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PURPOSE

The purpose of this policy is to describe the Institutional Review board (IRB) oversight of research participant recruitment in human participant research at Beaumont Health (BH).

SCOPE

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

BACKGROUND

Federal regulations require an Institutional Review Board (IRB) to review and have the authority to approve, require modifications or disapprove all research activities involving human participants. The IRB is required to ensure appropriate safeguards exist to protect the rights and welfare of research participants. In fulfilling these responsibilities, the IRB reviews all participant recruitment materials and associated documents in the interest of protecting the rights and welfare of potential participants.

In accordance with Good Clinical Practices (GCPs), recruitment of research participants must be equitable. The Principal Investigator (PI) must ensure, whenever possible, diversity of ethnicity, socio-economic status and gender be considered in participant selection and recruitment. A variety of groups must be afforded the opportunity to participate in and/or benefit from a research study, and no one group made to bear the majority of burdens inherent in research participation.

The recruitment process must respect the privacy and confidentiality rights of potential participants. The requirements set forth in the Health Insurance Portability and Accountability Act (HIPAA) for use and disclosure of Protected Health Information (PHI) for research provide protections against using private and confidential information to contact potential participants for research recruitment without appropriate review and approval by the IRB before the activities begin (refer to IRB Policy 218 *HIPAA and Research*).

POLICY

The planned participant recruitment strategies and materials must be included in each IRB project application. The IRB will review:

- The information contained in the advertisement,
- The mode of its communication,
- The final copy of printed advertisements,
- The final audio or video taped advertisements,
- If the selection of human participants is equitable, taking into account the purpose of the research, the setting in which the research will be conducted and the inclusion/exclusion criteria,
- Whether potential participants are vulnerable to coercion or undue influence,
- If special issues or potential problems exist related to involvement of vulnerable populations in the research, and
- If the recruitment process provides participants with sufficient information and an opportunity to consider whether or not to participate.

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The IRB must examine all recruitment materials and scripts prior to their use by the researchers to ensure advertisements do not:

- State or imply a certainty of favorable outcome or other benefits, beyond what is outlined in the consent document and the protocol
- Include exculpatory language,
- Emphasize the payment or the amount to be paid, by such means as larger or bold type,
- Promise "free treatment" when the intent is only to say participants will not be charged for taking part in the investigation.

Advertisements are limited to the information prospective participants need to determine their eligibility and interest, such as:

- The name and address of the researcher or research facility,
- The purpose of the research or the condition under study,
- In summary form, the criteria that will be used to determine eligibility for the study,
- A brief list of benefits to participants, if any,
- The time or other commitment required of the participants,
- The location of the research and the person or office to contact for further information.

Preparatory to Research

When conducting research it may be necessary for the PI or designee to review medical records and obtain limited PHI in order to **determine if there are enough potential participants** with the condition being studied. This activity is covered under HIPAA regulations as "preparatory to research" and is not considered part of the recruitment effort.

Using Medical Records to Identify Potential Participants

The review of medical records to **identify potential participants** for a specific study is considered part of the recruitment process. To access a potential participant's medical record for screening, the study must have received IRB approval and a HIPAA Waiver of Authorization (refer to IRB Policy 218, *HIPAA and Research*).

Direct Contact: Face-to-Face, Telephone, Mail or E-mail

Key research personnel may contact potential participants directly, if such contact is described in the approved IRB application. This contact may occur in person during a visit to a Beaumont facility or doctor's office, by telephone, mail or e-mail.

Mail, e-mail or telephone contact must be conducted in a manner which respects the individual's rights. If there is no response after three (3) attempts to contact an individual, the investigator must remove the individual from the contact list and cease attempting to make contact regarding study participation.

Physician-to-Physician Contacts

Investigators may provide physicians and other health care providers with information about a study in order to promote interest and gain referrals. IRB approval is required for general or recruitment correspondence directed to healthcare providers and must include any

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	conflict of interest disclosures required by management plans related to the study. Physician communications to providers concerning previously consented patients do not require IRB review and approval. Providing a list of studies and associated general information (not to exceed that posted on clinicaltrials.gov) and not directed at patients, does not require IRB review and approval. Payment for referrals (i.e., "finders fees") is expressly prohibited.
Public Advertising	Requests for advertising must be submitted through Beaumont's Marketing department. Prospective IRB review and approval is required for all recruitment materials intended to solicit participation for a research study. For additional guidance, see IRB Policy 220 *Compensation and Incentives Offered to Research Participants,* and IRB Policy 234 *Review of Advertising and Press Releases Related to Clinical Research.*
Public Information Sessions	The IRB must review and approve all information to be presented or given to potential participants at public information sessions.
Secondary Recruitment	Secondary recruitment occurs when an investigator wishes to recruit the relatives of an existing research participant enrolled in a genetic study. Secondary recruitment often involves providing a stamped envelope containing study solicitation materials to the primary participant, and requesting they address and mail the envelope to their relative. If the PI does not receive a response from the relative, the IRB may permit the PI to ask the primary participant to inquire if the relative received the study materials. However, the PI must not contact the relative directly. If the relative does not respond, the PI must remove the individual from the list of potential participants.
Recruiting Employees, Students or Trainees	Voluntary participation is a basic ethical principle of human participant research. Potential participants who are students, trainees or employees of BH should not be recruited by their supervisor or anyone in a direct reporting relationship. Additionally, these individuals may not be *directly* (i.e., in person, via direct email or telephone) solicited by a member of their current department, an administrator, medical director or faculty to enroll in Beaumont research. An employee may not be required to enroll in employer-initiated research as a condition of employment. Similarly, a student may not be required to enroll in Beaumont research as part of a course requirement. Refer the IRB Policy 256 *Vulnerable Populations: Enrollment of Employees, Students or Trainees* for additional requirements.
Finders' Fees	The IRB does not allow the use of finders' fees, which for the purposes of this policy, are payments made to individuals for research participant or patient referrals. Payment of finder's fees results in an inherent conflict of interest. Payments to the organization or research staff designed to accelerate recruitment, which are tied to the rate or timing of enrollment ("bonus payments") are also prohibited.

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REFERENCES

45 CFR 46.108(b) IRB Functions and Operations
21 CFR 56.108(b) IRB Functions and Operations
45 CFR 46.111 Criteria for IRB Approval of Research
21 CFR 56.111 Criteria for IRB Approval of Research
45 CFR 160 and 164 (Privacy and Security Rule)
Belmont Report
Guidance for Industry, E6 Good Clinical Practice

ASSOCIATED POLICIES
Involved in Research

Research Institute Policy 118 Conflict of Interest for Any Individual

IRB Policy 256, *Vulnerable Populations: Enrollment of Employees, Students or Trainees*
IRB Policy 218 *HIPAA and Research*
IRB Policy 220 *Compensation and Incentives Offered to Research Participants*
IRB Policy 234 *Review of Advertising and Press Releases Related to Clinical Research*
Clinical SOP 613 *Subject Recruitment and Screening*

☐ 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: _____ Date: _____

Research Administration Approval: _____ Date: _____
Administrative Director