1.0 Purpose:

1.1 The Department of Health and Human Services (DHHS) regulations (45 CFR 46.116 and 45 CFR 46.117) and FDA regulations (21 CFR 50.25 and 21 CFR 50.27) require that informed consent information be presented in a language understandable to the subject, and in most situations, that informed consent be documented in writing

1.2 Given the diversity of patients seen in the Hartford HealthCare (HHC) system, investigators may encounter non-English speaking patients who are interested in participating in a research study. When presented with this situation, investigators should carefully consider the ethical and legal ramifications of enrolling a subject when there is a language barrier. It is neither ethically justifiable to exclude potential subjects in a research study solely on the basis of language spoken nor ethically justifiable to obtain consent of subjects who do not have a clear understanding of the consent document or who do not have the opportunity to freely ask and receive answers to their questions. Without this understanding and opportunity, consent may not be truly informed and may not be legally effective.

1.3 The purpose of this policy, therefore, is to explain how researchers should obtain and document informed consent for subjects who:

1.3.1 Are non-English speakers and require an interpreter and translated consent materials, or

1.3.2 Understand English but cannot read due to blindness or illiteracy, or

1.3.3 Understand English but cannot talk or write due to incapacitation.

2.0 Definitions:

2.1 **Non-English Speaking Subject -** An individual who is unable to verbally comprehend spoken English or read and comprehend documents written in English. The inability to understand English makes it impossible for a prospective subject to meaningfully engage in the consent process and to make an informed decision about participation in research.

2.2 **Illiterate English Speaking Subject -** An individual who speaks and understands English but does not know how to read and write in English. An illiterate subject may also include those who are cognitively able to understand and comprehend spoken English, but are physically unable to talk or write.

2.3 **Interpretation -** For purposes of research informed consent, an interpretation is a verbal exchange between two parties and the person serving as interpreter is fluent (can speak, read and write) in English and the language of the subject.

2.4 **Translation** - the process of translating a written document (e.g., consent form) from one language into another, assuring the language of the translated document has the same meaning as the written document in the first language

2.5 **Short Form -** The short form is a document written in the subject's native language which summarizes the basic elements of informed consent required by 45 CFR 46.116. These elements are outlined on the form in general terms and will be presented to the subject (or their legally authorized representative) orally.

3.0 Underlying Guidance and Principles:

3.1 The Belmont Report identifies "justice" and "respect for persons" as two fundamental ethical principles that must underlie conduct of all human subjects' research. The principle of justice requires that the burdens and benefits of research are equitably distributed and calls for "…fair procedures and outcomes in the selection of research subjects." The principle of respect for persons requires that "adequate standards for informed consent are satisfied" so that subjects are provided with sufficient meaningful information to decide whether they want to enroll in a research study.

3.2 To ensure the principles of the Belmont Report are met;

3.2.1 Investigators must plan for populations that are likely to be recruited into the research prior to submitting their application to the IRB. Investigators should request translations of informed consent documents and related study documentation ahead of time to allow for appropriate recruitment and consenting.

3.2.2 If subjects who are non-English Speaking, illiterate or unable to talk or write will be excluded from the research, investigators must provide an ethical and scientific justification for their exclusion. Inconvenience or expense for the investigators is not an acceptable justification for excluding non-English speaking subjects.

3.2.3 Unless an ethical and scientific justification is provided and accepted by the IRB, investigators may not exclude non-English speaking or illiterate subjects from research when the subjects otherwise meet the criteria for inclusion in the research study.

3.2.3.1 Ethical or scientific justifications to exclude non-English Speaking Subjects may consist of:

3.2.3.1.1 Safety risks to subjects due to lack of English proficiency, but only where the safety risk could not be mitigated by providing an interpreter.

3.2.3.1.2 Study questionnaires which have not been validated in a foreign language

3.2.4 **IMPORTANT NOTE:** It is the investigator's responsibility to judge the subject's comprehension of the consent information including the understanding that participation is voluntary and that the subject has the right to withdraw at any time during the study. If the investigator doubts the subject's consent comprehension, he/she should not enroll the subject in the study. **The subject's autonomy must not be jeopardized due to a language barrier**.

