

Title: <b>Informed Consent and Authorization in Research</b>	*Applicable to: <b>Beaumont Health</b>	Effective Date: <b>03/16/2018</b>
		Last Periodic Review Date: <b>03/16/2018</b>
Policy Owner: <b>Administrative Director</b>	Document Type: <b>Policy</b>	Functional Area: <b>IRB and Clinical Research, Research Institute</b>

**\*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 describe the requirements for obtaining informed consent and authorization of research participants involved in research studies at Beaumont Health. Detailed steps consent providers must follow to conduct consent procedures in compliance with this policy are listed on pages 17-19 below.

**II. SCOPE:**

This policy applies to investigators, key personnel, research staff and IRB staff.

**III. BACKGROUND:**

A. The ethical conduct of research involving human participants is based on voluntary, informed consent of the participant. It is the responsibility of the IRB of record to require individuals considering participation in research, or the individual’s legally authorized representative (LAR) when appropriate, are provided with the information needed to make an informed decision about participation in the research, in accordance with Federal regulations. **The IRB of record may be Beaumont IRB or an approved external IRB.** The IRB can **waive or alter the consent process** by determining the criteria for such waivers or alterations are met. Additionally, the IRB can **waive the requirement to document the consent process** by determining the regulatory criteria for such waivers are met. The consent process provides the participant, or participant’s LAR when appropriate, with:

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1. A thorough explanation of what is involved in study participation, including any risks or benefits associated with participation;
2. Sufficient opportunity to consider all aspects of the research and whether or not to participate;
3. The opportunity to ask and receive answers to any questions about the research, thus minimizing the possibility of coercion or undue influence; **AND**
4. The opportunity to authorize or decline use and disclosure of the participant’s protected health information.

Informed consent and authorization is an ongoing process, involving more than the participant’s signature on the consent document. Participants, or their LAR, must be informed of new information about the research, as it becomes available, which may affect their willingness to continue participation.

**Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable Federal, State, or local law.**

**IV. DEFINITIONS:**

- A. **Assent** -To express acceptance or agreement. Mere failure to object may not, without affirmative agreement, be construed as assent. For child participants in research, assent is a child’s affirmative agreement to participate in a clinical investigation.
- B. **Children/Minors** - According to Federal regulations, children are “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.” In Michigan, the legal age for consent is 18 years of age.
- C. **Emancipated Minor** - A child who is legally recognized as an adult under Michigan law in the following circumstances: 1) when the minor is married, 2) during the period when the minor is on active duty with the armed services of the United States, or 3) emancipation by court order. Emancipated minors, as authorized by the State of Michigan, may provide informed consent for their own research involvement.
- D. **ICAD** - Informed Consent and Authorization Document.
- E. **Information Sheet** - A document given to the participant containing the applicable elements of informed consent, which does not require a signature. Information sheets may be utilized in circumstances when waiver of consent documentation has been granted by the IRB.

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- F. **Informed Consent and Authorization** An ongoing process by which a participant, or their 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.
- G. **Oral Consent** - Process of obtaining informed consent verbally, without the use of a written ICAD, when prospectively approved by the IRB for a specific study. Generally, the IRB will consider this only for minimal risk research when a waiver of documentation has been granted.
- H. **Witness – Three special circumstances require a witness to research informed consent. These special circumstances are: 1) consent of a non-English speaking (low English proficiency) participant, 2) consent of an illiterate participant, and 3) consent of a visually impaired participant (unable to read the ICAD).** In these circumstances, a witness to the *consent process* is required i.e., **the witness serves as “witness to the entire consent procedure and signature.”** The witness’ signature indicates the witness is attesting to their presence during the entire consent discussion 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 signature of a witness is required on the ICAD in these special circumstances.

Witness when participant is **Non-English speaking** (possesses low English proficiency): **The witness must be fluent in both English and the language best understood by the participant.** Additionally, the witness must be either 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.

Witness when potential participant is **unable to read the consent document due to low literacy or visual impairment:** The witness must be **IMPARTIAL.** The witness must be a BH physician, employee, student, intern/observer or volunteer who is NOT key personnel or otherwise associated with the study. The witness must NOT be a participant family member/close associate of the participant.

Summary of Witness Requirements	Bilingual	Impartial
Non-English Speaking (Low English Proficiency)	√	
Illiterate (Low Literacy)		√
Visually Impaired (Unable to Read ICAD)		√

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- I. **Consent Provider** - An individual designated by the principal investigator (PI) to obtain informed consent and authorization. When BH IRB serves as IRB of record, consent providers must be listed on the study-specific IRB approved key personnel roster prior to consenting. The BH IRB verifies adequate training and education prior to approving any key personnel. When an approved external IRB serves as IRB of record, consent providers must be approved as part of the Beaumont Administrative Review process. The administrative reviewer verifies adequate training and education prior to approving any key personnel.

Regardless of which IRB serves as IRB of record, listing an individual as a consent provider indicates the PI has adequately trained the individual to obtain consent, including identification of all risks and benefits, and reflects they are knowledgeable about the study and able to answer questions. The consent provider must be listed on the delegation of authority log/site signature log in the investigator’s file as a consent provider and acknowledged/approved to provide consent by the Beaumont IRB prior to consenting a participant.

