1. INTRODUCTION AND PURPOSE

Successfully recruiting subjects involves the development and implementation of a well-coordinated plan that may require the efforts of the entire research team. Once in place, subject recruitment efforts must be constantly assessed, with new strategies implemented as necessary. This standard operating procedure (SOP) describes the steps for fulfilling the regulatory and clinical requirements involved in subject recruitment and selection.

2. APPLICABLE REGULATIONS AND GUIDELINES

- 21 CFR 50.20 General requirements for informed consent
- 45 CFR 46.116
- 45 CFR 46.117
- 21 CFR 56.109 IRB review of research
- 45 CFR 46.109
- 21 CFR 312.60 General responsibilities of investigators
- 21 CFR 312.62 Investigator recordkeeping and record retention
- FDA Information Screening Tests Prior to Study Enrollment and Recruiting Sheets, October, 1995
- May 9, 1997 International Conference on Harmonisation: Good Clinical Practice: Consolidated Guideline
- FDA website: U S Food and Drug Administration Home Page
- OHRP website: HHS - Office for Human Research Protections
- ICH website: ICH

3. PROCEDURES

A. Develop and implement an overall recruitment plan

Based upon the specific inclusion/exclusion criteria for a study, identify the target population for potential study subjects.

Establish a recruitment goal and timeline if applicable.

Identify sources of potential subjects.

Determine recruitment methods, if applicable (e.g., referrals, radio ads, letters, community talks, newspaper articles, chart review, patient support groups, internet).

Consult with the Marketing and Communication Department at MMC or the sponsor recruitment service to develop recruitment methods for the public media, if applicable.

* May not apply to non-industry sponsored trials
Submit recruitment materials to the IRB and sponsor* for approval, as appropriate.

B. **Assess the effectiveness of the recruitment plan**

Continuously monitor progress and assess results of the recruitment strategy.
Develop and institute appropriate alternative strategies, if enrollment projections lag.

C. **Initiate screening procedures**

If indicated, request a [Review Preparatory to Research](#) and/or [Waiver of Authorization](#) for screening and recruitment from the IRB.

If applicable, maintain a [Sample Screening / Enrollment log Attachment B](#) to collect screening information on all potential subjects and track subjects who qualify within the inclusion and exclusion criteria.

Note if individuals went on to enroll in the study; if they were not enrolled, document the reason.

Obtain informed consent using the most recent IRB approved consent form. Store signed consents in a secure location.

Retain all signed informed consent forms from subjects who fail to meet screening criteria or terminate their participation in the study during the screening process. Maintain communication regarding screening and enrollment with the sponsor on a regular basis.

If it is necessary to review the subject’s inpatient bill for study charges, send a CONFMSG e-mail to “Study Notification Group”, listed in the GroupWise address book.

To obtain email notification that a subject has had additional care encounters at MMC, register the study with the Report Router system ([Email Notification Regarding Research Patients Admitted to the Hospital Attachment A](#)) and enter a research Health Issue in SCM for each enrolled subject.

3. **LINKS AND RESOURCES**

[Review Preparatory to Research](#) (Link)
[ Waiver of Authorization](#) (Link)
[Email Notification Regarding Research Patients Admitted to the Hospital Attachment A](#)
[Sample Screening / Enrollment log Attachment B](#)