available to use when unexpectedly encountering a prospective subject with LEP.

Federal regulations and the AAH RSPP allow the use of a short form consent process to ensure access to research participation for individuals unexpectedly encountered, regardless of their ability to communicate in English.

Prospective IRB approval of either method of enrolling individuals with LEP is required. See more on this later in this document.

Use of a translated consent/authorization document

How do I obtain a translated version of the English consent/authorization document?

It is recommended that the study team wait until the AAH IRB has approved the English version of the consent/authorization document before seeking a translation. Once the English version of the consent/authorization document is approved by the IRB, the study team should contact the Language Services Department for information on how to obtain a certified translation. The translation must be completed by a qualified medical interpreter, and the study team must receive a Certification of Translation from the company that does the translation. The cost of the translation is the responsibility of the PI or study sponsor.

The translator should be advised that **certain sections of the translated consent/authorization document must remain in English** so that they can be read/understood by an English-speaking/reading study team member. These sections include: the document header, and footer, the study team signature section, and the Risk/Benefits/Alternative signature page of the consent/authorization document. The version date of the translated document must be the same as that included on the AAH IRB approved English consent/authorization document.

The translated consent/authorization document and the Certificate of Translation must be submitted to the AAH IRB via a Change form. The Change form must include:

a. the date of the consent/authorization document that was translated,
b. a summary of how the interpretation process will occur,
c. your plans for interacting with the subject at future research visits, etc.

The AAH IRB has the authority to require that a 'back-translation' be done if there is any question as to the veracity of the translation. If a back-translation is necessary, this may add extra time to the approval process. Please plan accordingly.

The translated research consent/authorization document may not be used to enroll a potential subject with LEP until it has received approval from the AAH IRB.

If there are any other subject materials (diaries, questionnaire, subject instructions) used in the research study, these must also be translated into the language understandable to the subject. These translated subject materials will also require a Certification of Translation as well as IRB approval (via the Change process) prior to use.

What is the process for conducting the consent/authorization discussion when using a translated consent document?

When the consent/authorization document is translated into a language that is understandable to the potential subject, it is used as the guide for the discussion of research participation between the potential subject with LEP and the research team. The prospective subject should be given the opportunity to read the translated consent document prior to the consent discussion. After reading the translated consent document, it should be used to facilitate a discussion between the study team and the potential subject. Someone who speaks the language of the potential subject must participate in the consent discussion/process (see below).

- Scenario 1: Discussion between **a potential subject with LEP** and a **member of the research team who does not speak the language of the potential subject** when **using a fully translated consent document**.
  - While the translated, IRB approved consent/authorization document can be read/understood by the potential subject, a Qualified Medical Interpreter who can facilitate the discussion between the English-speaking study staff and the potential subject with LEP **must** be present.
    - A Qualified Medical Interpreter is an individual defined by AAH system policy 62918: *AAH Assistance for Persons with Communication Needs (Language Services)*.
  - Neither federal regulations nor AAH policy require that an impartial witness be present for the consent/authorization discussion when the research consent/authorization document has been translated into a language understandable to the subject.

- Scenario 2: Discussion between a potential subject with LEP and a **member of the research team who is a qualified/certified bilingual team member** (per AAH policy 62918) when using a **fully translated consent document.**
  - When there is a qualified/certified bilingual team member taking part in the consent discussion, such a situation would be analogous to the scenario where the consent document is in English, and the consent discussion occurs between an English-speaking study team member and a potential subject who reads/understands/speaks English. Therefore, when a qualified/certified bilingual team member conducts the consent discussion with the potential subject with LEP – in a language understandable to both - there is no need for a Qualified Medical Interpreter to be part of the consent discussion.
  - Neither federal regulations nor AAH policy require that an impartial witness be present for the consent/authorization discussion when the research consent/authorization document has been translated into a language understandable to the subject.

  Note that, per system policy 62918, bilingual team members
  - must be tested/approved by the Language Services Department **before** interacting with the potential subject with LEP as part of the consent discussion.
  - are **NOT** Qualified Medical Interpreters. Therefore, bilingual team members may **NOT** interpret conversations between patients/companions and any other team members who participate in the consent discussion, including other health care providers.

