Title: **Vulnerable Populations - Enrollment of Decisionally Impaired Participants**	*Applicable to: **Beaumont Health**	Effective Date: **03/20/2018** Last Periodic Review Date: **03/20/2018**
Policy Owner: **Administrative Director**	Document Type: **Policy**	Functional Area: **IRB and Clinical Research, Research Institute**

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

I. PURPOSE:

The purpose of this policy is to describe Institutional Review Board (IRB) oversight required to protect the rights and welfare of human participants who are, or are likely to become, decisionally impaired during the proposed time period of research participation at Beaumont Health (Beaumont).

II. SCOPE:

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

III. BACKGROUND:

There are no specific federal regulations concerning the inclusion of decisionally impaired participants in clinical research. These vulnerable participants have the same rights as other individuals to participate in research, but special care must be taken to avoid coercion.

The IRB oversees the protection of the rights and welfare of research participants who are temporarily or permanently decisionally impaired by requiring additional safeguards in study conduct and the informed consent and authorization process.

Some research protocols aim to enroll decisionally impaired individuals as the study population and specifically focus on their special problems. Examples include, but are not limited to, patients with a comatose state. Other research protocols may focus on an illness or condition unrelated to cognitive ability but will incidentally include one or more vulnerable participants when an individual with altered cognition meets enrollment criteria and is enrolled in the trial. In either case, special considerations must be made to ensure study conduct and the informed consent and authorization process is adequate and appropriate for the participant's level of comprehension.

IV. DEFINITIONS:

A. **Court** - The probate court or the court with responsibility with regard to mental health services for the county of residence of an individual with developmental disability, or for the county in which the individual was found if a county of residence cannot be determined.

B. **Legal Guardian** - *Plenary Guardian* or *Partial Guardian*.
Plenary guardian means a guardian who possesses the legal rights and powers of a full guardian of the person, or of the estate, or both.
Partial guardian means a guardian who possesses fewer than all of the legal rights and powers of a plenary guardian, and whose rights, powers, and duties have been specifically enumerated by court order.

C. **Legally Authorized Representative -** 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 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.

D. **Assent -** An individual's affirmative agreement to participate in research obtained in conjunction with permission from the individual's LAR. Mere failure to object should not be construed as assent.

E. **Decisionally or Cognitively Impaired -** Having a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorder), an organic brain syndrome (e.g., stroke, dementia), a developmental disability (e.g., Down syndrome, autism), or a catastrophic event that affects cognitive functioning (e.g., traumatic brain injury, coma) to the extent capacity for judgment and reasoning is temporarily or permanently diminished. Persons under the influence or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, or terminally or critically ill patients, may also be defined as decisionally impaired as their ability to make informed decisions may be affected.

F. **Dissent -** An individual's negative expressions, verbal and/or non-verbal, that they object to participation in the research or research activities.

V. POLICY:

It is the policy of Beaumont to protect the rights of all research participants, including those who may be decisionally impaired. The Beaumont Health IRB serves as the primary Institutional Review Board for human participant research conducted at Beaumont (for information about the use of external IRB's, see policy *Review by an External Institutional Review Board*. In accordance with federal regulations, IRB review and approval is required to protect the rights and welfare of human participants. It is the policy of the IRB to review, approve, and provide guidance on special ethical considerations when decisionally impaired participants are involved in research. The IRB will conduct initial and continuing review of each ongoing research trial, at intervals appropriate to the degree of risk to human participants, but at a minimum once per year. Research protocols may aim to enroll decisionally impaired participants as the intended study population or may incidentally enroll decisionally impaired participants. These studies will be reviewed to ensure additional safeguards are incorporated in the protocol and informed consent and authorization process to ensure the risks and benefits are commensurate with research participation.

A. **Determining Mental Capacity -** In the event a Patient Advocate or Legal Guardian provides information to the PI/Institution that such LAR must give

consent, then the PI will evaluate the information and work with the LAR, as appropriate. If no LAR documentation is provided, an adult is presumed to be competent.

It is the responsibility of the principal investigator (PI), and any authorized consent provider, to assess the individual's mental capacity at the time of initial consent and authorization, and continually throughout the research study to assure continued protection of the participant's rights. If mental capacity is questionable, the treating physician should make the appropriate consult to psychiatry, gerontology, etc. When a potential participant is determined to be decisionally impaired, the research consent and authorization must be obtained from the participant's LAR. The consent provider must document this determination and justification in the medical chart and research record at the time of the consent and authorization procedure. Assent from the participant should be obtained as appropriate and documented in the medical chart and research record.

B. **Changes in Cognitive Status During Research Participation** - Additionally, should the participant's cognitive status change during the course of the study and the participant no longer has the cognitive capacity to provide consent, the consent and authorization of the participant's LAR must be sought for continued involvement in the study. Any significant communication or interaction key personnel have with the participant or LAR, related to the participant's ongoing or newly developed cognitive impairment, must be documented in the research record.