- J. **Legally Authorized Representative (LAR)** -

A Legally Authorized Representative (LAR) is an individual authorized to consent on behalf of a prospective participant for her/his involvement in research. An LAR may consent on behalf of the participant only when it has been determined the participant does not have the mental capacity to knowingly and willingly make an informed decision, in accordance with Founding Beaumont Patient Care Policy 304 *Informed Consent*; Founding Oakwood Policy 1005 *Informed Consent Policy and Process for Verification of Informed Consent for Surgical/Medical and Other Procedures*; Founding Botsford Policy C118P *Consent Policy, Informed*.

Legally Authorized Representatives may include, in order of authority:

1. **Patient advocate pursuant to Durable Power of Attorney (DPOA) for health care:** A DPOA for health care is a written document by which a competent adult patient has given the power to make medical or psychiatric treatment care decisions on behalf of the patient when the patient is unable to participate in treatment decisions. The designated adult is called the patient advocate. If a DPOA is executed and the patient/potential participant is subsequently found to be incompetent, the consent of the patient advocate is necessary for participation in a research study. Before the patient advocate can make treatment or participation decisions for the patient, the patient advocate must sign an Acceptance Form and both the DPOA and the Acceptance Form must be in the participants’ medical record.
2. **Legal Guardian:** A Legal Guardian is appointed by a Court. The Legal Guardian is provided a letter or order by the Court documenting the scope of authority. A copy of the letter must be in the medical record or provided at the time of consent in order for the Legal Guardian to consent for the participant. If provided at the time of consent, the consent provider must make a copy of the letter for the medical and research records. It is the

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consent provider’s responsibility to confirm guardianship prior to obtaining consent, which is accomplished by reviewing the documentation to assure the Legal Guardian has the authority to provide consent for the participant.

3. **Family:** If it is determined a participant is incompetent and there is not a Court appointed Legal Guardian or a DPOA, the next of kin may consent to research participation provided all of the following conditions are met:
  - a. The investigator believes the research treatment should not be delayed until the participant recovers sufficiently to give consent.
  - b. The investigator documents the reason(s) in the participants’ medical and/or research record.
  - c. The participant’s prior wishes are known by the next of kin, even if not documented, and are consistent with participation; or, in the event the wishes are not known, neither the physician nor the next of kin knows the participant would be opposed to participating given the specific set of circumstances.

Family members, in order of decreasing authority, include (used only when no court appointed guardian or DPOA for health care exists):

- 1) Spouse
- 2) Adult daughter or son
- 3) Either parent
- 4) Adult sibling.

K. **Prisoner of War** - A person taken by or surrendering to enemy forces in wartime.

L. **Vulnerable Participants** - Persons incapable, due to an innate characteristic, of making an informed decision about participating in research or those at increased risk of undue influence or coercion related to their decision to participate. Vulnerable populations include, but are not limited to: unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, fetuses, neonates, students, employees, individuals with limited verbal or written English language communication skills, or cognitively impaired individuals.

## V. POLICY:

- A. The PI is responsible for all verbal and written consent and authorization processes conducted personally or by their designated consent providers. The PI and all consent providers must obtain informed consent and authorization in the manner described in the IRB-approved protocol and Application. All materials presented to participants, including the ICAD, information sheet(s) and other materials or methods employed, must be approved by the IRB prior to use. The IRB has the final authority regarding the content of the ICAD and can make

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the determination to waive or alter informed consent. The IRB may request or conduct observation and/or monitoring of the informed consent and authorization process.

- B. The IRB may require information be given to prospective participants, in addition to specified applicable regulations and/or the sponsor when, in the IRB’s judgment, the information meaningfully adds to the protection of the participants’ rights and welfare. The information given to the participant, or the LAR when appropriate, should be in language understandable to the participant or LAR. No informed consent and authorization, whether oral or written, may include any exculpatory language through which the participant or LAR is made to waive, or appear to waive, any of the participant’s legal rights, or releases or appears to release the investigator, sponsor, institution or its agents from liability for negligence.
- C. Informed consent must be obtained for every participant in a research study before the participant begins any aspect of research participation (i.e., prior to performing any research activities or procedures, including screening tests done exclusively for the purposes of research eligibility), unless a waiver of consent has been approved. In general, informed consent and authorization procedures are conducted in person utilizing a written IRB-approved ICAD. Variations may occur, as described in the section below entitled “Informed Consent Variations.” Except where explicitly stated, variations may only occur with prospective IRB approval.
- D. The signed original ICAD is a legal document. The PI must store these documents securely and in a readily retrievable manner, in compliance with IRB Policy *Research Record Retention* and Clinical Research SOP *Regulatory Files and Study Participant Records*.
- E. Generally, email should not be used to convey a signed ICAD to researchers, unless the participants have access to Secure Email.