- System policy exempts a licensed physician from required testing they have a medical degree from a country where English is not the primary language spoken. NOTE that licensed physicians must submit required documentation to the Language Services department (see policy 62918 for more information) to become a qualified/certified bilingual team member.

May technology be used in place of an in-person consent process with a potential subject with LEP?

While it is preferred that the consent discussion with the potential subject occur in person, it is understood that logistics sometimes require a consent process conducted via Interpretive services video/telepresence technology or Zoom technology (NOTE that Microsoft Teams is not allowed by the organization for remote consent discussions). The use of video/telepresence is acceptable as long as all participants of the consent discussion are able to use this technology appropriately, and that methodology has been approved by the AAH IRB.

NOTE that AAH RSPP policy requires the presence of an impartial witness to the consent process when video/remote technology is used.

The research team must be able to visualize when the potential subject and the impartial witness sign the consent document.

How do I document consent/authorization with a translated consent/authorization document?

After completion of the informed consent/authorization discussion, when the potential subject's questions have been appropriately addressed, and he/she has agreed to participate in the research, the consent/authorization document is signed in the following manner:

- 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 member of the study team who obtains informed consent/authorization and answers any questions of the subject signs the translated document in the appropriate area.
- The name of the qualified medical interpreter should be included in the research record – it does not need to be included on the consent document.

The subject should be provided a copy of the signed/dated translated consent/authorization document to fulfill regulatory informed consent requirements as well as HIPAA requirements. Because the translated document includes the HIPAA research authorization, the requirement for executing the authorization is fulfilled by providing the subject with a copy of the signed/dated translated document.

Where should the research team document that the consent process has occurred?

- It is recommended by the RSPP as best practice that notations in the research record/eMR be made by the research team when a translated consent document is used to enroll a research subject. These notes should document:
  - how the interpreter process was completed (e.g., in-person, remote process using telepresence technology, how the consent/authorization was/will be sent to and retrieved from a remote subject and/or witness);
  - the name of the Qualified Medical Interpreter that was used in the consent discussion.

There may be EPIC Smart phrases or ancillary tools created/provided by AARI that fulfill these recommendations.

- Copies of the signed consent/authorization documents should be uploaded to the EPIC system.
- Originals of the signed documents must be retained in the research record.

Short Form Process

Is prospective AAH IRB approval necessary when using the 'short form consent process' ?

AAH RSPP requires that **the enrollment of subjects with LEP be prospectively approved by the AAH IRB**. This includes when such an individual is unexpectedly encountered and enrolled using the short form consent process.

The research team may request prospective approval for the use of a short form consent process with the **initial submission** to the AAH IRB or **via the AAH Change process** (see RSPP SOP #9). The IRB will consider the study parameters in deciding whether the use of the short form process in the research study is appropriate, and if limitations on the number of uses in one language should be provided as part of the approval.

Once the request is approved by the IRB, the study team may use the short form process for enrollment of future unexpectedly encountered individuals with LEP.

The RSPP Initial Application or Change form asks for the following information:

a. a summary of the process that will be followed to obtain informed consent and HIPAA authorization from the prospective subject with LEP (e.g., who will serve as a qualified medical interpreter, who will serve as the impartial witness, how the consent/authorization will be sent to and retrieved from a remote subject and/or witness, etc.);
b. the research team's plans for interacting with the subject at future research visits;
c. the research team's plans to provide other materials (questionnaires, surveys, diaries) to the subject should they be required by the study;
d. plans to get the English IRB approved consent/authorization document translated for the subject's use.

Please allow enough time to ensure that you are able to get approved prior to need. The AAH IRB will review the Change form in a timely manner. However, for requests requiring same-day approval, please notify the RSPP office (via email at irboffice@aah.org) of this need.