Furthermore, should a previously decisionally impaired participant (enrolled in research through consent of their LAR) recover cognitive capacity, the participant must be consented, using a clean copy of the current informed consent and authorization document, to continue participating in the research.

During review of the research proposal, the IRB must find appropriate provisions are made for determining a participant's ability to provide consent or to withdraw, through evidence of one or more of the following characteristics pertaining to the individual:

1. The ability to willingly make a choice.
2. The ability to understand relevant information.
3. The ability to appreciate the situation and its likely consequences.
4. The ability to manipulate information rationally.

C. **Assent Requirements** - When utilizing the decisionally impaired participant's LAR, the participant's assent must also be obtained whenever possible. The decision to obtain assent should include considerations of the risks and benefits expected from participation in the proposed research, as well as the ability of the research participant to provide written or oral assent.

All research participants must be informed of all aspects of their research involvement to the extent possible. The following rules apply to the requirements for obtaining assent from a potential research participant who is decisionally impaired:

1. If there is a reasonable probability of benefit to the participant from participation in the research, **or** there is little direct benefit but minimal risk, written assent is not required. The participant's oral assent in addition to the written consent of the LAR would be sufficient.
2. **If participation in the research provides no reasonably expected benefit to the participant and involves more than minimal risk, the decisionally impaired participant's written assent must be obtained in addition to the written consent of the LAR. If the decisionally impaired participant cannot provide written assent due to their condition, they may not be enrolled in the study.**
3. When a participant is decisionally impaired and their LAR provides consent and authorization to enroll the participant in the research, the LAR completes the "Alternate Signature" fields on the IRB-approved informed consent and authorization document. When the intended research population is participants with cognitive impairment and the participant is able to provide written assent, the participant should sign an IRB-approved, study-specific assent document. An assent template is available on the IRB website. **If the participant's cognitive impairment was incidental to his/her eligibility for the study and the participant is able to provide written assent, the participant should sign and/or print on the last page of the informed consent and authorization document, <u>next</u> to the signature of the LAR.** The written or oral assent procedure, with consent by the LAR, must be documented in the medical record and research files by the consent provider at the time of the procedure.

D. **IRB Submission Requirements for Research Intending to Enroll Decisionally Impaired Participants -** When decisionally impaired participants are the intended research population, a study specific assent document should be prepared and submitted for IRB approval. The investigator must provide the IRB with the following:

1. Justification for aiming to enroll vulnerable participants.

2. A description of any special procedures or circumstances which apply to participant recruitment.
3. The method for identifying the participant's LAR, and the method for obtaining consent and authorization from the LAR.
4. The method of obtaining assent from the participant.
   These issues are addressed in the initial IRB protocol application within iMedRIS.

In addition, the informed consent and authorization document must include a signature line for the LAR, with a prompt to designate the basis for the LAR's authority to sign the informed consent and authorization document (e.g., court appointed guardian, next of kin, patient advocate pursuant to medical Durable Power of Attorney).

E. **Promotional Material Referencing Beaumont** - When promotional material mentions Beaumont, references a Beaumont department (e.g., Urology Research) or Beaumont physician, or provides a Beaumont phone number, Marketing approval is required. If the promotional material is targeted towards children or adults who are decisionally impaired, the marketing must be level/age appropriate for the study population's understanding, whenever possible. If the material is not going to be understood by the decisionally impaired participant based on the cognitive function level, the information is to be provided to the LAR. Additionally, the requirements of the *Clinical Research Study Promotion* policy and *Compensation and Incentives Offered to Research Participants* policy must be followed. Prospective IRB approval of any study-related promotional materials is required.

VI. REFERENCES:

21 CFR 50 Subpart B Informed Consent Requirements
21 CFR 56.107(a) IRB Membership
21 CFR 56.108 IRB Functions and Operations
45 CFR 46.111(b) Criteria for IRB Approval and Research
45 CFR 46.108 IRB Functions and Operations
45 CFR 46.116 Requirements for Informed Consent
45 CFR 46.117 Documentation of Informed Consent
The *Belmont Report*
Am J Psychiatry 155:11, November 1998, "Guidelines for Assessing the Decision-Making Capacities of Potential Research Subjects with Cognitive Impairment"

The Office of Human Subjects Research (OHSR), National Institutes of Health, Information Sheet #7, "Research Involving Decisionally Impaired Subjects: A Review of Some Ethical Considerations"

VII. ASSOCIATED POLICIES:

IRB Policy *IRB Initial Review of Research Protocols*
IRB Policy *Informed Consent and Authorization in Research*
IRB Policy *Compensation and Incentives Offered to Research Participants*
IRB Policy *Clinical Research Study Promotion*
IRB Policy *Recruiting Human Participants for Clinical Research*
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*

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.