4.0 Procedure:

4.1 To ensure adequate protections are in place, investigators must obtain IRB approval prior to enrolling the following subjects into a research study; non-English speaking, illiterate, blind or subjects who can not talk or write.

4.2 In order to address the considerations described above, when enrolling subjects who do not speak English in research, the subject must be provided with BOTH:

- a written consent document translated in a language understandable to them, ***AND***
- an authorized interpreter fluent in both English and the subject's spoken language

4.3 Depending upon the research, the written consent document can be either;

- a written translation, in the subject's native language, of the entire English version of the consent form approved by the IRB, ***OR***
- a written translation of the 'short form' consent document

4.3.1 The 'short form' should generally only be used when the research involves no more than minimal risk to subjects or, if more than minimal risk, presents the prospect of direct benefit to individual subjects.

4.4 The IRB determines which procedure is appropriate for documenting informed consent on a protocol-specific basis.

4.5 **<u>Non-English Speaking Subjects:</u>**

4.5.1 ***Written Translation of IRB-Approved English Informed Consent: (This method is preferred over use of the short form)***

4.5.1.1 The IRB requires a written translation of the full English informed consent document into a language understandable by potential subjects when:

- the research targets a specific population that is non-English speaking, or
- a significant proportion of subjects are anticipated to be non-English speaking

4.5.1.2 To have the consent forms translated, requests should be made either on the Research Application at the time of initial review or by submission of a written request on a cover letter to the IRB if the decision is made at a later time.

4.5.1.3 Hartford HealthCare (HHC) uses a contracted translation service. HRPP staff will submit IRB approved materials for translation at the request of the investigator.

- If the HHC IRB has agreed to allow another IRB to serve as the IRB of record for a particular study, then the HHC IRB will accept translations that have been approved by the IRB of record.

4.5.1.4 In addition to the informed consent document, the following documents should be alt be translated before enrolling non-English speaking subjects on a study:

- HIPAA Authorization
- Questionnaires/Rating Scales (unless they have not been validated in a foreign language)

- Recruitment Materials (Flyers, Newspaper Ads, Brochures etc.)

4.5.1.5 To ensure that non-English speaking subjects can provide legally effective informed consent, the consent process and discussion must occur with an HHC Authorized Interpreter who is fluent in both the subject's language and English. Authorized Interpreters have the designation "Interpreter" boldly displayed on their HHC employee Identification badge.

- Ideally this person would be a member of the study team who is CITI trained and very familiar with the protocol like a study coordinator or investigator.

- If no one on the study team is a HHC Authorized Interpreter you may contact **Patient Advocate at 972-1100** and arrange to have an Authorized Interpreter help facilitate the discussion with an English speaking coordinator.

4.5.1.6 If a member of the study team is not an Authorized Interpreter fluent in the subject's language, an Authorized Interpreter should be available to address the subject's questions and assess their comprehension throughout the study.

4.5.1.7 If the Authorized Interpreter is not a member of the study team then an English speaking team member must remain available to the subject and interpreter at all times to facilitate accurate discussion of the study.

4.5.1.8 **How to document consent using a translated consent**:

- The subject will sign and date the translated consent on the "Participant's Signature" line.
- If the Authorized Interpreter **is** also a member of the study team they would sign and date the translated consent on the "Person Obtaining Consenter's Signature" line.
- If the Authorized Interpreter **is not** a member of the study team, they would sign and date the consent on the "Witness Signature" line **AND** the English speaking study team member would sign and date the consent on the "Person Obtaining Consenter's Signature" line.
- Copies of the translated consent document should be given to the subject with originals retained in the investigator's research records.

4.5.2 ***Short Form Consent Process:***

4.5.2.1 The short form is a document written in the subject's native language which summarizes the basic elements of informed consent. These elements are outlined on the form in general terms and are presented orally to the subject (or their legally authorized representative) by a HHC Authorized Interpreter.