**VI. CONSENT FROM THE PARTICIPANT’S LEGALLY AUTHORIZED REPRESENTATIVE:**

The participant’s informed consent is a vital component of the research process. If the participant suffers temporary or permanent cognitive impairment which interferes with his/her ability to provide informed consent, the consent provider may approach the participant’s LAR to obtain consent to enroll the participant in a research study, consistent with IRB Policy *Vulnerable Populations: Enrollment of Cognitively Impaired Participants*. Inclusion of cognitively impaired participants is approved by the IRB on a study-by-study basis.



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**VII. CONSENT PROVIDERS:**

- A. If permitted by the IRB (and sponsor where applicable), the consent process may be delegated to approved key personnel the PI designates as consent providers. When the BH IRB is IRB of record for a study, consent providers are listed on the IRB application and approved by the IRB. When an external IRB serves as IRB of record for a study, consent providers are listed in the Administrative Review application and approved during administrative review. The PI is responsible for assuring all consent providers have received protocol-specific training in addition to training regarding obtaining informed consent and authorization.
- B. Consent providers are authorized to obtain informed consent and authorization based upon the degree of risk related to study participation. Non-physician key personnel may obtain informed consent and authorization from potential research participants in the following circumstances:
  - 1. Studies in which the **test article is a medication** may only rely on Research Nurse Clinicians as consent providers. In limited circumstances, IRB and Research Administration approval may be granted to non-Research Nurse Clinicians as described in letter “D” below.
  - 2. Studies in which the **test article is a device**, may have Research Nurse Clinicians or Clinical Research Coordinator II as consent providers.
  - 3. Studies which are **non-treatment studies**, i.e., no study article involved, but may **involve some risk** (e.g., imaging study with contrast) may have Research Nurse Clinicians, Clinical Research Coordinator II or Clinical Research Coordinator I as consent providers.
  - 4. Studies which are **data collection, no intervention trials and pose no risk** to participants (e.g., interview, chart review) may have Research Nurse Clinicians, Clinical Research Coordinator II, Clinical Research Coordinator I or Clinical Research Assistant II as consent providers.
- C. The suitability of individuals, who do not fall into one of these Research Institute (RI) job classifications, to obtain informed consent and authorization will be determined by the IRB or Administrative Reviewer. Non-Research Institute employees who are not physicians or physician extenders (e.g., NP, PA) must complete consent training prior to consenting a participant.
- D. In limited circumstances, IRB or Administrative Review and Research Administration approval may be granted to allow delegation of obtaining informed consent for studies involving medications to key personnel other than a licensed physician, physician extender or registered nurse. The licensed nurse professional may directly delegate this selected function provided the key personnel must:
  - 1. Have continuous availability of direct communication with supervising individual;
  - 2. Be provided ongoing guidance and oversight;

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3. Be deemed to have the education, experience and training to accept the delegation and obtain informed consent;
  4. Be educated regarding the scope of duties; **AND**
  5. Understand and can answer questions about the information included in the ICAD.
- E. Performance of the informed consent and authorization process by non-licensed professionals for studies involving medications should be observed and documented. The oversight by a licensed health professional (nurse or physician) must be ongoing.

**VIII. ELEMENTS OF INFORMED CONSENT:**

- A. In accordance with the Federal regulations, the **basic elements** required in the ICAD utilized for research involving greater than minimal risk include:
1. A statement that the study involves research.
  2. An explanation of the purposes of the research.
  3. The expected duration of the participant’s participation.
  4. A description of the procedures to be followed.
  5. Identification of any procedures which are experimental.
  6. A description of any reasonably foreseeable risks or discomforts to the participant.
  7. A description of any benefits to the participant or to others which may reasonably be expected from the research.
  8. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
  9. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. For FDA-regulated research, a statement that there is a possibility the FDA might inspect the records.
  10. An explanation as to whether any compensation and/or any medical treatments are available if injury occurs, and if so what they consist of, or where further information may be obtained.
  11. An explanation of whom to contact for answers to pertinent questions about the research and research participants’ rights, and whom to contact in the event of a research-related injury to the participant.
  12. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.
  13. A statement the participant is not forfeiting any legal rights.



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B. When appropriate, one or more of the following **additional elements** are required in the ICAD:

1. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus), which are currently unforeseeable, if the participant is or may become pregnant.
2. Anticipated circumstances under which the participant’s participation may be terminated by the PI without regard to the participant’s consent.
3. The amount and schedule of payments, when appropriate.
4. Any additional costs to the participant that may result from participation in the study.
5. The consequences of a participant’s decision to withdraw from the research and procedures for orderly termination of participation by the participant.
6. A statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided to the participant.
7. The approximate number of participants involved in the study.
8. A statement indicating a description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law.

