Title:	*Applicable to:	Effective Date:
Enrolling Non-English Speaking Study Participants in Clinical Research Studies	**Beaumont Health**	**03/16/2018**
		Last Periodic Review Date: **03/16/2018**
Policy Owner: **Administrative Director**	Document Type: **Policy**	Functional Area: **IRB and Clinical Research, Research Institute**

***For This Document, Beaumont Health Includes**:
Beaumont Corporate Shared Services
Beaumont Hospital, Dearborn
Beaumont Hospital, Farmington Hills
Beaumont Hospital, Grosse Pointe
Beaumont Hospital, Royal Oak
Beaumont Hospital, Taylor
Beaumont Hospital, Trenton
Beaumont Hospital, Troy
Beaumont Hospital, Wayne
Beaumont Medical Group
Beaumont Pharmacy Solutions
Post Acute Care

I. PURPOSE:

The purpose of this policy is to provide guidelines for obtaining informed consent and authorization at Beaumont Health (BH) from a potential research participant with limited English language proficiency (LEP).

II. SCOPE:

This policy applies to investigators, key personnel, research staff, Institutional Review Board (IRB) members and IRB staff.

III. INTRODUCTION:

Federal regulations require an Institutional Review Board (IRB) to review, approve, require modifications or disapprove human participant research to ensure the protection of the rights and welfare of participants. The IRB of record for Beaumont research may be the Beaumont IRB (BH IRB) or an approved external IRB (see IRB policy *Review by an External Institutional Review Board).*

This policy provides guidance for obtaining informed consent and authorization for Beaumont research involvement from a potential research participant with LEP. Requirements apply regardless of which IRB serves as IRB of record, excepting the policy section with the following header; “When Working with the BH IRB as IRB of Record.” Researchers are also responsible for complying with additional external IRB requirements related to potential LEP, when an approved external IRB serves as IRB of record for a study.

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III. DEFINITIONS:

A. Clinical Language Services (CLS): A department within Beaumont Health providing a model of clinical support to provide equal access to health services through the provision of:

- Qualified medical interpreters for limited English proficiency patients.
- Qualified American Sign Language for Deaf and Hearing Impaired patients and their companions.
- Healthcare document translation.
- Bilingual staff screening, evaluation and qualification.

B. ICAD: Informed Consent and Authorization Document.

C. Informed Consent and Authorization: An ongoing process by which a participant, or their Legally Authorized Representative (LAR) when appropriate, voluntarily confirms willingness to participate in a research project and allow the use of their protected health information, after having been informed of all aspects of the research relevant to the participant's decision to participate.

D. Limited English Proficiency (LEP) Individuals: Individuals whose primary language is not English and who cannot speak, read, write or understand the English language at a level sufficient to permit effective interaction with healthcare providers. In the research context, LEP individuals are unable to effectively communicate in English with key personnel during the research informed consent process and ongoing research participation.

E. Interpreter: An interpreter assists two or more persons, who speak different languages, to communicate orally (or in a signed language) with one another.

F. Qualified Medical Interpreter: A professional interpreter is a bilingual person who has received training in the arts of interpreting (consecutive, simultaneous), healthcare terminology, cultural competency, HIPAA, and is competent in cultural and ethical issues surrounding interpretations. The qualification and training program process is determined and approved by Clinical Language Services.

G. Certified Medical Interpreter (CMI): An interpreter who is certified through rigorous testing by one of the two national agencies (National Board of Certification for Medical Interpreters [NBCMI] or Certification Commission for Healthcare Interpreters [CCHI]) and has obtained the credential of a certified healthcare interpreter or equivalent.

H. Translator: A person who re-writes the content of a text from one language to another.

I. Legally Authorized Representative (LAR): An individual or judicial or other body, authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the research study. In Michigan if an adult is incapable of consenting, then his/her appointed health care representative has the authority to consent. If there is no appointed health care representative, priority will be given to a legal guardian or other court-appointed guardian. If there is no such person, then the prospective subject's spouse, adult daughter or son, either parent, or adult sibling has the authority to consent. For an un-emancipated minor child, a parent or an individual *in loco parentis* (in the position or place of a parent) can consent if there is no legal guardian or other court-appointed representative, or if the legal guardian or court-appointed representative(s) is unavailable. In addition, an adult sibling of a minor can consent if the parent or person acting *in loco parentis* is not available. Use of an LAR for research informed consent and authorization is limited to cognitively impaired, critically ill and minor participants.

