1 PURPOSE
This procedure describes the process to be followed for confirming the eligibility of subjects to participate in all human subject research conducted within the Memorial Healthcare System.

2 GENERAL INSTRUCTIONS AND RESPONSIBILITIES
a) The Investigator and/or designee is responsible for ensuring comprehensive evaluation and written confirmation of the subject’s eligibility to be enrolled in a clinical study prior to the subject’s enrollment on the study. This typically includes first obtaining consent from the subject and reviewing their medical records to ensure that all the inclusion and exclusion criteria are met.

3 SPECIFIC PROCEDURES
3.1 Preparing Subject Eligibility Documentation
a) After all required regulatory authorities have approved a clinical protocol, the Investigator or designee should prepare a Subject Eligibility Checklist (unless one is provided by the Sponsor/protocol) to include all inclusion/exclusion criteria listed in the protocol (See Attachment A).
   i. If a Subject Eligibility Checklist has not been provided by the Sponsor, and the Eligibility Criteria listed in the protocol is extensive, the Investigator or designee may copy the Inclusion/Exclusion criteria page(s) from the protocol to use as a reference/checklist.
   ii. Only those persons authorized and qualified by the Investigator on the Delegation of Authority Log should assess eligibility (See SOP 103, Investigator Responsibility and Delegation of Authority Log).

b) The Investigator should prepare a Screening and Enrollment Log (unless one is provided by the Sponsor) for use at the site (See Attachment B). This will be used to track all
investigator standard operating procedures

participants who were approached and provided informed consent whether or not they were placed on the study. All persons who screen fail should also be included on the log, as well as those who refused to participate after signing the consent.

3.2 conducting screening and pre-screening activities

as a general rule, informed consent must be obtained before any protocol specific screening procedures are performed on potential subjects (unless expressly stated in the protocol). A request for “reviews preparatory to research” should be submitted to the IRB prior to pre-screening patients for the study.

a) The investigator should use the Screening and Enrollment Log as a running list of all potential subjects consented, screened and/or enrolled on the study. The clinical trial management system (ctms) may also be used for this purpose.

b) the investigator or designee should record the status of all potential subjects on the screening and enrollment log or in the ctms.

c) When a potential subject is identified, the investigator and/or designee should obtain all relevant medical records and information regarding the subject. This must be done in compliance with mhs requirements and HIPAA regulations.

d) Based on the discussions with the subject and review of the medical records, and after obtaining written consent (i.e. informed consent form signed by the subject or legally authorized representative), the investigator or designee should complete a subject eligibility checklist for each potential subject.

i. the subject eligibility checklist (attachment A) should be completed by the research specialist and/or investigator who identified the potential subject, and who obtained consent. Supporting source documentation should be provided for each criteria that has been fulfilled, or documentation to show where it was verified in the medical record.

ii. the completed subject eligibility checklist should be signed and dated by the research specialist and provided to the research nurse manager (or designee), along with the supporting documentation for review and approval. Once the review has been completed by the research specialist and the nurse manager (or designee) has signed and dated, it should then be provided to the accruing physician for final review, approval and sign-off before enrollment/randomization into the study. If the subject needs to be enrolled onto the study prior to the nurse manager (or designee) reviewing the eligibility (in urgent circumstances for example, when a patient’s window for inclusion into the study would expire) then the enrolling physician may sign off on eligibility prior to the subject’s enrollment. The nurse manager (or designee) should still review eligibility as soon as they are able.

e) all logs and checklists and originals or copies of appropriate supporting documentation will be maintained in the site’s study file, or subject file, as appropriate.

f) on occasion, the sponsor may require that the subject eligibility checklist, along with the supporting documentation, be provided to them for review and approval before the subject is enrolled onto the research study. When this is provided ahead of time, all PHI must be removed prior to sending to the sponsor.
3.3 Subject Numbering

a) Each Sponsor and/or Investigator participating in a study must have procedures for assigning a unique subject numbering system that includes a site number and sequential subject number. This procedure should be defined in the protocol (Reference SOP 301, Clinical Protocol Development, Implementation and Compliance).

b) Any other protocol-specific subject assignment provided by the Sponsor needs to be included. The protocol should be referenced for these instructions.

c) Once a subject’s eligibility to participate in a clinical study has been confirmed, the subject will be assigned the unique subject number according to the protocol.

d) All study records that are maintained on each subject will use the unique subject number where possible to protect the subject’s confidentiality and will be retained per SOP 503 Documentation and Records Retention.

e) Monitors will routinely review the Subject Eligibility Checklist and Screening and Enrollment Logs for accuracy during their monitoring visits (Reference SOP 504 Routine Monitoring Visits).

4 REFERENCES TO OTHER APPLICABLE SOPS

- 103 Investigator Responsibility and Delegation of Authority log
- 301 Clinical Protocol Development, Implementation and Compliance
- 503 Documentation and Records Retention
- 504 Routine Monitoring Visits
- 601 Informed Consent

5 ATTACHMENTS

A. Subject Eligibility Checklist
B. Screening and Enrollment Log

6 APPLICABLE REGULATIONS AND GUIDELINES

- General Responsibilities of Investigators (21 CFR 312.60)
- Specific Responsibilities of Investigators (21 CFR 812.110)
- Compliance with Protocol (ICH E6, Section 4.5)
- Randomization Procedures and Unblinding (ICH E6, Section 4.7)
- Trial Management, Data Handling, and Record Keeping (ICH E6, Section 5.5)