

## **108.1 PRE-SCREENING AND SCREENING OF SUBJECTS**

Note: Depending on protocol specifics, pre-screening, screening, and enrollment may occur on the same day or occur days or even weeks apart.

### **I. PURPOSE**

Research clinical trials will be conducted in accordance with FDA regulations and ICH GCP guidelines in order to protect the safety and welfare of study participants. This SOP describes the procedures to be performed to assure that any identifiable personal and sensitive information collected during screening and enrollment into a research study will be handled appropriately for individuals who are both eligible and ineligible for enrollment.

### **II. BACKGROUND**

Pre-screening of potential subjects to determine their eligibility for, and interest in, a study is a common practice during the recruitment process. Potential subjects may also respond to recruitment advertisements. Telephone and in person pre-screening to determine whether the potential subject meet minimal inclusion/exclusion criteria is helpful. This can be completed after the IRB study approval process has been completed.

### **III. ROLES/PROCEDURES**

Contact with the potential participant through a variety of IRB approved avenues (ads, flyers, referrals, EMR or path review).

#### **1. Pre-Screening per phone conversation:**

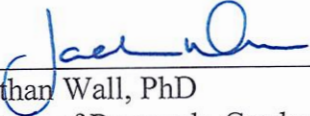
- a. Inform the potential subject of the nature of the phone call and study specifics
- b. Ask whether it is an appropriate time to talk
- c. Inform them of how long the phone call will last
- d. Explain that they may be asked a set of questions to determine if they are eligible for the potential research study
- e. Protect the privacy of the potential subject
- f. Maintain confidentiality of PHI collected
- g. If an IRB approved phone script is available, utilize it
- h. If potential subjects seem to meet eligibility, discuss the length of the study participation and study procedures/visits
- i. Document on the pre-screening log that the patient was pre-screened
- j. Collect contact information and schedule screening visit if applicable

#### **2. Pre-Screening/Screening in Person and Enrollment of a study participant**

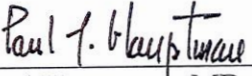
- a. If pre-screening of an UTMC inpatient or clinic patient is required, notify the appropriate staff of research related activity to be discussed/completed (nurse, practitioner, etc.)
- b. Inform the patient of the nature and sensitivity of the questions to be

- asked relating to the research study
- c. Inform of how long the pre-screening process is expected to take
  - d. Explain that they will be asked a set of questions to determine if they qualify for the research study
  - e. Protect the privacy of the subject
  - f. Maintain confidentiality of PHI
  - g. Ask questions that address the criteria to enter the study
  - h. If the potential subject seems to meet the criteria, inform them of the length of participation in the study, and the study procedures/visits
  - i. Document on pre-screening log that the patient was pre-screened
  - j. Pre-screening, screening, and enrollment may be completed on the same day if the protocol allows. If it is not applicable to screen the patient on the same day, schedule appointment for patient to return for informed consent and study screening if consent was not obtained.
  - k. If they appear to meet the eligibility criteria and are interested, collected contact/identifying information and provide an IRB Informed Consent Form for review.
  - l. If informed consent can be obtained after the pre-screening process has been completed, follow GSM SOP 103.1 for the proper way to obtain and document the informed consent process.
  - m. Any enrollment activity should be completed per the GSM investigator IRB approved protocol and GCP guidelines only after the subject provides consent.

APPROVED:

  
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9/23/2021  
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