IV. POLICY:

It is the policy of BH to protect the rights of all individuals participating in research and to be consistent with federal regulations when a participant has limited ability to understand oral or written English. The goal is to be inclusive and provide each potential participant with the information necessary to make an informed and voluntary decision about participation. For LEP potential participants, additional steps must be taken to ensure the written and verbal information provided is in a language understandable to the potential participant and their consent is truly informed. It is not permissible to exclude eligible participants based on language.

A. Consent Process/Interview.

The consent process/interview must be in a language understandable to the participant or, when appropriate, their Legally Authorized Representative (LAR). The participant's inability to understand English is not justification for using an LAR. **All research informed consent and authorization procedures involving LEP potential participants require: 1) a Qualified Medical Interpreter (QMI), 2) a bilingual witness, 3) a consent provider, and 4) a participant. The QMI may serve as both interpreter and witness.**

Interpreter Requirements*:* Qualified medical interpretation is available throughout BH. The following modes are available, although all modes are not available at every Beaumont facility.

- **CLS Staff Interpreters:** A BH employed, qualified medical interpreter. At the time of this

policy writing, CLS staff interpreters are available only at BH - Dearborn.

- **Agency interpreters:** Qualified medical interpreters provided by screened and approved vendors and available for in-person interpretation.
- **Video Remote Interpreters (VRI):** Qualified medical interpreters available over a secure remote video interpretation platform from an approved vendor using approved devices. My Accessible Real Time Trusted Interpreter (Martti) is BH's approved vendor. The approved devices include a wheeled video screen or iPad.
- **Over the phone interpreting (OPI):** The provision of qualified medical interpreters over a standard phone line connection.

To locate interpreter services at a Beaumont facility, visit the Beaumont.org intranet> Departments/Services>Clinical Language Services>Find an Interpreter at a Beaumont Facility. Should a Beaumont location not be listed, contact Language Services Leadership for guidance.

Use of Adult Family and Friends as Interpreters: Family or other close associates of the research participant should NOT be used as interpreters for research informed consent procedures. Family or close associates may be included in the consent interview, in accordance with the prospective participant's wishes, but should not replace a QMI. Occasionally, a prospective research participant may insist on using a family or other close associate as the interpreter during research informed consent and refuse a QMI. The research team should educate the potential participant regarding the benefits of using a QMI, who is familiar with medical terminology and healthcare issues. If the potential participant continues to refuse a QMI, preferring to use a family member/close associate as interpreter, the refusal should be thoroughly documented in the electronic health record and research record and a QMI must be present to ensure the accuracy and competency of the information delivered. If the potential participant refuses to allow the presence of a QMI, the participant may not be enrolled.

Use of Bilingual, Non-CLS Employees as Interpreters: Bilingual employees, proficient in English and another foreign language and employed in capacities other than medical interpretation, should NOT be used as interpreters for research consent and authorization procedures or other clinical situations, unless they have been deemed "qualified bilingual staff" by CLS. The qualification process involves language skills evaluation and successful completion of a competency exam (refer to Policy *Clinical Language Services; Access Services for Limited English Proficiency Patients*).

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Interpreters must be part of ongoing communication between the LEP participant and research personnel throughout the study. A QMI must be utilized during communications of a clinical nature, including but not limited to:

- Informed consent and reconsent processes
- Explanations of medical or research procedures and test articles
- Participant education and instruction
- Obtaining medical history
- Soliciting participant subjective responses
- Symptom and adverse event assessments.

For non-clinical situations, such as providing parking instructions or general questions regarding demographics/contact information, a QMI is not required and another bilingual person (e.g., family or close associate) may be utilized, in accordance with participant wishes.

Witness Requirements. A bilingual witness must serve as witness to the entire consent procedure and signature for LEP participants. The witness signature indicates the witness is attesting to their presence during the entire consent discussion and procedure and witnessed the participant sign the ICAD. The witness is also attesting the information in the ICAD (and any other written information) was accurately explained to and apparently understood by the participant, and informed consent was freely given by the participant. The witness must be bilingual (i.e. fluent in both English and the language best understood by the participant.). Additionally, the witness must be a BH physician, employee, student, intern/observer, volunteer or key personnel (approved by BH Administrative Review or BH IRB), or participant family member/close associate.