After-hours need

It is understood that sometimes research teams will unexpectedly encounter a prospective subject with LEP outside of normal business hours and IRB approval has not yet been requested. Should such a situation arise, you may proceed with use of the short form consent document – as long as you:

- ensure that the study allows for the inclusion of such individuals and there are no anticipated barriers in the study for an individual with LEP;
- there is an approved AAH RSPP translated short form consent available in the needed language (you may not conduct an ad hoc interpretation of the RSPP approved English short form consent document); and
- you follow the process outlined in this document for enrollment of the unexpectedly encountered prospective subject with LEP.

However, it is expected that:

- such situations will be **rare.** Excessive use of this practice may be considered an incidence of continued noncompliance with IRB processes;
- the process to enroll the unexpectedly encountered subject follows the procedures outlined by the regulations and in this document;

- the research team will submit a Change form to the IRB the next business day after the occurrence notifying the IRB of the use and requesting IRB approval of future use.

It should be noted that the **RSPP will review the number of uses of the short form consent/process at the time of continuing review** (see more on this topic later in this document). Instances of translated short form consent use without IRB approval (outside of the 'after hours need' discussed above) will be considered an incidence of noncompliance with IRB processes.

Where can I obtain a translated short form consent document?

The AAH RSPP has created an English language version of the short form consent document that includes the basic elements of a research informed consent in accordance with 45 CRF 46.117(b)(2). This document has been used to translate (by certified translators) the short form consent document into over 20 languages. These documents can be found on the RSPP website or by calling the RSPP office.

Should study teams require a version of the short form consent in a language that is not available in the RSPP, study teams may use the RSPP English short form consent to obtain a translation of the document into the needed language. The study team should work with AAH Language Services to obtain a certified translation of the document. Once received, this translated document (and the Certificate of Translation) must be provided (via the Change process) to the AAH IRB for **approval prior to use**. Any cost associated with the translation of the short form consent document into a language not found on the RSPP website is the responsibility of the PI or study sponsor.

See response earlier in this document (page 5) to the question of whether technology may be used to conduct the remote consent discussion.

What does the 'short form' process entail?

As part of the short form process, federal research regulations and AAH require that the potential subject be presented with a summary of the research study in addition to the translated short form consent document. The English version of the IRB approved informed consent/authorization document (the 'long form') may be used as the 'summary' of the research study. If another summary is to be used, you must submit that document to the RSPP via the Change process and obtain AAH IRB approval of this document before use.

The Short Form process:

- Obtain AAH IRB approval for the inclusion of subjects with LEP in the study. [see above]
- The prospective subject is provided the translated short form consent in a language he/she understands. Translated versions of the RSPP short form consent are available on the RSPP website or by contacting the RSPP Office (irboffice@aah.org). No ad hoc interpretation of the English short form consent is allowed. If there is no version of the short form consent translated into the language of need, the PI will need to secure the translation at their own cost and obtain AAH IRB approval of the document prior to use.
- After allowing the prospective subject time to review the translated short form consent, the English long form consent/authorization document or other IRB approved study summary is orally presented (interpreted) to the prospective subject by a Qualified Medical Interpreter (as defined by system policy 62918). This summary document is used as guide for the discussion of the research study and subject responsibilities between the prospective subject and the research team. In addition to interpreting the English summary for the prospective subject, the interpreter will assist by orally interpreting questions, responses or comments that may arise as part of this discussion

between the study team member obtaining research consent/authorization and the potential subject.
    - NOTE that per system policy, bilingual team members are not Qualified Medical Interpreters and may not interpret discussion between individuals with LEP and English-only speaking study team members.
- Per federal regulation and AAH policy, an impartial witness MUST be present either in person or via video/telepresence for the entire consent/authorization discussion.
    - Per AAH RSPP policy, an impartial witness is defined as someone who speaks both English and the language of the prospective subject who is **not** part of the subject's immediate family or a member of the research team.
    - AAH RSPP policy allows the interpreter to serve as the impartial witness to the consent process if **he/she is willing** to do so AND is **deemed appropriate by the AAH Language Services department**. The inclusion of the AAH interpreter as the impartial witness must be confirmed **prior** to the short form process
    - The role of the impartial witnessin the short form process is to attest that the information in the consent/authorization form and any other written information was accurately explained to the prospective subject, the subject's questions were answered, and that informed consent for participation in the research was freely given by the subject. Make sure to inform the witness of his/her responsibilities prior to start of the consent discussion.