**IX. WRITTEN INFORMED CONSENT AND AUTHORIZATION DOCUMENT:**

- A. In general, informed consent must be documented using a written ICAD which has been prospectively IRB approved, unless a waiver of consent or waiver of consent documentation has been approved. The document should be written at the 6th-8th grade reading level in language understandable to the research participant. The document must be reviewed with the research participant, or LAR when appropriate, as part of the consent process. It is preferred all ICADS are developed using the BH IRB informed consent/assent template(s) or, the BH-external IRB approved templates. When another template is utilized to draft the ICAD (e.g., sponsor template), all elements of the IRB template must be included. Any changes proposed to the standard language of the IRB consent templates must be approved by the IRB or, when an approved external IRB serves as IRB of record, the Beaumont Administrative Reviewer. If vulnerable participants are to be included in the research, the following policies should be consulted for special considerations: IRB Policy *Vulnerable Populations: Children as Research Participants*; IRB Policy *Vulnerable Populations: Enrollment of Cognitively Impaired Participant*.
- B. **IRB Approval Stamp** - The ICAD will be stamped by the IRB; the format and specific details of the stamp vary with each IRB of record. The most current version of the IRB-approved ICAD, **bearing the IRB-approval stamp**, must always be used. For BH IRB documents, the current ICAD version expires at midnight on the date of expiration. Previously consented participants

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are not required to sign a revised consent unless required by the BH IRB (see section below “Revisions to the ICAD” for more detail). Each document revision must bear the version date and IRB-assigned project number (e.g., IRB 2017-061). Upon approval, the ICAD and IRB approval letter will be forwarded electronically to the PI and designated key personnel, for immediate use.

- C. **Revisions to the Informed Consent and Authorization Document** - During the study, it may become necessary to modify the ICAD. If safety related information which may present potential or real hazard to the participant becomes available, it must be communicated to the participant(s) or LAR(s) and reported to the IRB of record as soon as possible. A revised ICAD containing the new information must be submitted to the IRB via an Amendment Request and must be IRB-approved prior to use.

The sponsor or IRB may request an ICAD revision resulting from:

1. A protocol amendment (e.g., change in study procedure),
2. Significant change(s) to the risk/benefit ratio of the research, **OR**
3. New information becoming available (e.g., previously unanticipated problems involving increased risk to participants or changes regarding economic considerations).

When changes are made to the ICAD, the document receives the IRB approval stamp and all participants enrolled from that point forward must be consented using the newly revised and approved document. Generally, the IRB will not require re-consenting of previously consented, active patients in response to minor changes to the ICAD. For example, the IRB generally will not require re-consenting of active participants when the document is revised grammatically or other minor changes are made which do not affect the risk/benefit ratio. Additionally, the IRB generally does not require re-consenting of participants no longer receiving study treatment. However, the IRB will require re-consenting of **ALL** participants with a revised document, or an addendum, when new information is discovered that may affect the participant’s willingness to continue participation or may increase the long-term risks associated with participation (e.g., discovery of a previously unknown side effect). The IRB will consider the seriousness of the new information when determining the acceptable timeline for informing participants and re-consenting.

- D. In cases when a participant visit occurs prior to the research department receiving the newly IRB-approved ICAD, the consent provider must inform the participant of any new information which may affect the participant’s participation in the study (e.g., new risk identified). This re-consenting process must be documented in the participant’s medical or clinic chart and/or research records.

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**X. DOCUMENTATION OF INFORMED CONSENT AND AUTHORIZATION:**

- A. Documentation of the informed consent and authorization process, when a fully signed ICAD document is required by the IRB, occurs through the participant’s signature on the IRB-approved ICAD in addition to a written note made in the participant’s medical chart, clinic chart and/or research record. The consent provider is required to write a note describing the consent procedure, including but not limited to the following statements: **no study activities were initiated prior to obtaining the participant’s signature, the participant was provided with ample time to ask questions and consider whether or not to participate in the research, and a copy of the participant’s signed document was provided to the participant, or LAR when appropriate.**

Complete details of required components of documentation of consent are provided at the end of this policy in *Procedures for Obtaining Informed Consent and Authorization of Research Participants*.

**XI. INFORMED CONSENT VARIATIONS:**

Informed consent must be obtained for each participant in a research study (unless the IRB determines regulatory criteria for a waiver or alteration of informed consent exists and approves this for the specific study) **before** the participant begins any aspect of research participation. In most cases, a written ICAD and a face-to-face exchange with the participant constitutes the consent process; however, variations may occur. Except where explicitly stated, prospective **IRB approval is required prior to using a different method (consent variation)** for consenting an individual participant. When a variation will be employed for all participants, the variation must be approved by the IRB prior to project initiation.

Informed consent variations include:

- A. Waiver of consent documentation.
  - 1. Obtaining informed consent and authorization via telephone using a scripted statement.
  - 2. Obtaining informed consent and authorization via telephone in conjunction with a mailed ICAD or previously provided ICAD.
- B. Obtaining written informed consent via facsimile.
- C. Assent and parental permission.
- D. Assent of cognitively impaired participants.
- E. Alteration or waiver of consent in non-emergency research.
- F. Alteration or waiver of consent in planned emergency research.
- G. Short form informed consent for non-English speaking (low English proficiency) participants.
- H. Exception from informed consent for single-time emergency use of a test article.

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- I. **Waiver of Consent Documentation - The IRB is allowed to waive the requirement to document the consent process by determining the regulatory criteria for waivers are met.** The IRB may **waive the requirement for obtaining a participant’s signature** (*documentation of consent*) on the ICAD if it finds and documents its findings justifying the waiver, either:
1. Based upon harm: The only record linking the participant and the research would be the consent document, and the primary risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether they want documentation linking themselves with the research, and the participant’s wishes will govern. The research is not FDA regulated. **OR**
  2. Minimal risk: The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research study.