B. Informed Consent and Authorization Document for Limited English Proficiency (LEP) Participants

The regulations provide **two consent document options** to obtain informed consent and authorization from individuals who do not understand English:

1. A Translated version of the full English language consent (preferred) **or**
2. The "Short form" consent option.

1. Translated Version of the Full English Language ICAD*

Whenever possible, an ICAD written in a language understood by the prospective research participant should be utilized. This document must include all elements of informed consent and be approved by the IRB of record prior to use. The translated ICAD must directly mimic the content and format of the English language version of the document, with the only difference being the language in which the document is written. **The written translation must be completed by a professional translator.**

Costs associated with the written translation process are charged to the study's PeopleSoft department ID. If the study is unfunded, the PI must identify an alternate source to cover the expense. Contact the CLS for additional guidance on the translation.

If a study expects to enroll LEP participants, a translated version of the ICAD in the expected language must be obtained and submitted to the IRB at the time of initial IRB Application.

2. **Short Form Consent***

Although the use of a translated version of the full original, English-language ICAD is preferred, this is not always possible. Federal regulations permit verbal presentation of the informed consent information in conjunction with a **Short Form Consent document**. The Short Form Consent is only for occasional and unexpected enrollment of an LEP participant in a study for which no consent document in the participant's language has been prepared. The one-page Short Form Consent document is a standard document, written in the participant's own language, which describes research participation in general and contains the basic elements of informed consent. There are no study-specific details in the Short Form Consent. Study-specific information must be provided verbally by the interpreter, who interprets the consent provider's statements (see section regarding the Consent Process/Interview). Additionally, **an IRB-approved written summary** of what is said to the participant must be used; the IRB-approved English version informed consent document may be utilized.

When a researcher intends to utilize a Short Form Consent document, a document approved by the IRB of record overseeing the specific study must be obtained. Copies of both the signed IRB-approved Short Form Consent document and the English language ICAD must be given to the participant and placed in the participant's medical record. The original, signed documents are placed in the participant's research record.

*** A QMI and bilingual witness must be utilized during the informed consent and authorization process regardless of the type of consent document utilized. The QMI and bilingual witness can be the same person.**

When Working with the BH IRB as IRB of Record: The BH IRB maintains approved versions of the Short Form Consent documents in several languages on the IRB web site, for use when: 1) BH IRB is IRB of record for a specific study, and 2) the need to enroll LEP participants was not anticipated.

The Short Form Consent documents posted on the BH IRB website may be used without prior approval BH IRB approval. If a Short Form Consent is not provided on the IRB

website in the participant's language, the PI must obtain a translation as described above. The addition of a new Short Form Consent in a new language must have IRB approval prior to use; refer to Appendix A for an English version.

When the BH IRB serves as IRB of record for a particular study, two (2) or more uses of the Short Form Consent in the same foreign language may indicate a translated version of the English-language ICAD should be developed and approved by the BH IRB.

When the need for a Short Form Consent document is identified and BH IRB is <u>not</u> IRB of record, the research team must obtain a document from the external IRB.

Signature Requirements for the Short Form Consent. There are specific signature requirements when obtaining consent through the use of a foreign language Short Form Consent document. The process involves 2 documents: 1) The Short Form Consent, and 2) the IRB-approved, written summary (the approved English version consent document).

<u>The Short Form Consent document must be signed by **all** of the following</u>:

a. The participant,
b. The QMI*, **and**
c. The bilingual witness **

The consent provider does not sign the short form consent

<u>The written summary (English language BH IRB-approved ICAD) must be signed by:</u>

a. The authorized consent provider,
b. The QMI*, **and**
c. The bilingual witness**

* *When the QMI used is VRI (e.g., Marrti), the consent provider writes "Marrti" in the interpreter signature field. When the QMI used is OPI, the consent provider writes the interpreter ID # in the interpreter signature field.*

** *The interpreter and bilingual witness may be the same person.*

C. Documentation of the Informed Consent Process

Documentation of informed consent must include the **executed consent document** (translated full English version **or** Short Form Consent with English written summary) **<u>and</u>** a **consent process note** in the electronic health record or research record. The consent process note must include the elements described in IRB policy *Informed Consent and Authorization in Research*. Additionally, the consent process note for LEP participants must include <u>all</u> of the following:

a. LEP status of the participant and their primary language.

b. **Type of consent document** utilized-full translated ICAD **or** Short Form Consent with written summary (English version of consent document).
c. Statement that copy(s) of consent document(s) were provided to participant.
d. Identity of the **QMI** and description (i.e., CLS Staff Interpreter, Agency, VRI or OPI). Identification numbers provided by VDL (Marti) or OPI.
e. Identity of the **witness,** description of their bilingual status and statement of their presence throughout the entire consent interview. If the QMI serves as both interpreter and witness, this should be stated.
f. Description of the consent process (e.g., describe those present during the interview, specific questions/concerns raised by the participant or LAR, information provided and participant's response).

