

Beaumont®

William Beaumont Hospital

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Prepared By Human Investigation Committee		Prior Issue Date 8/25/2011	Issue Date 9/8/2014
<u>PURPOSE</u>	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.		
<u>SCOPE</u>	This policy applies to investigators, key research personnel, Human Investigation Committee (HIC) members and HIC staff.		
<u>GENERAL</u>	The HIC mandates informed consent of the participant to the extent required by Federal regulations and Beaumont policies. The HIC 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 HIC can approve and implement “additional safeguards” for the consent process with visually impaired participants and, in the event they are also cognitively impaired, their legally authorized representative (LAR).		
<u>POLICY</u>	The HIC 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.		
<u>PROCEDURE</u>	<p>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.</p> <p>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.</p> <p>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).</p> <p>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 <u>entire</u> consent process. The witness serves as “witness to the entire consent procedure” rather than witnessing the signature only. This must be</p>		

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appropriately documented on the final page of the ICAD and described in the consent process documentation in the participant's case history.

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**
- 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 HIC.

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.

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

REFERENCES TO OTHER APPLICABLE POLICIES

HIC Policy #221 *Informed Consent and Authorization Process*

Beaumont Hospitals Patient Care Corporate Policy #304 *Informed Consent*

Clinical Research SOP #612 *Informed Consent and Authorization Development and Implementation*

☐ Original
 ☒ Revision or Review

Research Institute Compliance Committee Review Date: _____

Corporate Administration Approval: _____ Date: _____
V.P. of Research or Chief Medical Officer

Research Institute Board Approval: NA Date: _____

Research Administration Approval: _____ Date: _____
Administrative Director

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