



Title Informed Consent and Authorization in Research	Location ALL Beaumont Health	Functional Area Research Institute
Policy Owner Administrative Director	Document Type Policy	Effective Date 10/21/2016

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 under the jurisdiction of the Beaumont Health (BH) Institutional Review Board (IRB) consistent with Federal, State and local laws and regulations. Detailed steps consent providers must follow in order to conduct consent procedures in compliance with this policy are listed on pages 16-22 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 subject. The BH IRB serves as the Institutional Review Board (IRB) for all human participant research conducted at BH facilities. It is the responsibility of the IRB to require individuals considering participation in research, or the individual's legally authorized representative (LAR) when appropriate, are provided with the information needed in order to make an informed decision about participation in the research, in accordance with Federal regulations. The IRB is allowed to **waive or alter the consent process** by determining the criteria for such waivers or alterations are met. Additionally, the IRB is allowed to **waive the requirement to document the consent process** by determining the regulatory criteria for such waivers are met. The consent process provides the subject, or subject's LAR when appropriate, with:
 - 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 subject's protected health information.

Informed consent and authorization is an ongoing process, involving more than the subject's signature on the consent document. Subjects, or their LAR, must be informed of new information about the research, as it becomes available, that 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.

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IV. DEFINITIONS:

- A. **Assent** -To express acceptance or agreement. Mere failure to object may not, without affirmative agreement, be construed as assent. For child subjects 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.
- D. **ICAD** - Informed Consent and Authorization Document.
- E. **Information Sheet** - A document given to the subject 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.
- F. **Informed Consent and Authorization** An ongoing process by which a subject, 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 subject'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** - In a standard consent procedure, the witness serves as "witness to the subject's signature only," and is attesting they were present when the subject signed the document. In special circumstances, such as when English is not the subject's first language or the subject is illiterate, the witness serves as "witness to the entire consent procedure and signature." In the latter case, the witness' signature indicates the witness is attesting to their presence during the entire consent discussion and procedure and witnessed the subject sign the ICAD. The witness is also attesting the information in the consent and authorization document (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. The witness must be a BH employee or physician. In rare instances, when a BH employee or physician is unavailable to serve as witness (i.e., off site physician's office), an employee of the investigator or physician may serve as witness.

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- I. **Consent Provider** - An individual designated by the principal investigator (PI) to obtain informed consent and authorization. This individual must be listed on the study-specific IRB approved key personnel roster prior to consenting subjects. Inclusion on the key personnel roster indicates the principal investigator (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 IRB verifies adequate training and education prior to approving any key personnel.
- J. **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.
- K. **Prisoner of War** - A person taken by or surrendering to enemy forces in wartime.
- L. **Vulnerable Subjects** - 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, pregnant women, 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 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 IRB Application. All materials presented to subjects, 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 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.



Title Informed Consent and Authorization in Research	Location ALL Beaumont Health	Functional Area Research Institute
Policy Owner Administrative Director	Document Type Policy	Effective Date 10/21/2016

- B. The IRB may require information be given to prospective subjects, in addition to that specifically required by applicable regulations and/or the sponsor when, in the IRB's judgment, the information meaningfully adds to the protection of the subjects' rights and welfare. The information given to the subject, or the LAR when appropriate, should be in language understandable to the subject or LAR. No informed consent and authorization, whether oral or written, may include any exculpatory language through which the subject or LAR is made to waive, or appear to waive, any of the subject's legal rights, or releases or appears to release the investigator, sponsor, institution or its agents from liability for negligence.
- C. Informed consent, or waiver of informed consent, must be obtained for every subject in a research study before that subject 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). 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 232, *Research Record Retention* and Clinical Research SOP 608, *Regulatory Files and Study Subject Records*.

VI. CONSENT FROM THE SUBJECT'S LEGALLY AUTHORIZED REPRESENTATIVE:

The subject's informed consent is a vital component of the research process. If the subject suffers temporary or permanent cognitive impairment which interferes with his/her ability to provide informed consent, the consent provider may approach the subject's LAR to obtain consent to enroll the subject in a research study, consistent with IRB Policy 243, *Vulnerable Populations: Enrollment of Cognitively Impaired Participants*.