D. Questionnaires and other documents: When LEP participants join research studies involving self-completion questionnaires, educational material, diaries or other documents directed to participants, the documents must be translated into the participant's language. The translated questionnaires or other documents must contain identical content to the English versions, to obtain comparable responses from LEP participants. Written, translated documents must be approved by the IRB of record prior to use. The same translation process is utilized for research questionnaires as for translating the ICAD (described above). Verbal administration of a questionnaire in a language understood by the participant or the participant's LAR is permitted. However, verbal administration must be completed by a QMI if the information gathered is clinical in nature.

V. REFERENCES:

21 CFR 50.25 General Requirements for Informed Consent
21 CFR 50.27 Documentation of Informed Consent
21 CFR 56.108(b) IRB Functions and Operations
21 CFR 56.111 Criteria for IRB Approval of Research
45 CFR 46.108(b) IRB Functions and Operations
45 CFR 46.111 Criteria for IRB Approval of Research
45 CFR 46.116 General Requirements for Informed Consent
45 CFR 46.117 Documentation of Informed Consent
Guidance for Industry, E6 Good Clinical Practice
Memorandum from Melody H. Lin, Ph.D., Director, Division of Human Subject Protections, OHRP to Professional Staff, OHRP, dated 9 November 1995, *SUBJECT: OBTAINING AND DOCUMENTING INFORMED CONSENT OF SUBJECTS WHO DO NOT SPEAK ENGLISH*

Limited English Proficiency (LEP).gov. A Federal Agency Website
FDA Information Sheet: A Guide to Informed Consent, January 2016.
DHHS policy guidance on Title VI of the Civil Rights Act of 1964 regarding services to LEP patients
Non-Discrimination Provision Section 1557 of the Affordable Care Act (ACA)

VI. ASSOCIATED POLICIES:

IRB and Clinical Research Policy Informed Consent and Authorization in Research
IRB and Clinical Research Policy Vulnerable Populations - Enrollment of Decisionally Impaired Participants
Founding Beaumont Patient Care Policy 304 *Informed Consent*
Beaumont Health Policy Clinical Language Services: Language Access Services for Limited English Proficiency (LEP) Patients
Beaumont Health policy Clinical Language Services: Healthcare Documents Translation Services
The Joint Commission Patient Centered Communication Standards
DHHS Office of Minority Health Culturally and Linguistically Appropriate Standards (CLAS)

CORPORATE AUTHORITY:

Beaumont Health ("BH") as the corporate parent to William Beaumont Hospital, Botsford General Hospital, and Oakwood Healthcare Inc., ("Subsidiary Hospitals") establishes the standards for all policies related to the clinical, administrative and financial operations of the Subsidiary Hospitals. The Subsidiary Hospitals, which hold all health facility and agency licenses according to Michigan law, are the covered entities and the providers of health care services under the corporate direction of BH. The Subsidiary Hospitals' workforces are collectively designated as BH workforce throughout BH policies.

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APPENDIX A

SAMPLE SHORT FORM WRITTEN CONSENT DOCUMENT FOR PARTICIPANTS WHO HAVE LIMITED ENGLISH PROFICIENCY

This document must be written in a language understandable to the subject

Consent to Participate in Research

[Study title, in English]

IRB #:_____

You are being asked to participate in a research study.

Before you agree, the investigator must tell you about (i) the purposes, procedures, and duration of the research; (ii) any procedures which are experimental; (iii) any reasonably foreseeable risks, discomforts, and benefits of the research; (iv) any potentially beneficial alternative procedures or treatments; and (v) how confidentiality will be maintained.

Where applicable, the investigator must also tell you about (i) any available compensation or medical treatment if injury occurs; (ii) the possibility of unforeseeable risks; (iii) circumstances when the investigator may halt your participation; (iv) any added costs to you; (v) what happens if you decide to stop participating; (vi) when you will be told about new findings which may affect your willingness to participate; and (vii) how many people will be in the study.

If you agree to participate, you must be given a signed copy of this document and a written summary of the research.

You may contact *name* at *phone number* any time you have questions about the research.

You may contact *name* at *phone number* if you have questions about your rights as a research subject or what to do if you are injured.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.

_____ _____ _____ _____

Signature of Participant Date Signature of Witness Date

_____ _____

Signature of Interpreter Date