4.5.2.2 Use of the 'short form' method for obtaining informed consent should only be used for the occasional and unexpected

enrollment of a non-English speaking subject in a study for which no consent form in the subject's language has been prepared.

4.5.2.3 Copies of "short form" consent documents, translated into the following languages are available in from the HHC HRPP Office: Spanish, Polish, Italian, Vietnamese, and Bosnian.

4.5.2.4 The IRB may approve (either administratively or via a full board review) the use of an oral presentation along with a 'short form' consent document in a language understandable to the subject when:

- the research does not target a non-English speaking population, and
- only a small proportion of subjects are anticipated to be non-English speaking.

4.5.2.5 The IRB must approve a written summary of what is to be said to the subject (or their legally authorized representative). The English consent document may be used the summary.

4.5.2.6 The IRB approved written summary or full-description informed consent document should be presented orally to the subject in his/her native language and all questions answered.

4.5.2.7 This oral presentation must be witnessed by an independent third party to attest to the adequacy of the consent process and to the subject's voluntary consent. This is someone who is both fluent in both the subject's language and English AND is **not** a member of the study team. The Authorized Interpreter may also serve this role, if they are **not** a member of the study team. The interpreter should also be available to address the subject's questions and assess their comprehension.

NOTE: ****Family members and friends of the patient cannot act as the interpreter****

4.5.2.8 To schedule an in-person language interpreter or sign language interpreter for a patient, please utilize one of the following contact methods listed below (a minimum 2 hours' notice is required):

4.5.2.8.1 Email: request@ititranslates.com

4.5.2.8.2 Call: 860.647.0686

4.5.2.9 Options for accessing Language Services:

4.5.2.9.1 Over the Phone Interpreters (OPI) – Call iTi directly at 1.888.420.9740

4.5.2.9.2 Video Remote Interpreters (VRI) – Look for the iTi Icon on desktops; no login required,

4.5.2.9.3 Onsite Interpreter Services – To scheduled Spoken Languages or ASL (American Sign Language) call iTi directly at 1.800.648.0686 or email your request

to request@iTitranslates.com . Alternatively, you may fax your request to 860.646.3590.

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4.5.2.10 **How to document consent using a 'short form':**

Signatures on the short form itself;

- The subject should sign and date the "short form" consent document on the "signature of participant" line.
- The Authorized Interpreter would sign and date the "short form" consent on the "signature of interpreter" line.
- If the Authorized interpreter is unable to also serve as the independent witness then the witness would sign and date the "short form" consent on the "signature of witness" line.

Signatures on the standard consent in English;

- The investigator obtaining informed consent should sign and date the standard informed consent document on the "Person Obtaining Consenter's Signature" line.
- The Authorized interpreter should sign and date the standard informed consent document on the "Witness Signature" line.
- The subject does not sign the standard consent document.
- Copies of the signed "short form" consent document and standard informed consent document should be given to the subject with originals of both documents retained in the investigator's research records.

4.6 **Illiterate Subjects:**

When enrolling subjects who cannot read the consent materials due to illiteracy:

4.6.1 An impartial witness should observe the consent process.

4.6.2 Consent materials should be presented orally.

4.6.3 Sufficient time should be allowed for questions to be asked and answered, both by the subject, and by the person obtaining consent to ensure the subject comprehends the consent information.

4.6.4 Consider using aids like pictures or models to help facilitate the consent process.

4.6.5 Consider using a video/audio recording of the consent discussion as part of the documentation of informed consent.

4.6.6 Documentation of consent if the subject verbally agrees to participate in the study:

- If capable of doing so, the subject signs, or marks an X to signify consent on the "signature of participant" line.
- The witness signs and dates the consent form on the "Witness Signature" line. By doing so the witness attests that the consent information was accurately explained and that the subject apparently understood the information and informed consent was given freely.
- The person obtaining consent signs and dates the consent form on the "Person Obtaining Consenter's Signature" line.
- Signed copies of the consent are given to the subject.