VII. CONSENT PROVIDERS:

- A. If permitted by the IRB (and sponsor where applicable), the PI may delegate the consent process to any key personnel listed as designated consent providers on the IRB Application. 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 subjects in the following circumstances:
 - 1. Studies in which the **test article is a medication** may only rely on Research Nurse Clinicians as consent providers.
 - 2. Studies in which the **test article is a device**, may have Research Nurse Clinicians or Clinical

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Title Informed Consent and Authorization in Research	Location ALL Beaumont Health	Functional Area Research Institute
Policy Owner Administrative Director	Document Type Policy	Effective Date 10/21/2016

- 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 subjects (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. Non-Research Institute employees who are not physicians or physician extenders (e.g., NP, PA) must attest to reviewing relevant Research Institute (RI) policies, and complete the “RI Policy/Standard Operating Procedure Tracking Tool” and submit it with the IRB Application.
 - D. In limited circumstances, IRB 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;
 - 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 be able to 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 subject'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 subject.
 - 7. A description of any benefits to the subject or to others which may reasonably be expected

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- from the research.
8. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
 9. A statement describing the extent, if any, to which confidentiality of records identifying the subject 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 subjects' rights, and whom to contact in the event of a research-related injury to the subject.
 12. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
 13. A statement the subject is not forfeiting any legal rights.
- 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 subject (or to the embryo or fetus), which are currently unforeseeable, if the subject is or may become pregnant.
 2. Anticipated circumstances under which the subject's participation may be terminated by the PI without regard to the subject's consent.
 3. The amount and schedule of payments, when appropriate.
 4. Any additional costs to the subject that may result from participation in the study.
 5. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
 6. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
 7. The approximate number of subjects involved in the study.

IX. WRITTEN INFORMED CONSENT AND AUTHORIZATION DOCUMENT:

- A. In general, the IRB requires informed consent to be documented using a written ICAD which has been prospectively IRB approved. The document should be written at the 6th-8th grade reading level in language understandable to the research subject. The document must be reviewed with the research subject, or LAR when appropriate, as part of the consent process. It is preferred all ICADS are developed using the IRB informed consent/assent template(s). 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

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approved by the IRB. If vulnerable subjects are to be included in the research, the following policies should be consulted for special considerations: IRB 242, *Vulnerable Populations: Children as Research Participants*; IRB 243, *Vulnerable Populations: Enrollment of Cognitively Impaired Participants*; IRB 244, *Vulnerable Populations: Inclusion of Pregnant Women, Fetuses, and Neonates in Research*.

- B. **IRB Approval Stamp** - The ICAD will be stamped by the IRB, indicating approval and expiration dates at the time of initial approval, annual renewal and revision. The most current version of the IRB-approved ICAD, **bearing the IRB-approval stamp**, should always be used. The current ICAD version expires at midnight on the date of expiration. Previously consented subjects are not required to sign a revised consent unless required by the 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 2016-061). 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 course of a study, it may become necessary to modify the ICAD. If safety related information which may present potential or real hazard to the subject becomes available, it must be communicated to the subject(s) or LAR(s) and reported to the IRB 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 subjects or changes regarding economic considerations).

When changes are made to the ICAD, the document receives the IRB stamp and all subjects enrolled from that point forward must be consented using the newly revised and approved document. The IRB will not require reconsenting 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 subjects 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 subjects no longer receiving study treatment. However, the IRB will require re-consenting of **ALL** subjects with a revised document, or an addendum, when new information is discovered that may affect the subject'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 subjects and reconsenting.

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Policy Owner Administrative Director	Document Type Policy	Effective Date 10/21/2016

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

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

- A. Documentation of the informed consent and authorization process occurs through the subject's signature on the IRB-approved ICAD in addition to a written note made in the subject's medical chart, clinic chart and/or research record, in accordance with Federal regulations. 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 subject's signature, the subject was provided with ample time to ask questions and consider whether or not to participate in the research, and a photocopy of the subject's signed document was provided to the subject, 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:**

- A. Informed consent must be obtained for each subject 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 subject begins any aspect of research participation. In most cases, a written ICAD and a face-to-face exchange with the subject 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 subject. When a variation will be employed for all subjects, the variation must be approved by the IRB prior to project initiation.