In cases which the informed consent documentation requirement is waived by the IRB, the PI may be required to provide participants with an IRB-approved written statement (**Information Sheet**) regarding the research. Distribution of information sheets to participants may need to be documented. When the IRB considers waiving the requirement to obtain written documentation of the consent process, the IRB will review a written description of the information which will be provided to participants. The PI may request alterations or waivers to the informed consent and authorization process by completing the appropriate sections of the IRB Application. When the PI proposes to obtain informed consent and authorization from participants over the **telephone**, he/she must describe the proposed process in the IRB Application, and explain why this type of consent process does not violate any rights of the participant. When the IRB grants a waiver of consent documentation and the PI proposes to conduct the informed consent process via telephone, the IRB may require special procedures. Two examples: a) Obtaining informed consent and authorization via telephone using a scripted statement or b) Obtaining informed consent and authorization via telephone in conjunction with a mailed ICAD or previously provided ICAD, are described in detail below.

A sponsor may require a signed ICAD despite the IRB granting a waiver of consent documentation. In such cases, the document employed must be IRB-approved prior to use.

1. ***Obtaining informed consent and authorization via telephone using a scripted statement.*** This option may be appropriate in some limited circumstances for minimal risk research. The IRB may prospectively grant a waiver of documentation while requiring researchers to read a scripted statement to potential participants. These circumstances may include telephone questionnaires or surveys, where an IRB-approved scripted statement is read over the

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telephone to the prospective participant and the prospective participant given the opportunity to decline involvement and end the telephone call prior to the administration of the research questionnaire or survey. In such cases, after receiving an IRB waiver of consent documentation and IRB approval to obtain consent via telephone using the scripted statement, the PI may employ the steps listed below:

- a. The consent provider contacts the participant by telephone to discuss the research study and confirm the participant’s interest.
- b. The consent provider reads an IRB-approved scripted telephone statement to the potential participant, to assess the potential participant’s interest in the trial and to provide the participant with the opportunity to end the telephone call if uninterested. If the participant is interested in participating, the consent provider notes the participant’s agreement in the research record and research participation may begin. The note should include documentation the scripted statement was read and the participant’s questions about the research were answered prior to initiation of the questionnaire/survey.

**It is NOT appropriate to obtain telephone informed consent and authorization from an LAR.**

**2. *Obtaining informed consent and authorization via telephone in conjunction with a mailed ICAD or previously provided ICAD.***

This option is used under limited circumstances and only when the study is minimal risk or when there has been a change to the ICAD that may affect the participant and the participant is not scheduled for a study visit in the near future. The IRB may also approve this option when the IRB has approved a waiver of documentation but the sponsor still requires a signed ICAD. Steps in the informed consent process are as follows:

- a. The consent provider contacts the participant by telephone to discuss the research study and confirm the participant’s interest.
- b. If the participant is interested in participating, the consent provider mails two unsigned copies of the ICAD to the participant.
- c. When the participant has received the ICAD and has it in front of them for reference, the consent provider conducts the consent interview by telephone, verifying the participant’s understanding of the research and answering any questions.
- d. If the participant consents to research participation, the participant signs one copy of the ICAD and returns it to the consent provider.
- e. When the consent provider receives the signed document, they apply their own signature and provide the participant with a copy of the document bearing both signatures.
- f. Appropriate documentation of the entire process should be made in the research record.



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Informed consent is not effective until the consent provider has the ICAD bearing the participant’s signature in their possession. It is not appropriate to obtain informed consent and authorization via telephone and mail from an LAR.

**IRB approval is required prior to implementing such a process for obtaining informed consent and authorization over the telephone for any participant.**

**J. Obtaining Written Informed Consent via Facsimile** - When an in-person consent procedure with the participant is not feasible, obtaining informed consent via facsimile may be acceptable. **When possible, IRB approval is required prior to implementing a process for obtaining informed consent and authorization via facsimile.** Two acceptable processes for obtaining informed consent by facsimile are as follows:

1. The informed consent process begins in person with the participant, or the LAR when appropriate. The potential participant then takes the ICAD home to consider participation. The consent provider later contacts the participant or LAR by telephone, confirms their understanding of the research and answers all questions. The participant has the written ICAD before them for reference during a telephone discussion. If the participant consents to involvement, he/she signs and returns the signed document to the consent provider by facsimile. The consent provider immediately signs the document upon receipt of the facsimile. A copy bearing both signatures is faxed back to the participant or LAR.
2. The entire consent and authorization procedure may take place over the telephone, obtaining the signature by facsimile. The consent provider would fax an unsigned ICAD to the study participant, or LAR when appropriate, prior to the consent discussion. The participant has the document before them while the study is discussed over the telephone. The participant, or LAR when appropriate, must then sign and fax the ICAD to the consent provider. Upon receipt of the facsimile document, the consent provider must sign and date the document. A copy bearing both signatures is faxed back to the participant. Consent is in effect when the fully executed ICAD is returned to the consent provider. The informed consent and authorization process involving faxed documents must be appropriately documented by the consent provider in the participant’s research record. The participant must return the ICAD bearing their original signature (either at the next visit or via mail) to the consent provider at his/her earliest opportunity. The appropriate recipient of the signed, original ICAD should sign and date it, file it with the facsimile, and make appropriate notes in the participant’s research record. The consent provider’s notes coinciding with the dates and signatures on the ICAD(s) provide the source documentation to confirm and explain the process.