How do I document consent/authorization in the short form process?

After completion of the informed consent/authorization discussion, when the prospective subject's questions have been appropriately addressed, and they have agreed to participate in the research, the consent is documented in the following manner:

- The subject will sign/date:
    - the translated short form consent document;
    - the English long form consent/authorization IF that document is being used to execute the subject's research authorization;
        - if the English study summary does not contain the elements of a valid HIPAA authorization, a stand-alone research authorization must be orally presented to and properly executed (signed) by the subject.
- The study team member obtaining informed consent and answering questions of the prospective subject will sign/date the English study summary document.
- The impartial witness, will sign/date the translated short form consent and the English summary document on the Witness signature line of the documents.
    - NOTE that the interpreter does not need to sign the documents if they are not serving as the impartial witness.

How is HIPAA authorization obtained in the short form process?

- In order for valid HIPAA authorization to be obtained for the research study, the prospective subject with LEP must sign and date a document that includes all elements of a research authorization.
- If used as the English study summary, the IRB approved English long form consent/authorization document will contain the necessary elements of a research authorization. Therefore, if the English long form consent/authorization document is orally presented by the interpreter, the prospective subject with LEP may sign this document and have it function as a valid, executed research authorization.

- If the IRB approved English long form consent/authorization is NOT used as the study summary, and a waiver/alteration of authorization has not been granted by the Research Privacy Board (AAH IRB), a stand-alone research authorization will need to be presented orally by the interpreter. The English stand-alone research authorization, signed by the prospective subject with LEP will function as a valid, executed research authorization.

In either case, the subject must receive a copy of the signed/dated research authorization.

What documents must be provided to the subject?

- A copy of the translated short form consent.
  - If the study follows ICH/GCP regulations this copy must be signed/dated
- A copy of the subject signed/dated research authorization document. In most cases, the research authorization will be included in the English IRB approved combined consent/authorization document used as the study summary, and therefore this is required to be signed by the subject and a copy given to themr. If a stand-alone research authorization is signed by the subject instead, a copy of this document must be given to the subject.

Where should the research team document the consent process that has occurred?

- It is recommended by the RSPP as best practice, that notations in the research record/eMR be made by the research team when the short form process is used to enroll a research subject with LEP. These notes should document:
  - how the interpreter process was completed (e.g. in-person, remote process using telepresence technology, how the consent/authorization was/will be sent to and retrieved from a remote subject and/or witness);
  - the name of the Qualified Medical Interpreter that was used in the consent discussion;
  - who served as the impartial witness to the consent process.

  There may be EPIC Smart phrases or ancillary tools created/provided by AARI that fulfill these recommendations.
  - Copies of the signed consent/authorization documents should be uploaded to the EPIC system.
  - Originals of the signed documents must be retained in the research record.

How often can the short form process be used?

It is the PI's ethical responsibility to ensure that the subject's understanding of the consent information is truly "informed." In the short form process, when the PI/research team member and prospective subject do not share a language, and the informed consent document is not provided to the subject in a language understood by them, the PI relies on the medical interpreter to ensure that the prospective subject is being provided the information required to make an informed decision. The investigator should take into account the complexity of the study and the information being provided solely in an oral format when considering whether the use of the short form consent process is appropriate.

It is also the responsibility of the PI to consider the on-going use of the short form process in the study, and at what point the consent/authorization document should be translated into a language understood by the individuals being enrolled as subjects. If the PI/investigators find that they are enrolling a substantial number/percentage of subjects who do not speak English, it is incumbent upon the PI to consider the ongoing use of the short form process. For this reason, and others outlined below, it is important for the short form uses, and the languages of the subjects enrolled under this process, to be tracked by the research team and periodically reviewed by the PI.

The AAH RSPP has no finite limit on the number of times that the short form process in a particular language can be used to enroll subjects with LEP. The IRB can consider imposing a limit when the request to use the short form process is being considered.