Informed consent variations include:

1. Waiver of consent documentation.
 - Obtaining informed consent and authorization via telephone using a scripted statement.
 - Obtaining informed consent and authorization via telephone in conjunction with a mailed ICAD.
2. Obtaining written informed consent via facsimile.
3. Assent and parental permission.
4. Assent of cognitively impaired subjects.
5. Alteration or waiver of consent in non-emergency research.
6. Alteration or waiver of consent in planned emergency research.
7. Short form informed consent for non-English speaking subjects.
8. Exception from informed consent for single-time emergency use of a test article.

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Title Informed Consent and Authorization in Research	Location ALL Beaumont Health	Functional Area Research Institute
Policy Owner Administrative Director	Document Type Policy	Effective Date 10/21/2016

- B. **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 subject'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 subject and the research would be the consent document, and the primary risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether they want documentation linking themselves with the research, and the subject'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 subjects and involves no procedures for which written consent is normally required outside of the research study;
- C. In cases which the informed consent documentation requirement is waived by the IRB, the PI may be required to provide subjects with an IRB-approved written statement (**Information Sheet**) regarding the research. 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 subjects. 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 subjects 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 subject. 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 and b. Obtaining informed consent and authorization via telephone in conjunction with a mailed ICAD) are described in detail below.
- D. 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.
- A. ***Obtaining informed consent and authorization via telephone using a scripted statement.*** Obtaining informed consent and authorization from subjects via telephone using a scripted statement 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 subjects. These circumstances may include telephone questionnaires or surveys, where an IRB-approved scripted statement is read over the telephone to the prospective subject and the prospective subject 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

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Title Informed Consent and Authorization in Research	Location ALL Beaumont Health	Functional Area Research Institute
Policy Owner Administrative Director	Document Type Policy	Effective Date 10/21/2016

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 subject by telephone to discuss the research study and confirm the subject's interest.
- b. The consent provider reads an IRB-approved scripted telephone statement to the potential subject, to assess the potential subject's interest in the trial and to provide the subject with the opportunity to end the telephone call if uninterested. If the subject is interested in participating, the consent provider notes the subject's agreement in the research record and research participation may begin. The note should include documentation that the scripted statement was read and the subject'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.*

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 subject and the subject 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 subject by telephone to discuss the research study and confirm the subject's interest.
- b. If the subject is interested in participating, the consent provider mails two unsigned copies of the ICAD to the subject.
- c. When the subject has received the ICAD and has it in front of them for reference, the consent provider conducts the consent interview by telephone, verifying the subject's understanding of the research and answering any questions.
- d. If the subject consents to research participation, the subject 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 subject with a copy of the document bearing both signatures. No witness is required.
- f. Appropriate documentation of the entire process should be made in the research record.

Informed consent is not effective until the consent provider has the ICAD bearing the subject'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 subject.



Title Informed Consent and Authorization in Research	Location ALL Beaumont Health	Functional Area Research Institute
Policy Owner Administrative Director	Document Type Policy	Effective Date 10/21/2016

- E. **Obtaining Written Informed Consent via Facsimile** - When an in person consent procedure with the subject 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. If prior IRB approval is not possible, the IRB must be notified within 5 days of conducting a consent procedure by facsimile.**

Two acceptable processes for obtaining informed consent by facsimile are as follows:

1. The informed consent process begins in person with the subject, or the LAR when appropriate. The potential subject then takes the ICAD home to consider participation. The consent provider later contacts the subject or LAR by telephone, confirms their understanding of the research and answers all questions. The subject has the written ICAD before them for reference during a telephone discussion. If the subject 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 subject 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 subject, or LAR when appropriate, prior to the consent discussion. The subject has the document before them while the study is discussed over the telephone. The subject, 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 subject. Consent is in effect when the fully executed ICAD is returned to the consent provider.

A witness is not utilized for consent procedures involving faxed documents. The informed consent and authorization process must be appropriately documented by the consent provider in the subject's research record. The subject 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 subject'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.

- F. **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 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 subjects 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, as described below:

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Title Informed Consent and Authorization in Research	Location ALL Beaumont Health	Functional Area Research Institute
Policy Owner Administrative Director	Document Type Policy	Effective Date 10/21/2016

Category 1: Minimal risk. Requires the signature of one parent or guardian on the ICAD.

Category 2: Greater than minimal risk with the potential of benefit. Generally requires the signature of one parent or guardian on the ICAD, but both parents should be consulted when available.

Category 3: Greater than minimal risk, no prospect of direct benefit. Child must provide assent (as appropriate) and sign the Assent document, if an IRB-approved Assent document exists for the study. Signatures of both parents on the ICAD are required.

