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.

SCOPE

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

RESPONSIBILITY

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

PROCEDURES

Develop and implement an overall recruitment plan

- The planned participant recruitment strategies and materials must be included in each HIC project application and HIC-approved prior to implementation.
- Based upon the specific inclusion/exclusion criteria for a study, identify the target population for potential study participants.
- Review sponsor requirements for enrollment and establish a recruitment timeline.
- Identify sources of potential participants.
- Consider research promotion options, as described in HIC Policy #234, Clinical Research Study Promotion. To place a research recruitment advertisement, initiate the following steps:
  - Assist the Research Accountant to create a budget for the advertisement/recruitment material.
  - 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.
  - Once the information on the form is verified, Marketing will contact the media agency with a buy proposal for the advertisement.
  - The radio summary or print advertisement and schedule is faxed to the research department for approval.
  - Submit an Amendment Request to the HIC and include the script or print advertisement for approval. Do not initiate any research promotion, including advertising until written HIC approval is obtained.
  - Once written HIC approval is obtained, an HIC-stamped, approved copy of the advertisement is sent to Marketing.
• Marketing contacts the media agency regarding approval and the
decision to buy the advertisement, and informs the research
department of the advertisement dates.
• The media agency places the advertisement.
• Create tools to track recruitment efforts.
• Perform pre-screening activities:
  o Once approval of the recruitment material has been obtained from
    Marketing, Research Accounting, Research Administration and
    the HIC, pre-screening activities may begin.
  o Develop a pre-screening tool based on the protocol’s inclusion
    and exclusion criteria.
  o Pre-screen participants via chart review (electronic or paper)
    and/or phone contact to evaluate basic eligibility.
  o Determine eligible participants’ interest in participation.
  o Develop and maintain a pre-screening log.

**Initiate screening procedures**
• 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.
• Maintain a screening log to record all participants who enter screening
  and include the enrollment date, and detailed reasons why the
  individual was not enrolled (if applicable), 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.

**Assess the effectiveness of the recruitment plan**
• Monitor progress and assess results of the recruitment plan.
• Keep the principal investigator and sponsor apprised of actual
  enrollment in relation to the enrollment goal.
• Create alternative strategies if actual enrollment is less than
  enrollment goals.

### 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 by phone must be
prospectively HIC approved.** Refer to HIC Policy #234, *Clinical
Research Study Promotion* for information on preparing and submitting a
recruitment phone script. Additionally, some research involves periodic
phone contact with participants. Presenting a professional image while
respecting the rights of potential and actual participants is essential.

**General phone contact tips**
• Speak clearly in a professional and cheerful manner. Be courteous
  and polite.
• Address the caller properly by his or her title (e.g., good morning
  Mr. Brown). Never address an unfamiliar caller by his or her first
  name.
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!

Voicemail messages should be avoided. If messages are necessary, they should be brief and not contain information about the participant’s diagnosis, treatment, hospitalization or the nature of research involvement. For example, “This is Beaumont Health System Research calling for Mr._____. Please call Susan at 248-____-____.

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.

Stick to the purpose of the phone call! Adhere to the script as closely as possible.

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.

HIC 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 HIC and provide contact information (HIC 248-551-0662) should they wish to follow-up. If the participant seems reluctant to continue, remind them their participation is voluntary, thank them for their time and end the phone call.

Protecting caller’s phone number: Calls to participants or potential participants must be made from Beaumont. Phone numbers may not be physically taken from Beaumont. For personal safety reasons, if phone calls must be made from a personal phone (i.e., answering a participant’s page after hours), contact the switchboard to route your call and protect your personal phone number.

**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

**REFERENCES TO OTHER APPLICABLE SOPs**

- Research Administration Policy #118 Responsibilities of the Principal Investigator
- Clinical Research Policy #605 Responsibilities of the Research Team
- HIC Policy #252 Recruiting Human Subjects for Clinical Research
- Clinical Research Policy #600 Assessing Protocol Feasibility
- Clinical Research Policy #608 Regulatory Files and Subject Records

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Clinical Research Policies and Procedures

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