

Title: Enrollment of Visually Impaired Participants	*Applicable to: Beaumont Health	Effective Date: 01/12/2018
		Last Periodic Review Date: 01/12/2018
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 protect the rights and welfare of human participants who are, or are likely to become visually impaired during the proposed time period of their research participation.

II. SCOPE:

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

III. GENERAL:

The IRB mandates informed consent of the participant to the extent required by Federal regulations and Beaumont policies. The IRB oversees the protection of the rights and welfare of research participants temporarily or permanently visually impaired by including “appropriate additional safeguards”. For the purposes of this policy, a “visually impaired individual” is a person who cannot see sufficiently to read the informed consent and authorization document (ICAD) without the use of an assistive device. For the purposes of this policy, assistive devices include but are not limited to hand-held magnifiers, scanners/projectors, computer reading systems and embossed Braille writing system. Eyeglasses are not considered assistive devices. This policy specifies mechanisms by which the IRB can approve and implement “additional

Title: Enrollment of Visually Impaired Participants	*Applicable to: Beaumont Health	Effective Date: 01/12/2018
		Last Periodic Review Date: 01/12/2018
Policy Owner: Administrative Director	Document Type: Policy	Functional Area: IRB and Clinical Research, Research Institute

safeguards” for the consent process with visually impaired participants and, in the event they are also cognitively impaired, their legally authorized representative (LAR).

IV. POLICY:

The IRB must conduct initial and continuing review of each ongoing protocol at intervals appropriate to the degree of risk to human participants, but at least once per year. Research protocols that intend to, or may as a course of the research, enroll visually impaired participants should receive appropriate review of the risks and benefits commensurate with participating in the research, as well as the protection of the visually impaired subjects’ right to informed consent and authorization.

V. PROCEDURE:

- A. Investigators planning research with human participants who are, or are likely to become, visually impaired must take appropriate provisions for obtaining informed consent and authorization.
- B. Since a visually impaired individual is unable to read the approved informed consent and authorization document without use of assistive devices, special consideration must be given to protect their rights.
- C. In the event the ICAD is read by the participant using an assistive device, this must be fully described in the consent process documentation in the participant’s case history (i.e., clinic, hospital or research chart).
- D. When the participant is unable to read the ICAD due to visual impairment, with or without an assistive device, it may be read to them. The participant would then sign the ICAD, consenting to research involvement. There must be a witness present during the entire consent process. The witness serves as “**witness to the entire consent procedure**” rather than witnessing the signature only. This must be appropriately documented on the final page of the ICAD and described in the consent process documentation in the participant’s case history.
- E. When the ICAD is read to a visually impaired participant, there must be three signatures on the document:
 - 1. the participant*, **and**
 - 2. the witness, **and**

Title: Enrollment of Visually Impaired Participants	*Applicable to: Beaumont Health	Effective Date: 01/12/2018
Policy Owner: Administrative Director	Document Type: Policy	Last Periodic Review Date: 01/12/2018 Functional Area: IRB and Clinical Research, Research Institute

3. the informed consent provider.

* If the participant is cognitively impaired, the LAR’s signature is required rather than the participant’s signature. The need for assent of a participant who is both visually and cognitively impaired must be reviewed with the IRB.

If a participant’s vision status is not static, (e.g., required assistive device to read or required the document read to them, and subsequently became able to read the ICAD independently), the change in vision status should be included in the documentation of the consent process in the participant case history.

VI. APPLICABLE REGULATIONS AND GUIDELINES:

- 21 CFR 50-Subpart B Informed Consent
- 21 CFR 56.107 IRB Membership
- 45 CFR 46.108 IRB Functions and Operations
- 45 CFR 46.109 IRB Review of Research
- 45 CFR 46.111 Criteria for IRB Approval of Research
- 45 CFR 46.117 Documentation of informed consent

VII. REFERENCES TO OTHER APPLICABLE POLICIES

- IRB Policy [*Informed Consent and Authorization in Research*](#)
- Founding Beaumont Patient Care Corporate 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*
- Clinical Research SOP 612 *Informed Consent and Authorization Development and Implementation*

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.

Disclaimer: User must ensure that any printed copies of this policy/procedure are current by checking the online version of the policy/procedure before use.