1 PURPOSE
This procedure describes the steps to be taken while conducting subject recruitment for all human subject research within the Memorial Healthcare System.

2 GENERAL INSTRUCTIONS AND RESPONSIBILITIES
   a) The Institutional Review Board (IRB) is responsible for reviewing the methods, language, and materials in all applicable media that Investigators propose to use to recruit their subjects. The IRB must approve recruitment materials prior to implementation by the site personnel.
   b) Investigators are responsible for the content of all subject recruitment materials and ensuring that those materials have been properly reviewed and approved by the IRB.
   c) Investigators are responsible for consulting with the IRB to ensure that all regulatory requirements have been taken into consideration in the development of these materials.
   d) Investigators are responsible for overseeing subject recruitment and screening efforts for individual clinical research studies. This includes approaching subjects to determine interest, discussing the requirements of the study, reviewing the informed consent, as well as any advertisements that may be placed in the media or flyers placed at specific locations, social media posts, etc.

3 SPECIFIC PROCEDURES
3.1 Reviewing and Approving Recruitment Materials
   a) No claims (explicit and implicit) should be made in the recruitment materials that the investigational product is safe and effective for the purpose(s) under investigation, or that the investigational product is equivalent or superior to the currently marketed products.
   b) Recruitment materials should not use terms such as “new treatment” or “new medication” or “new drug” that may confuse the prospective subject into thinking that the product is approved for that use.
c) All materials should clearly state that the product is investigational or an alternative term substituted that is understandable to the subject population.

d) Recruitment materials should not be misleading in any way, or coerce to vulnerable populations, such as overemphasizing monetary payments or making promises about the certainty of treatment success.

e) The amount of monetary compensation (if applicable) needs to be carefully determined so as to not be coercive, thus enabling the prospective subject to make an informed and objective decision about participating in the study.

f) Only language appropriate for the target population will be used in any recruitment advertisements/materials intended for that population.

g) FDA guidance permits the following information to be provided in subject recruitment materials (See Attachment A):

- Name and address of the Investigator and/or study facility
- Purpose of the study and summary of eligibility criteria
- Expected duration of the study
- Straightforward and truthful description of benefits to subject
- Location of the study and who to contact for information

h) The Investigator should have draft recruitment literature, telephone scripts, and the text of materials to be audio-taped or videotaped evaluated by the IRB for regulatory compliance.

i) All recruitment materials will be submitted to the IRB for review and approval prior to use.

j) Subjects will be recruited in an unbiased manner, irrespective of race, religion, sexual orientation, or economic status; unless a specific inclusion or exclusion is dictated in the clinical protocol and approved by the IRB.

k) To ensure unbiased selection of subjects, screening logs will be maintained by the site for each study (Reference SOP 603, Attachment B, Screening and Enrollment Log).

l) Special issues regarding the recruitment and enrollment of vulnerable populations will be submitted to and reviewed by the IRB.

m) No publishing and distributing or other use of any recruitment materials may occur until the materials have been approved by the IRB.

n) Copies of all IRB approved recruitment materials must be maintained in the appropriate section of the Regulatory Master File.

3.2 Developing and Implementing the Recruitment Plan

a) The following are important elements of a recruitment plan:

- The Investigator is responsible for following all institutional policies on recruitment and identifying the target population for potential study subjects based on specific inclusion/exclusion criteria for a study.
- The Investigator should establish a recruitment timeline and strategy with his/her research team to identify the sources of potential subjects.
The Sponsor and Investigator should determine appropriate recruitment methods (e.g. video/audio ads, letters, community talks, newspaper articles, patient support groups, Internet) based on these assessments.

The Investigator should monitor the progress of patient recruitment on study enrollment and assess the results of the recruitment strategy, and develop appropriate alternative strategies, if necessary, if subject enrollment is less than optimal.

4 REFERENCES TO OTHER APPLICABLE SOPS
- SOP 803 Subject Screening and Enrollment

5 ATTACHMENTS
A. Guidelines for Recruitment and Advertisement

6 APPLICABLE REGULATIONS AND GUIDELINES
- General Requirements for Informed Consent (21 CFR 50.20)
- Elements of Informed Consent (21 CFR 50.25)
- Criteria for IRB approval of Research (21 CFR 56.111)
- Promotion and Charging for Investigational Drugs (21 CFR 312.7)
- IND Content and Format (21 CFR 312.23)
- Prohibition of Promotion and Other Practices (21 CFR 812.7)
- (Investigational Device Exemption) Application (21 CFR 812.20)
- Communicating with IRB/IEC (ICH E6, Section 4.4)
- Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects (FDA Guidance, March 19, 1999)