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PURPOSE

The purpose of this policy is to provide guidelines for obtaining informed consent and authorization from a potential research participant who is unable to understand (speak or write) the English language.

SCOPE

This policy applies to investigators, key personnel, research staff, Human Investigation Committee (HIC) members and HIC staff.

BACKGROUND

Federal regulations require an Institutional Review Board (IRB) to review and have the authority to approve, require modifications or disapprove all research activities involving human participants. The HIC is the IRB of record for Beaumont Health System (BHS). The HIC is responsible for protecting the rights and welfare of research participants. This is accomplished in part, through the review, and approval of a written informed consent and authorization document (ICAD) summarizing the procedures, risks and potential benefits of the study.

POLICY

It is the policy of BHS to protect the rights of all individuals participating in research and to be consistent with regulations when a participant is unable to speak or read English. The goal of the HIC is to be inclusive and provide each participant with the information necessary to make an informed and voluntary decision about participation. When a potential participant who does not speak or read English is being considered for a research study, additional steps must be taken to ensure the written and verbal information provided is in a language understandable to the potential participant or appropriate translation procedures are followed. It is not permissible to exclude eligible participants on the basis of language.

Informed Consent Document for Non-English Speaking Participants

The regulations provide **two consent document options** to obtain informed consent and authorization from potential study participants who are unable to understand English:
1. A translated version of the full English language consent (preferred) **or**
2. The "short form" consent option.

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 to obtain informed consent. This document must include all elements of informed consent (refer to HIC Policy #221 *Informed Consent and Authorization in Research)* and must be approved by the HIC 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, certified translator.** Costs associated with the written translation process are charged to the study's responsibility center (RC). If the study is unfunded, the principal investigator (PI) must identify an alternate source to cover the expense.

If a study expects to enroll non-English speaking participants, a translated version of the ICAD in the expected language must be obtained and submitted to the HIC at the time of initial HIC Application. A

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translator/interpreter and bilingual witness must be utilized during the informed consent and authorization process regardless of the type of consent document utilized, as described below in the section entitled "Consent Process/Interview."

Short Form Consent

Although the use of a translated version of the full original, English-language ICAD is preferred, the HIC acknowledges this is not always possible. Federal regulations permit verbal presentation of the informed consent and authorization information in conjunction with a Short Form Consent document (see Appendix A). 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 translator/interpreter, who interprets the consent provider's statements (see below for instruction on the consent interview). The HIC maintains approved versions of the Short Form Consent documents in several languages on the HIC web site for use by investigators who did not anticipate the need to enroll non-English speaking participants. The Short Form Consent may be used without prior approval by the HIC. If a Short Form Consent is not provided on the HIC 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 HIC approval prior to use.

The Short Form Consent is **only for occasional and unexpected** enrollment of a non-English speaking participant in a study for which no consent document in the participant's language has been prepared. 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 HIC. **Each use of a Short Form Consent must be reported to the HIC within five (5) business days of occurrence via an HIC Amendment Request Form.**

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 Short Form Consent document must be signed by **all** of the following:

1. The participant, **and**
2. The witness to the verbal translation of the ICAD, **and**
3. The translator*, **and**
4. The consent provider.

The English language HIC-approved ICAD must be signed by:

1. The participant, **and**
2. The authorized consent provider, **and**
3. The witness to the oral translation of the ICAD, **and**
4. The translator*.

*When the Martti system is used to interpret, the consent provider writes "Maarti" in the translator signature fields. For more information about using Martti, see page 5 of this policy.

Copies of both the signed HIC 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.

