

| | | |
|--|---|--|
| Title: Participant Recruitment and Screening | *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: Clinical Research SOP's, 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 recruitment and screening phase of a clinical study is frequently challenging. Successfully recruiting and screening participants involves the development and implementation of a well-coordinated plan which may require the efforts of all key research personnel. Once in place, participant recruitment efforts must be constantly assessed for effectiveness, and new strategies implemented as necessary. After potential participants have been identified through recruitment efforts, the process of participant selection begins.

This standard operating procedure (SOP) describes the steps for fulfilling the regulatory and clinical requirements involved in participant recruitment and screening.

II. SCOPE:

This SOP applies to the activities involved in recruiting and screening participants for clinical studies at Beaumont Health.

III. RESPONSIBILITY:

This SOP applies to key research personnel involved in conducting clinical studies at Beaumont Health.

| | | |
|--|---|--|
| Title: Participant Recruitment and Screening | *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: Clinical Research SOP's, Research Institute |

IV. PROCEDURES:

Studies vary in screening complexity. Screening procedures must be prospectively approved by the Institutional Review Board (IRB) of record. While for some studies, it is possible to determine full eligibility prior to informed consent, other studies require a multi-step screening process (i.e., patients meet initial criteria but require additional procedures or study specific testing after informed consent to determine final eligibility). For purposes of this SOP, pre-screening is considered any screening activity that takes place prior to informed consent. Screening activity will refer to post consent activities to determine final eligibility.

A. Develop and implement an overall recruitment plan

1. The planned participant recruitment strategies and materials must be included in each IRB project application and approved by the IRB prior to implementation.
2. Based upon the specific inclusion/exclusion criteria for a study, identify the target population for potential study participants.
3. Review sponsor requirements for enrollment and establish a recruitment timeline.
4. Identify sources of potential participants.
5. Consider research promotion options and review against the IRB of record’s research promotion policies. The policy for Beaumont Health’s IRB is IRB Policy [*Clinical Research Study Promotion*](#). To place a research recruitment advertisement, initiate the following steps:
 - a. Work with Marketing and the Research Accountant to create a budget for the advertisement/recruitment material. Assure funding for the ad is available and approved.
 - b. Submit a *Request for Research Promotion* form to Marketing for assistance preparing the advertisement/recruitment material content or to request approval of content provided by the sponsor. Review publicity options, such as news releases, public service announcements, print or radio advertisements.
 - c. Once the information on the form is verified, Marketing will contact the media agency with a buy proposal for the advertisement.
 - d. The radio summary or print advertisement and schedule is faxed to the research department for approval.
 - e. Submit the advertising to the IRB of record for approval. **Do not initiate any research promotion, including advertising until written IRB approval is obtained.** When Beaumont Health IRB serves as IRB of record and the ad was not part of the initial approval, submit an *Amendment Request* to the IRB and include the script or print advertisement for approval.
 - f. Once written IRB approval is obtained, an IRB-stamped, approved copy of the advertisement must be provided to Marketing.
 - g. Marketing contacts the media agency regarding approval and the decision to buy the advertisement, and informs the research department of the advertisement dates.

| | | |
|--|---|--|
| Title: Participant Recruitment and Screening | *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: Clinical Research SOP's, Research Institute |

- h. The media agency places the advertisement.
- i. Once approval of the recruitment material has been obtained from Marketing, Research Accounting, and the IRB of record, it may be used in pre-screening activities.
- 6. Perform pre-screening activities to identify those potential participants you plan to approach for consent:
 - a. Develop a pre-screening tool based on the protocol’s inclusion and exclusion criteria.
 - b. Pre-screen participants via chart review (electronic or paper) and/or phone contact to evaluate basic eligibility.
 - c. Determine eligible participants’ interest in participation.
 - d. Approved Consent providers will administer Informed Consent for those who meet the pre-screening eligibility criteria and are determined to be eligible for the study. Consent will be administered to determine a participant’s level of interest in participation.

B. Initiate screening procedures

- 1. Once the informed consent and authorization process has been completed and the participant’s signature has been obtained, the participant may be screened for potential participation.
- 2. Maintain a screening log to record all participants who have consented, enter the consent date, the enrollment date (if enrolled), and if not enrolled, the reason for screen failure, in accordance with ICH 4.1.1.29. This log demonstrates the lack of bias in the selection of participants and the investigators attempt to enroll a representative sample of participants.

C. Assess the effectiveness of the recruitment plan

- 1. Monitor progress and assess results of the recruitment plan.
- 2. Keep the principal investigator and sponsor apprised of actual enrollment in relation to the enrollment goal.
- 3. Identify alternative strategies if actual enrollment is not meeting the recruitment timeline.