**K. Assent and Parental Permission** - In general, permission from the parent or guardian must be obtained prior to approaching a minor to participate in research. Once permission from the



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parent(s) or guardian is obtained, the information within the informed consent document must be reviewed with the child, if possible, in terms understandable to that child. If it is expected children will be participants in the study, an Assent document must be included with the IRB Application. An Assent template is available on the IRB website. Generally, a minor must provide assent (as appropriate), indicated by their signing the Assent document. Signature requirements permitting the child’s participation in research are related to the level of risk involved in the research. For more specific information, refer to the IRB and Clinical Research Policy, [Vulnerable Populations: Children as Research Participants](#).

- L. **Assent of Cognitively Impaired Participants** - It may be appropriate to approach a participant’s LAR for consent when the participant is cognitively impaired. Inclusion of cognitively impaired individuals is approved on a study-by-study basis. Assent from the cognitively impaired participant should be sought when appropriate. See IRB Policy *Vulnerable Populations: Enrollment of Cognitively Impaired Participants*.
- M. **Alteration or Waiver of Informed Consent in Non-Emergency Research** -The IRB may approve a consent and authorization procedure which does not include, or which alters some or all the elements of informed consent and authorization set forth above. The IRB is allowed to waive or alter the consent process by determining the regulatory criteria for waivers or alteration of the consent process are met. The IRB may waive the requirement to obtain informed consent and authorization provided the IRB finds and documents:

**Public Demonstration Project:**

1. The research or demonstration project is to be conducted by, or is participant to the approval of State or local government officials and is designed to study, evaluate, or otherwise examine:
  - a. Public benefit of service programs,
  - b. Procedures for obtaining benefits or services under those programs,
  - c. Possible changes in or alternatives to those programs or procedures; **OR**
  - d. Possible changes in methods or levels of payment for benefits or services under those programs; **AND**
2. The research could not practicably be carried out without the waiver or alteration.

Other circumstances in which the IRB may approve an alteration or waiver of informed consent and authorization include the following (**All** must apply):

1. The research involves no more than minimal risk to the participants, **AND**
2. The waiver or alteration will not adversely affect the rights and welfare of the participants, **AND**
3. The research could not practicably be carried out without the waiver or alteration, **AND**
4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

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- N. **Waiver of Informed Consent in Planned Emergency Research** - The FDA permits “planned emergency research” and has developed a process whereby this type of research can be conducted **without prior informed consent** of the participants or their LAR if the research meets the **strict criteria for approval**. The IRB also permits waiver of informed consent for emergency research in line with strict FDA requirements. See IRB Policy [Planned Emergency Research](#) for additional guidance.
- O. **Short Form for Non-English Speaking (Low English Proficiency) Participants** - A short form ICAD may be used to consent a non-English speaking participant, or LAR when appropriate, with prior IRB approval. Short form consents in various languages may be available through the IRB of record for the specific study. See IRB Policy [Enrolling Non-English Speaking Study Participants in Clinical Research Studies](#) for guidance.
- P. **Exception from Informed Consent for Single Time Emergency Use of a Test Article** -The FDA permits single-time use of an investigational drug or device, under strict criteria, in immediate life-threatening situations when informed consent and authorization is not possible. See IRB Policy [Emergency Use of a Test Article](#) for guidance.

**XII. DEPARTMENT OF DEFENSE (DoD) RESEARCH:**

When research involving funding, DoD collaboration, DoD facilities or DoD personnel or is supported by any branch or department of the (DoD):

1. If the research participant meets the definition of “**experimental participant,**” a **waiver of the consent process is prohibited** (unless a waiver is obtained from the Secretary of Defense for Research and Engineering.) For more information about experimental participants and Secretary of Defense waivers refer to guidance “Requirements for Research Involving or Supported by the Department of Defense.” For “**classified**” research, **waivers of consent are prohibited**. Beaumont has not conducted classified research in the past. For more information about classified research, [DoD Directive 3216.02](#).
2. Research involving prisoners of war is prohibited.