Consent Process/Interview

The consent process/interview must be conducted in a language understood by the participant or their LAR. Guidance on appropriate use of an LAR to provide consent may be found in HIC Policy #243 *Vulnerable Populations: Enrollment of Cognitively Impaired Subjects.* **The participant's inability to understand English is not justification for using an LAR.** The consent interview must include a bilingual translator/interpreter and bilingual witness (both further described below), the consent provider and the participant. **Both the translator/interpreter and witness must be bilingual and may not be the same person.**

Translator/Interpreter Requirements

A translator/interpreter, fluent in both English and the language best understood by the participant or their LAR, **is required during <u>all</u> non-English speaking participant consent procedures**, regardless of whether a translated full consent or a Short Form Consent is used. Additionally, translators/interpreters should be part of ongoing communication between the participant and research personnel throughout the study, to assist with verbal and written translation as needed. When the consent provider is bilingual, speaking and writing both English and the participant's language, the consent provider may also serve as both translator/interpreter and consent provider. Otherwise, whenever possible, the translator/interpreter should be a professional provided through BHS Nursing Resource Office (248-898-0933) or an approved vendor known to Research Administration. The Martti system may be used for these interpretation needs (see page 5 for more details). Costs associated with use of oral translator/interpreter are charged to the study's responsibility center (RC); if the study is unfunded, the PI must identify an alternate source to cover the expense. Alternative oral translator/interpreters, such as a BHS healthcare provider or relative/close associate of the participant, fluent in the participant's language, may only be used when the BHS Nursing Office or Research Administration has been contacted and is unable to provide a professional and the Martti system is unavailable. The consent provider must be present during the consent process in order to answer any questions posed by the participant, their LAR or the translator/interpreter.

Individuals Serving as Translator/Interpreter:

a) **When a Professional (Serving as Translator/Interpreter) is Used**

This is the most common scenario. The consent interview will include the following individuals:

1. A consent provider,
2. A professional translator/interpreter provided by BH Nursing Office or vendor known to Research Administration,
3. A witness fluent in both English and the language best understood by the participant (and their LAR when applicable). A professional translator/interpreter or bilingual health care provider is preferred.

The witness may be related to or a close associate of the participant, if bilingual.

4. The research participant (and their LAR when applicable).

b) **When a Bilingual Consent Provider Serves as Translator/Interpreter**
When the consent provider is bilingual, speaking and writing both English and the participant's language, the consent provider may serve as both translator/interpreter and consent provider. The consent provider must document these details in the participant medical chart or research record. The consent interview will include the following individuals:

1. A bilingual consent provider, who also serves as translator/interpreter,
2. A witness fluent in both English and the language best understood by the participant (and their LAR when applicable). A professional translator/interpreter or bilingual health care provider is preferred. The witness may be related to or a close associate of the participant.
3. The research participant (and their LAR when applicable).

c) **When the Martti System is Used for Translation**
When the Martti system is used for translation, the consent interview will include the following:

1. The consent provider,
2. The interpretation system, Martti*
3. A witness fluent in both English and the language best understood by the participant (and their LAR when applicable). A professional translator/interpreter or bilingual health care provider is preferred. The witness may be related to or a close associate of the participant, if bilingual.
4. The research participant (and their LAR when applicable).

*Use of Martti for interpretation must be documented in the consent note. See page 5 for more information on using Martti.

d) **When a Bilingual Relative or Close Associate of the Participant Serves as Translator/Interpreter -** Although the HIC discourages the use of a translator/interpreter/interpreter related to, or closely associated with the participant, the HIC acknowledges this may be the only option in some cases. When BHS Nursing Office is unable to provide a professional translator/ interpreter, the Martti system is unavailable and no bilingual BHS healthcare provider is available, an individual related to or a close associate of the participant may be used as translator/interpreter/interpreter. The consent interview will involve the following individuals:

1. The consent provider,
2. The translator/interpreter who is a bilingual relative or close associate of the participant,
3. The witness who must be a bilingual Beaumont employee/physician. When a relative or close associate of the participant serves as translator/interpreter/interpreter, a relative or close associate of the participant ***may not*** serve as witness,
4. The research participant (and their LAR when applicable).

Witness Requirements
The **witness** to the informed consent must serve as **witness to the entire**

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informed consent process, not signature only, regardless of whether a written translated full consent or a Short Form Consent with verbal translation of the full consent is used. The witness must be **bilingual**, fluent in both English and the participant's language in order to witness the information being presented is understood. The witness **should** be a bilingual BHS employee/physician or a professional translator/interpreter provided by BHS Nursing Office. When it is not possible to have a BHS employee, professional translator/interpreter serve as the witness, the witness may be related to or a close associate of the participant or their LAR, except when a bilingual family member/close associate serves as translator (as described under "d)" on page 4). In these cases, the witness **must** be a bilingual BHS employee or professional translator interpreter - not a family member/close associate. The witness certifies a verbal presentation was made to the participant or their LAR, in a language understood by the participant, describing the content of the English language ICAD.