A court appointed guardian must provide a letter from the court authenticating guardianship, in order to serve as the minor subject's LAR and provide permission to involve the child in research. The IRB may grant a waiver of parental or guardian permission in specific circumstances to protect the child subject. See IRB Policy 242, *Vulnerable Populations: Children as Research Participants* for additional guidance.

The IRB is allowed to **waive parental permission** by determining that the criteria for waivers or alterations are met. The criteria:

1. The research involves no more than minimal risk to the subjects
2. The waiver or alteration did not adversely affect the rights and welfare of the subjects
3. The research cannot practicably be carried out without the waiver or alteration
4. When appropriate, the subjects will be provided with additional pertinent information after participation
5. The research is not FDA-regulated.

Waiver of Parental Permission-Public Demonstration Project

1. The research is conducted by or subject to the approval of state or local government officials.
2. The research or demonstration protocol is designed to study, evaluate, or otherwise examine:
 - Public benefit or service programs
 - Procedures for obtaining benefits or services under those programs
 - Possible changes in or alternatives to those programs or procedures
 - Possible changes in methods or levels of payment for benefits or services under those programs.
3. The research cannot practicably be carried out without the waiver or alteration
4. The research is not FDA-regulated

Waiver of Consent Process-Permission is not a reasonable requirement

1. The research is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects
2. An appropriate mechanism for protecting children who will participate as subjects in research is substituted
3. The research is not FDA-regulated.

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Title Informed Consent and Authorization in Research	Location ALL Beaumont Health	Functional Area Research Institute
Policy Owner Administrative Director	Document Type Policy	Effective Date 10/21/2016

G. **Assent of Cognitively Impaired Subjects** - It may be appropriate to approach a subject's LAR for consent when the subject is cognitively impaired. Assent from the cognitively impaired subject should be sought when appropriate. See IRB Policy 243, *Vulnerable Populations: Enrollment of Cognitively Impaired Participants*.

H. **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 of 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 and that the research is **not FDA-regulated** (excluding Planned Emergency Research, described below). 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 subject 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.
3. The research is not FDA-regulated.

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 subjects, **AND**
 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects, **AND**
 3. The research could not practicably be carried out without the waiver or alteration, **AND**
 4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation, **AND**
 5. The research is not FDA-regulated.
- I. **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 subjects 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 227, *Planned Emergency Research* for additional guidance.



Title Informed Consent and Authorization in Research	Location ALL Beaumont Health	Functional Area Research Institute
Policy Owner Administrative Director	Document Type Policy	Effective Date 10/21/2016

- J. **Short Form for Non-English Speaking Subjects** - A short form ICAD may be used to consent a non-English speaking subject, or LAR when appropriate, with prior IRB approval. Short form consents in various languages are available through the IRB Office. See IRB Policy 211, *Enrolling Non-English Speaking Study Participants* for guidance.
- K. **Illiterate Subjects** - An impartial witness (an individual not listed as key personnel and not subject to unfair influence by people involved in the trial) is required for the consent procedure of illiterate participants. The witness must be a “witness to the entire consent procedure” rather than witness to the signature only. Additionally, the witness must attest the information in the consent and authorization document (and any other written information) was accurately explained to and apparently understood by the participant, and informed consent was freely given by the participant.
- L. **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 210, *Single Time Use of a Test Article* for guidance.
- M. **Department of Defense (DoD) Research** - When research involves or is supported by any branch or department of the (DoD):
 - 1. If the research subject meets the definition of “experimental subject,” 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 subjects and Secretary of Defense waivers refer to Appendix K or the IRB application.
 - 2. For “classified” research, waivers of consent are prohibited. Beaumont has not conducted classified research in the past. For more information about classified research, refer to Appendix K or to the IRB application.
 - 3. Research involving prisoners of war is prohibited.