V. RECRUITER PHONE SCRIPTS AND OTHER PHONE CONTACT:

Some proposed research involves making initial contact with potential participants by phone (or actually conducting the research by phone via questionnaire). **Contacting potential participants for recruitment by phone must be prospectively IRB approved.** When Beaumont Health is the IRB of record, refer to IRB Policy, [Clinical Research Study Promotion](#) for information on preparing and submitting a recruitment phone script. Additionally, some research involves periodic phone contact with participants to arrange follow-up appointments or other purposes. Presenting a professional image while respecting the rights of potential and actual participants, is essential.

A. General phone contact tips

- 1. Speak clearly in a professional and cheerful manner. Be courteous and polite.

| | | |
|--|---|---|
| Title: Participant Recruitment and Screening | *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: Clinical Research SOP's, Research Institute |

2. ***Speak directly with the participant or potential participant, not a family member or housemate.*** Do not provide further information about the reason for your call to anyone but the intended recipient of the call.
3. Address the participant/potential participant properly by her or his title (e.g., Good morning Ms. Jones). Never address an unfamiliar caller by his or her first name.
4. Identify yourself properly. Provide your name and department. For example, "Good afternoon Mr. Brown, this is Ms. Simpson from Beaumont Research Institute." Be aware of people around you while talking on the phone. Avoid using speaker phone. Be discreet!
5. Voicemail messages should be avoided. If messages are necessary, they should be brief and **must not** contain information about the participant's diagnosis, treatment, hospitalization or the nature of research involvement. For example, "This is Beaumont Health Research Institute calling for Mr._____. Please call Susan at 248-____-_____."
6. ***Stick to the purpose of the phone call!*** Adhere to the script as closely as possible.
7. ***Medical results and advice:*** Never look up and relay test results or give medical advice unrelated to the potential study. Always refer the participant to their primary physician or health care provider.
8. ***IRB approval and contact information:*** If a participant states concern as to how their contact information was obtained or how the researcher is authorized to contact them, describe how the study was approved by the IRB of record and provide contact information should they wish to follow-up. Report the participant concern to your research manager or Research Compliance Coordinator. If the participant seems reluctant to continue, remind them their participation is voluntary, thank them for their time and end the phone call.
9. ***Protecting key personnel phone numbers:*** Calls to participants or potential participants must be made from a Beaumont phone line. Participant/potential participant phone numbers may not be physically taken from Beaumont. For personal safety reasons, key personnel are not permitted to share their personal phone numbers (cell phone or home phone) with potential/actual participants; staff pagers or call lines established by research departments/the medical school should be used. If return phone calls must be made from personal phones (i.e., answering a participant's page after hours), contact the Beaumont Health switchboard and ask them to route your call in order to protect your personal phone number.

VI. EMAIL COMMUNICATION WITH PARTICIPANTS/POTENTIAL PARTICIPANTS:

Email communications with participants should be limited to general information and should never include Protected Health Information (PHI) or specific study information which might identify the participant's medical condition or disease. In the event it is necessary to communicate with a participant or potential participant by email, you must use secure email. This can be achieved by using one of the following methods:

| | | |
|--|---|--|
| Title: Participant Recruitment and Screening | *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: Clinical Research SOP's, Research Institute |

1. Type <SECURE> in the subject line of the email. Be sure SECURE is in all caps and the <> is surrounding.
 2. Set the sensitivity to “Confidential” by selecting the Dialog Box Launcher in the Tags section on the toolbar and then change Sensitivity to “Confidential”.
- Contact the IT Service Desk at 888-481-2448 for more information on how to send secure email.

VII. APPLICABLE REGULATIONS AND GUIDELINES:

- 21 CFR 50.20 General requirements for informed consent
- 21 CFR 56.109 IRB review of research
- 21 CFR 312.60 General responsibilities of investigators
- 21 CFR 312.62 Investigator recordkeeping and record retention
- FDA Information Sheets, October 1998: Screening Tests Prior to Study Enrollment and Recruiting Study Subjects
- International Conference on Harmonization; Good Clinical Practice: Consolidated Guideline, May 1997

VIII. REFERENCES TO OTHER APPLICABLE SOPs

- Research Administration Policy [Responsibilities of the Principal Investigator](#)
- IRB Policy [Informed Consent and Authorization in Research](#)
- IRB Policy [Clinical Research Study Promotion](#)
- IRB Policy [Recruiting Human Participants for Clinical Research](#)
- Clinical Research Policy [Responsibilities of the Research Team](#)
- Clinical Research Policy [Regulatory Files and Study Subject Records](#)

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.