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 oral translation of the original English version ICAD) and a consent process note in the medical record or research record. The consent process note must include the elements described in HIC policy #221 *Informed Consent and Authorization in Research.* Additionally, the consent process note for non-English speaking participants must include all of the following:

- The non-English speaking status of the participant and their primary written/spoken language.
- The type of consent document utilized (full translated ICAD **or** Short Form Consent with oral translation of the original English ICAD). If a Short Form Consent is used, include reason for unavailability of translated full version of the English document.
- Identity of the **translator/interpreter** and description of their qualifications to serve as translator/interpreter (e.g., professional translator/interpreter provided by Nursing Office, native speaker with scientific background, etc.). If the Martti system is used, indicate this use in the consent process note. If the translator/interpreter is not a professional known to Nursing Office/Research Administration and the Martti system is not used, explain why this occurred. If the consent provider is bilingual and served as both translator/interpreter and consent provider, this should be fully described.
- Identity of the **witness,** description of their bilingual status and statement of their presence throughout the entire consent interview.
- 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).

Use of Martti System

Martti is an acronym for **M**y **A**ccessible **R**eal **T**ime **T**rusted **I**nterpreter, a remote video interpretation platform available throughout Beaumont in patient care areas. To request a Martti system, contact the Nursing unit or clinical department serving the potential research participant and be prepared to provide the name and room number of the potential participant. If the

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machine is unavailable, contact Nursing Resource Office (248-898-0933) to request a loaner. The machines cannot be reserved in advance. Beaumont Wi-Fi is required. Martii may be used for non-English speaking participant consent procedures, regardless of form type used (full translated ICAD versus short form). Use of Martti for translation must be documented in the consent process note. The consent provider should write "Martti" in the translator signature fields on both the short form and full ICAD. **Use of the Martti system must be reported to the HIC within 5 days of occurrence via an HIC Amendment Form.**

Questionnaires

When participants who do not understand the English language are involved in research studies which require self completion questionnaires, it is important for the questionnaires to be translated into a language the participant understands. It is also important for the translated questionnaires to contain identical content in order to obtain comparable responses from non-English speaking participants.

Written research questionnaires translated into languages other than English must be approved by the HIC prior to use. The same translation process is utilized for research questionnaires as for translating the ICAD (described above). The written questionnaire must mimic the English language version in content and format.

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 person fluent in both English and the other language.

Other Documents

If the research involves non-English-speaking participants and includes verbal scripts, educational materials, advertisements, or other documents in addition to the ICAD and questionnaires, the PI must describe in the HIC Application, measures which will be taken to ensure each participant's comprehension of this material.

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*
FDA Information Sheet: A Guide to Informed Consent, September 1998.

ASSOCIATED POLICIES

HIC Policy 221 *Informed Consent and Authorization Process*

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HIC Policy 243 *Vulnerable Populations: Enrollment of Cognitively Impaired Participants*
Beaumont Patient Care Policy 304 *Informed Consent*
Beaumont Patient Care Policy 316 *Interpreters for Patients with Limited English Proficiency*
Beaumont Patient Care Policy 316.1 *Obtaining Interpreters for Patients with Limited English Proficiency*
Beaumont Patient Care Policy 359 *Translating Written Material*

☐ Original ☒ Revision or Review

Research Institute Compliance Committee Review Date: _____

Corporate Administration Approval: _____ Date: _____
VP of Research or Chief Medical Officer

Research Institute Board Approval: _____ Date: _____

Research Administration Approval: _____ Date: _____
Administrative Director

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APPENDIX A

SAMPLE SHORT FORM WRITTEN CONSENT DOCUMENT FOR PARTICPANTS WHO DO NOT SPEAK ENGLISH
This document must be written in a language understandable to the subject

Consent to Participate in Research

[Study title, in English]

HIC #:_____

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 Translator/interpreter	Date