XII. ASSOCIATED POLICIES:

IRB Policy 210 *Single Time Emergency Use of a Test Article*
 IRB Policy 211 *Enrolling Non-English Speaking Participants*
 IRB Policy 212 *Enrolling Visually Impaired Participants*
 IRB Policy 227 *Planned Emergency Research*
 IRB Policy 238 *IRB Review of Research Involving Tissue/Specimen Banking*
 IRB Policy 242 *Vulnerable Populations: Children as Research Participants*
 IRB Policy 243 *Vulnerable Populations: Enrollment of Cognitively Impaired Participants*
 IRB Policy 244 *Vulnerable Populations: Including Pregnant Women in Research*
 IRB Policy 245 *Inclusion of Women and Minorities in Research*
 IRB Policy 250 *Compassionate Use and Expanded Access*
 Clinical Research SOP 608, *Regulatory Files and Study Subject Records*

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Title Informed Consent and Authorization in Research	Location ALL Beaumont Health	Functional Area Research Institute
Policy Owner Administrative Director	Document Type Policy	Effective Date 10/21/2016

BH Corporate Policy 304 *Informed Consent*
 Appendix K to the IRB application: *Requirements for Research Involving or Supported by the Department of Defense*

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)

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Title Informed Consent and Authorization in Research	Location ALL Beaumont Health	Functional Area Research Institute
Policy Owner Administrative Director	Document Type Policy	Effective Date 10/21/2016

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 subjects in compliance with IRB Policy 221, *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 subject or Legally Authorized Representative (LAR)

- A. Any research personnel approaching a potential subject to obtain informed consent for a research study must be designated by the Principal Investigator (PI), listed on the IRB key personnel roster and approved by the IRB as a consent provider. The PI's regulatory binder should include a Delegation of Authority Log which lists all individuals and their role in the study, including authorization to obtain informed consent.
- B. Obtain permission from the subject's attending physician to approach and enroll the individual, as applicable.
- C. Through interaction with the subject, consultation with the healthcare team, and review of the medical record, assess the potential subject's capacity and readiness to provide informed consent. Consider cognitive status of the subject. For example, if the subject suffers temporary or permanent cognitive impairment and is unable to provide informed consent, the consent provider should involve the subjects' Legally Authorized Representative (LAR). Consider whether the subject belongs to a vulnerable population and if additional safeguards may be required. Additionally, consider special circumstances, such as visual impairment or inability to understand spoken and/or written English. Refer to the appropriate policies for guidance in special circumstances, such as enrolling cognitively impaired subjects or vulnerable populations, as listed in "Unique Circumstances" at the end of this document.
- D. Ensure the potential subject is not enrolled in another research study. If the subject 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

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Title Informed Consent and Authorization in Research	Location ALL Beaumont Health	Functional Area Research Institute
Policy Owner Administrative Director	Document Type Policy	Effective Date 10/21/2016

(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 subject 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 particular attention to the basic elements of consent.
- G. Allow the potential subject 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 subject should be provided the opportunity to take the ICAD home to review.
- H. If the potential subject 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 subject's (or the subject'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 subject agrees to participate in the research study, ensure the subject or LAR prints and signs (with date and time) their name on the ICAD in the space provided. Additionally, the subject or LAR must initial and date each page of the ICAD, if these fields are present. If consent is obtained from the subject's LAR because the subject is a child or cognitively impaired, the subject should assent whenever possible, either orally or in writing, per policy. 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. A Beaumont employee or physician must witness the subject's signature on the ICAD. Ensure the witness completes all fields and indicates 'witness to signature' or 'witness to process and signature.' In rare situations, when a consent procedure is conducted outside of BH facilities and no BH employee or physician is on the premises to serve as witness, an employee of an investigator or physician may serve as witness.
- 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 subject, or LAR when appropriate. A signed copy is filed in the medical record (e.g., hospital or clinic chart) and the original ICAD is filed in the research record.

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Title Informed Consent and Authorization in Research	Location ALL Beaumont Health	Functional Area Research Institute
Policy Owner Administrative Director	Document Type Policy	Effective Date 10/21/2016

- N. No one may complete fields on behalf of another individual. For example, no one should complete the subject's printed name on their behalf.
- O. Retain all executed consents, including screen failures or subjects who withdraw participation, as well as all subject re-consent documents.