The IRB will monitor the use of the short form consent process as part of the continuing review process. The continuing review form includes a place for the study team to document the number of times the short form consent process has been used in the study, and the languages of the subjects enrolled under this process.

As part of the continuing review, the IRB will consider the complexity of the study as well as the risks of the research in deciding whether the consent/authorization document should be translated into a 'language understood by the subject' for future enrollment or to be provided by current subjects with LEP. The IRB will consider these factors as they relate to the ethical principles of human subject research as outlined in the Belmont Report, namely Respect for Persons, Beneficence and Justice.

In most No Greater Than Minimal Risk Research (NGTMR) no limit will be placed on the number of times prospective subjects with LEP may be enrolled using the short form process. However, consideration will be given to this issue by the Expedited Reviewer at the time the request is made of the IRB (either at initial review or via the Change process) to use the short form process. The PI is also expected to track short form usage in NGTMR research, and to make a decision, based upon actual usage, if/when the informed consent document should be translated into a language understood by the subject. The RSPP Director or IRB Chair may be consulted.

How do I get the IRB approved English consent document translated into another language?

If not provided by the sponsor, the IRB approved English consent document should be provided to the AAH Language Services department in order to obtain a certified translation of the document. Once received, this translated document (and the Certificate of Translation) must be provided (via the Change process – see RSPP SOP #9) to the AAH IRB for **approval prior to use**. Any cost associated with the translation of the short form consent document into a language not found on the RSPP website is the responsibility of the PI or study sponsor.

Do I need to provide the translated consent document to enrolled subject?

It should be considered best practice – and the moral/ethical 'right' way to proceed – to provide the translated consent document to the already enrolled subjects. The provision of the consent/authorization document in 'a language understandable to the subject' will allow the subject to decide for themself whether research participation is appropriate and if they wish to continue research participation or withdraw. If the subject's participation was appropriately and voluntarily obtained using a valid short form consent process, there should be no need to secure written informed consent using the translated document.

You should include on the RSPP Change form your plans to provide the translated consent document to already enrolled subjects. If not included on the Change form, the AAH RSPP will assume that it is your plan to provide the translated document to all currently active, enrolled subjects.

To assist in future audits, it is recommended that you include in the subject's research record/EPIC the date that the IRB-approved translated consent document was provided to the already enrolled subject.

Should the sponsor be consulted on the inclusion of individuals with LEP in the study?

Yes, it is recommended that the research team consult with the study sponsor before considering enrollment of an individual with LEP into the research. Some sponsors may have opinion on the inclusion of such individuals especially as it relates to study conduct and/or provision of 'other subject materials' to the subject.

What about "other subject materials" that are currently only IRB approved in English?

All subject materials must either be translated into the language understandable to the subject (preferred) OR interpreted by a Qualified Medical Interpreter. The study team should consider the impact of these 'other subject materials' on the study prior to enrolling a subject with LEP.

It is especially important to consider if the study requires completion of diaries or questionnaires outside of a study visit or if there are care instructions that must be provided to subjects. In the case of questionnaires or diaries, it may be logistically impossible to get these study materials completed by the subject if not provided in a language that they understand – for example if these documents are in English and must be completed 'at home'. The lack of translated documents could have an adverse effect on the health/well-being of the subject or the study design/outcome.

If a diary or questionnaire cannot be completed as required by the protocol, this would be an incident of noncompliance that must be reported to the AAH RSPP.

What about future study visits?

If the research study involves additional visits, a Qualified Medical Interpreter must be present for each visit. The interpreter will facilitate the discussion between the study team and the subject, help ensure the subject's questions are answered, and that the subject remains willing to continue participation in the research study. It is recommended by the RSPP that the study team document the inclusion of a qualified medical interpreter in the study visit within the research record/EPIC.

REQUIREMENTS

- Common Rule Regulations: 45 CFR 46.116 and 46.117
- FDA Regulations:21 CFR 50.20
- 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
- AAHRPP Accreditation Standards/Elements: II.3.F, III,1.F
- AAH RSPP SOPs: 9
- AAH system policies: Policy 62918: *AAH Assistance for Persons with Communication Needs (Language Services)*