4.7 **Legally Blind Subjects**

When enrolling subjects who cannot read the consent materials due to blindness, or the subject's legally authorized representative is legally blind:

4.7.1 An impartial witness should observe the consent process.

4.7.2 The IRB approved consent form should be presented orally.

4.7.3 Sufficient time should be allowed for questions to be asked and answered, both by the subject, and by the person obtaining consent to ensure the subject comprehends the consent information.

4.7.4 Consider using an audio recording of the consent discussion as part of the documentation of informed consent.

4.7.5 Documentation of consent if the subject verbally agrees to participate in the study:

- If capable of doing so, the subject signs and personally dates the consent form on the “signature of participant” line.
- The witness signs and personally dates the consent form on the “Witness Signature” line. By doing so the witness attests that the consent information was accurately explained and that the subject apparently understood the information and informed consent was given freely.
- The person obtaining consent signs and dates the consent form on the “Person Obtaining Consenter’s Signature” line.
- Signed copies are given to the subject.

4.8 **Subjects Who Cannot Talk or Write**

To enroll subjects who understand English but who are unable to talk or write due to physical limitations, investigators must assess the subject's ability to understand the consent materials and to indicate their wish to participate or not. The subject may be entered into the study if the person:

4.8.1 Retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally (still competent), and

4.8.2 is able to indicate approval or disapproval to study entry

4.8.3 Informed consent should be obtained as follows:

- An impartial witness should be present during the entire consent discussion.
- The IRB-approved consent form should be presented orally and clearly explained by the person obtaining consent
- Sufficient time should be allowed for questions to be asked if the subject is capable of doing so. The person obtaining consent should ask questions to ensure the subject comprehends the consent information.

4.8.4 If the subject indicates agreement to participate in the study, informed consent should be documented as follows:

- The consent form should be annotated by hand to describe the method used for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the study.
- Consider using a video tape recording to further document the consent discussion.
- The witness signs and personally dates the consent form on the "Witness Signature" line. By doing so, the witness attests that the consent information was accurately explained and that the subject apparently understood and informed consent was given freely.
- The person obtaining consent signs and dates the consent form on the "Person Obtaining Consenter's Signature" line.
- Signed copies are given to the subject.

5.0 Documentation:

5.1 The HHC HRPP office will maintain all records related to the implementation of this policy, electronic communications, and notifications to investigators, funding or regulatory agencies, etc.

5.2 Records will be archived for a period of at least six (6) years following the termination or completion of the research activities.

6.0 References:

6.1 45 CFR 46.109(b), 45 CFR 46.111(a)(4), 45 CFR 46.116, 45 CFR 46.117

6.2 21 CFR 50.20, 21 CFR 50.25(a), 21 CFR 50.25(b), 21 CFR 50.27(a), 21 CFR 50.27(b), 21 CFR 56.111(a)(4), 21 CFR 56.111(a)(5)

6.3 ICH-GCP: 2.9, 3.1.5, 4.8.9

6.4 Informed Consent: Obtaining and Documenting Informed Consent of Non-English Speakers (OPRR Memo, 1995)

6.5 OHRP Informed Consent Frequently Asked Questions (http://answers.hhs.gov/ohrp/categories/1566)

6.6 OHRP Tips on Informed Consent (http://www.hhs.gov/ohrp/policy/ictips.html)

6.7 FDA Information Sheets-A Guide to Informed Consent (http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm)

6.8 The Agency for Healthcare Research and Quality (AHRQ) Informed Consent and Authorization Toolkit for Minimal Risk Research - AHRQ Publication No. 09-0089-EF; Current as of September 2009 (http://www.ahrq.gov/fund/informedconsent/)

7.0 Revision History:

Rev #	Initials	Effective Date	Description of Change(s)
01	PMJ	7/1/2011	Conversion to new policy template; elaboration of procedures; expansion of policy based on recent review of available guidance; incorporated new elements of HHC policies on interpretation
02	CLB	3/15/20	General review. Minor updates to institutional process

Elements II.3.F. and III.1.F.