**XII. ASSOCIATED POLICIES:**

- IRB Policy [Emergency Use of a Test Article](#)
- IRB Policy [Enrolling Non-English Speaking Study Participants in Clinical Research Studies](#)
- IRB Policy [Enrollment of Visually Impaired Participants](#)
- IRB Policy [Review by an External Institutional Review Board](#)
- IRB Policy [Planned Emergency Research](#)
- IRB Policy [IRB Review of Research Involving Biospecimen Banking](#)

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IRB Policy [\*Vulnerable Populations: Children as Research Participants\*](#)  
 IRB Policy [\*Vulnerable Populations - Enrollment of Decisionally Impaired Participants\*](#)  
 IRB Policy [\*Inclusion of Women and Minorities in Clinical Research\*](#)  
 IRB Policy [\*Expanded Access and Use of a Test Article for Compassionate Purposes\*](#)  
 IRB Policy [\*Research Supported by the Department of Defense\*](#)  
 Clinical Research SOP, *Regulatory Files and Study Participant Records*  
 BH Corporate Policy *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\*](#)  
 Beaumont Health policy [\*Clinical Language Services for the Deaf, Blind, and Hard of Hearing \(DBHH\) Patients and their Companions\*](#)  
 The Joint Commission Patient Centered Communication Standards  
 DHHS Office of Minority Health Culturally and Linguistically Appropriate Standards (CLAS)

### **XIII. APPLICABLE REGULATIONS AND GUIDELINES:**

21 CFR 50 Informed Consent Requirements  
 45 CFR 46.116 Requirements for Informed Consent  
 45 CFR 46.117 Documentation of Informed Consent  
 IRB Informed Consent and Authorization Template  
 IRB Assent Template  
 Short Form Informed Consent and Authorization Template (non-English translations available)  
 Limited English Proficiency (LEP).gov A Federal Agency Website  
 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)  
 National Council on Interpreting in Healthcare (NCIHC)  
 International Medical Interpreting Association (IMIA)  
[DoD Directive 3216.02](#)

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**PROCEDURES FOR OBTAINING INFORMED CONSENT  
AND AUTHORIZATION IN RESEARCH**

**I. PURPOSE:**

This standard operating procedure (SOP) describes the steps for conducting informed consent and authorization procedures with research participants in compliance with IRB and Clinical Research Policy *Informed Consent and Authorization in Research*.

**II. SCOPE:**

This SOP applies to investigators, key personnel, research staff and IRB staff.

**III. PROCEDURES:**

**Obtaining written consent and authorization from the participant or Legally Authorized Representative (LAR)**

- A. Any research personnel approaching a potential participant to obtain informed consent for a research study must be designated by the Principal Investigator (PI) and listed as a consent provider on delegation of authority/site signature log in the PI's regulatory file. When BH IRB is IRB of record, consent providers must be listed as key personnel and approved as consent providers by BH IRB. When an external IRB is IRB of record, consent providers are approved during by the Administrative Review Process.
- B. Obtain permission from the participant's attending physician to approach and enroll the individual, as applicable.
- C. Through interaction with the participant, consultation with the healthcare team, and review of the medical record, assess the potential participant's capacity and readiness to provide informed consent. Consider cognitive status of the participant. Inclusion of cognitively impaired participants must be approved on a study-by-study basis by the IRB. If permitted by IRB approval, when a participant suffers temporary or permanent cognitive impairment and is unable to provide informed consent, the consent provider should involve the participants' Legally Authorized Representative (LAR). Consider whether the participant belongs to a vulnerable population and if additional safeguards may be required. Additionally, consider special circumstances, such as visual impairment, literacy or inability to understand spoken and/or written English. Refer to the appropriate policies for guidance in special circumstances as listed in "Unique Circumstances" at the end of this document.

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- D. Ensure the potential participant is not enrolled in another research study. If the participant is already enrolled in a study, consider whether enrolling in a second study will affect either study's outcome. Non-interventional studies, such as registries, may permit dual-enrollment. Examine the protocols and IRB-approved informed consent and authorization documents (ICADs) for both studies to determine if simultaneous enrollment is permitted. If permitted, assure and document each sponsors' approval of simultaneous enrollment before proceeding.
- E. Ensure the potential participant meets all inclusion criteria and confirm the absence of exclusions listed in the study protocol.
- F. In a private location, conduct the consent interview by reviewing the ICAD in detail with the participant or LAR., with particular attention to the basic elements of consent.
- G. Allow the potential participant ample time and opportunity to read the ICAD and ask questions. Encourage input from family members and other care providers, if appropriate. Whenever possible, the potential participant should be provided the opportunity to take the ICAD home to review.
- H. If the potential participant is unable to provide informed consent due to cognitive impairment and the study protocol permits obtaining informed consent from their LAR, conduct the consent process with the LAR, when appropriate.
- I. Assess the participant's (or the participant's LAR when appropriate) comprehension of the study by requesting he/she describe the basic elements of the study, including the study's purpose, risks, activities and/or duration of involvement.
- J. Once the participant agrees to participate in the research study, ensure the participant or LAR prints and signs (with date and time) their name on the ICAD in the space provided. Additionally, the participant or LAR must initial and date each page of the ICAD, if these fields are present. If consent is obtained from the participant's LAR because the participant is a child or cognitively impaired, the participant should assent whenever possible, either orally or in writing, per policy and study-specific IRB approval. Written assent may be documented on an IRB-approved Assent document or, if no Assent document exists for the study, by printing and signing their name next to their LAR on the ICAD.
- K. Witness: A witness to the entire consent process is required when a participant is visually impaired (unable to read the consent document), illiterate or Non-English speaking.
  - 1. The witness for a Non-English speaking participant must be fluent in both English and the language best understood by the participant. Additionally, the witness must be either a BH

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employee or physician, student, intern/observer, volunteer or key personnel (approved by BH Administrative Review or BH IRB), or participant family member/close associate.