Documentation of the informed consent and authorization process

- A. Document the consent procedure with a written entry in the subject's medical record (e.g., hospital or clinic chart, paper or electronic) or research record. This documentation can be in the form of a narrative note, checklist, or note to file (see Appendix 1) and must be completed by the consent provider.
- B. The consent documentation note must include the following:
 - o Statement that consent was obtained prior to the initiation of any research-specific activities (e.g., screening laboratory tests).
 - o Statement that the subject was given ample time and opportunity to consider participation and all questions were answered. If discussion occurred, document the subject's specific questions and how these were addressed.
 - o Statement that a signed copy was provided to the subject or LAR, a signed copy was filed in the medical record and the originally-signed ICAD was filed in the research record.
 - o Printed name and dated/timed signature of the consent provider.
- C. The consent process documentation note may include other information when appropriate, such as a statement or confirmation regarding meeting inclusion criteria and absence of 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 subject (e.g., consent revised to reflect new risks), the consent provider should document the reconsent process, including date and time, rationale, and discussion with the subject. When conducting the re-consent interview with the subject, ensure the subject understands why re-consent is necessary. Allow the subject 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. **Unique Circumstances -**
When involving particular populations or consenting in specific circumstances, refer to the following policies:

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Title Informed Consent and Authorization in Research	Location ALL Beaumont Health	Functional Area Research Institute
Policy Owner Administrative Director	Document Type Policy	Effective Date 10/21/2016

IRB Policy 210 *Single Time Emergency Use of a Test Article*
 IRB Policy 211 *Enrolling Non-English Speaking Study Participants*
 IRB Policy 212 *Enrolling Visually Impaired Participants*
 IRB Policy 227 *Planned Emergency Research*
 IRB Policy 242 *Vulnerable Populations: Children as Research Participants*
 IRB Policy 243 *Vulnerable Populations: Enrollment of Cognitively Impaired Participants*
 IRB Policy 244 *Vulnerable Populations: Inclusion of Pregnant Women, Fetuses and Neonates in Research*

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Title Informed Consent and Authorization in Research	Location ALL Beaumont Health	Functional Area Research Institute
Policy Owner Administrative Director	Document Type Policy	Effective Date 10/21/2016

1. Narrative Note - record or dictate in medical record or research record, as applicable.

Date/Time: [Subject Name] was consented to [Research Study Title] [or consent was obtained from Legally Authorized Representative (LAR), provide rationale for use of LAR]. The subject meets all inclusion criteria for the study and does not meet any exclusion criteria [document any sponsor-granted protocol exemptions]. The subject was given ample time to consider participation in the study and all questions were addressed [document any discussion items or specific questions answered]. Consent was obtained prior to the initiation of any research-specific activities [identify first research procedure as applicable, e.g., screening laboratory test]. A copy of the signed consent and authorization document was given to the subject and filed in the medical record. The originally-signed consent and authorization document was filed in the research record.

/ _____ /
 Printed Name of Consent Provider Signature of Consent Provider Date

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Title Informed Consent and Authorization in Research	Location ALL Beaumont Health	Functional Area Research Institute
Policy Owner Administrative Director	Document Type Policy	Effective Date 10/21/2016

2. Checklist -file in medical record or research record, as applicable.

Informed Consent and Authorization Document (ICAD) Checklist	Yes / No
1. Subject met all inclusion criteria; did not meet any exclusion criteria.	
2. Subject is a member of a vulnerable population. If Yes, review IRB Policy 221 to ensure consent requirements are met. Details:	
3. Attending physician or health care provider gave permission to approach the patient. Details:	
4. Consent was obtained prior to initiation of any study-specific activities.	
5. Ample time was given for consideration to participate and all questions were answered. Details:	
6. Utilized current and complete, IRB-stamped ICAD. Version date:	
7. Performed consent procedure per details in policy and procedure 221	
8. Checked ICAD for completeness: <ul style="list-style-type: none"> • Subject completed all applicable data fields in their hand (printed name, signature with date and time, initialed and dated each page if applicable). • Consent provider completed all applicable data fields in their hand. Note: Consent provider must be listed as key personnel, authorized by the IRB to obtain consent. • Witness completed all applicable data fields in their hand. Note: Witness must be Beaumont employee or physician. • Legally Authorized Representative (LAR) completed all applicable data fields in their hand, or <input type="checkbox"/> NA Rationale for use of LAR: 	
9. Provided a signed copy of the ICAD to the subject or LAR.	
10. Filed a signed copy of the ICAD in the medical record.	
11. Filed the originally-signed ICAD in the subject's research record.	

/ Printed Name of Consent Provider

/ Signature of Consent Provider

Date/Time

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Title Informed Consent and Authorization in Research	Location ALL Beaumont Health	Functional Area Research Institute
Policy Owner Administrative Director	Document Type Policy	Effective Date 10/21/2016

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.