2. The witness for an illiterate or visually impaired participant must be IMPARTIAL. The witness must be a BH physician, employee, student, intern/observer or volunteer who is NOT key personnel or otherwise associated with the study. The witness must NOT be a participant family member/close associate of the participant.

The witness must sign/date/time the consent document.

- L. The consent provider then prints and signs (with date and time) their name on the ICAD.
- M. The consent provider provides a signed copy of the ICAD to the participant, or LAR, when appropriate. A signed copy is uploaded into the EMR and the original ICAD is filed in the research record.
- N. **No one may complete fields on behalf of another individual. For example, no one should complete the participant’s printed name on their behalf.**
- O. Retain all executed consents, including screen failures or participants who withdraw participation, as well as all participant re-consent documents.

**Documentation of the informed consent and authorization process**

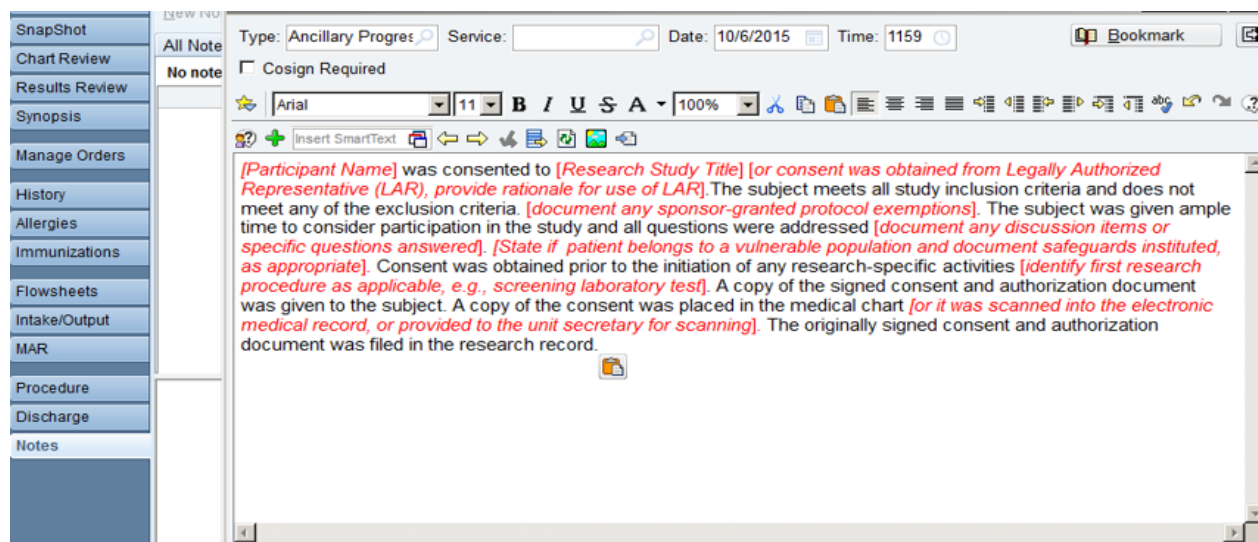
- A. Document the consent procedure with electronic consent process note in the EMR. When the participant is not a Beaumont patient and does not have an Epic record, a paper based note in the research record is acceptable.
- B. The consent documentation note must include the following:
  1. Statement that consent was obtained prior to the initiation of any research-specific activities (e.g., screening laboratory tests).
  2. Statement that the participant was given ample time and opportunity to consider participation and all questions were answered. If discussion occurred, document the participant’s specific questions and how these were addressed.
  3. Statement that a signed copy was provided to the participant or LAR, a signed copy was filed in the medical record and the originally-signed ICAD was filed in the research record.
  4. Electronic signature of the consent provider.
- C. The consent process documentation note should include other information when appropriate, such as a statement or confirmation regarding meeting inclusion criteria and absence of



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exclusion criteria or information emphasized during the consent interview, such as a description of follow-up activities or an explanation of randomization.

- D. All key personnel should be informed of any changes related to conduct of the research study. Specifically, consent providers should always be made immediately aware of any significant changes to the ICAD, when a new version has been approved for use, and how to locate the most recent ICAD.
- E. When the IRB requires re-consent of the participant (e.g., consent revised to reflect new risks), the consent provider should document the re-consent process, including date and time, rationale, and discussion with the participant. When conducting the re-consent interview with the participant, ensure the participant understands why re-consent is necessary. Allow the participant ample time to consider the changes and answer any questions he or she or the LAR may have. Document the consent procedure as previously outlined.
- F. For Unique Circumstances involving particular populations or consenting in specific circumstances, refer to the following policies:
  - IRB Policy [Emergency Use of a Test Article](#)
  - IRB Policy [Enrolling Non-English Speaking Study Participants in Clinical Research Studies](#)
  - IRB Policy [Enrollment of Visually Impaired Participants](#)
  - IRB Policy [Planned Emergency Research](#)
  - IRB Policy [Vulnerable Populations: Children as Research Participants](#)
  - IRB Policy [Vulnerable Populations - Enrollment of Decisionally Impaired Participants](#)



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**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.