***Screening and Enrollment of Subjects***

1. **PURPOSE**

To document the process used to identify, evaluate, recruit and enroll research subjects in order to meet the objectives of the clinical trial and satisfy the reporting requirements established by local, state and federal regulatory bodies.

**(MANDATORY LANGUAGE)**

1. **SCOPE**

This procedure applies to clinical trial study-related screening and enrollment practices. It includes the methods used to track and document subject participation based on local, state and/or federal requirements. The process of informed consent of research participants is outside the scope of this SOP.

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details necessary to further define the scope of this SOP]*

1. **POLICY**

This Standard Operating Procedure supports the Good Clinical Practices guidelines established by the International Conference on Harmonization (ICH), Section 4.2.1:

*The investigator should be able to demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.*

In addition, ICH Section 4.10 Progress Reports indicates the *investigator should submit written summaries of the trial status to the IRB/IEC annually, or more frequently, if requested by the IRB/IEC.*

FDA Regulation ☐ N/A

*[If this SOP is not intended for FDA regulated clinical trials, check the N/A box]*

TheFDA requires that an IRB review and have authority to approve, require modifications in, or disapprove all research activities covered by the IRB regulations [21 CFR 56.109(a)]. An IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects [21 CFR 56.107(a) and 56.111]. In fulfilling these responsibilities, an IRB is expected to review all the research documents and activities that bear directly on the rights and welfare of the subjects of proposed research. Therefore, the IRB should review the methods and materials that investigators propose to use to recruit subjects.

In addition, Section 312.64 (Investigator Reports) (a) *Progress reports* states: *The investigator shall furnish all reports to the sponsor of the drug who is responsible for collecting and evaluating the results obtained. The sponsor is required under 312.33 to submit annual reports to FDA on the progress of the clinical investigations.*

**A**d**ditional Regulations or Policies ☐ N/A**

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*[Optional: Insert any additional project, department, sponsor, institution, state or federal policies that apply]*

1. **DEFINITIONS**

ENROLLED**:** For purposes of this SOP, enrolled means *to be consented and screened, with eligibility verified.* This includes dropouts (withdrawals). It does not include screen failures.

GOOD CLINICAL PRACTICE (GCP)**:** A standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

HIPAA AUTHORIZATION WAIVER: A waiver provided by the IRB that permits [use and/or disclosure](http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/privacy-board/protected-health-information-phi/uses-and-disclosures-protected-health-information-phi) of [PHI](http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/privacy-board/protected-health-information-phi) for research purposes, without obtaining subject authorization.

INCLUSION/EXCLUSION CRITERIA: The medical or other standards determining whether a person may or may not be allowed to enter a research study. These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. It is important to note that inclusion and exclusion criteria are not used to reject people personally, but rather to identify appropriate participants and keep them safe.

INSTITUTIONAL REVIEW BOARD (IRB): An independent body- constituted of medical, scientific, and non-scientific members that is responsible for ensuring the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

INTERNATIONAL CONFERENCE ON HARMONISATION (ICH): A joint initiative involving both regulators and research-based industry representatives of the European Union, Japan and the USA in scientific and technical discussions of the testing procedures required to assess and ensure the safety, quality and efficacy of medicines.

PROTECTED HEALTH INFORMATION (PHI): Information (including demographic information) about a patient that (i) is created or received by a health care provider or health plan; (ii) relates to the past, present, or future physical or mental health of the patient; and (iii) identifies the patient or with respect to which there is a reasonable basis to believe it could be used to identify the patient.

RECRUITMENT: The process in which potential research subjects are introduced to a study.

RECRUITMENT MATERIALS: Announcements; advertisements; flyers; posters; scripts for telephone or other oral communication; letters or email messages; bulletin board tear-offs; Internet postings; newspaper, radio, television, or video broadcasts, or other media used to attract potential participants for research.

SCREENING: For purposes of this SOP, screening is defined as the evaluation or investigation of something as part of a methodical survey, to assess suitability for a particular role or purpose. Screening procedures in research may not involve interaction or intervention, and may happen before or after consent.

SCREENING AND ENROLLMENT LOGS: Logs used to document screening and enrollment activity for a clinical trial.

SUBJECT: An individual who participates in research, either as a recipient of the investigational product (s) or as a control.

 “Many of the definitions above were obtained from the IRBMed Glossary.  These definitions were current as of 12-Jun-2015 and are subject to change.  Please see the [IRBMed Glossary](http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/guidance/glossary) for the most current definitions and additional guidance”.

 **(MANDATORY LANGUAGE)**

*[Optional: Insert any additional definitions for technical or special terms used within the Standard Operating Procedure that may not be familiar to the lay reader]*

1. **ROLES AND RESPONSIBILITIES**

**Principal Investigator/Designee**

An individual filling the role of Principal Investigator (PI) is accountable for the recruitment, screening and enrollment of research subjects. The PI shall be responsible for either directly completing or overseeing the following activities:

* Reviews and approves all recruitment materials prior to sending to the IRB for approval
* Ensures enrollment of appropriate subjects based on inclusion and exclusion eligibility criteria
* Ensures that subjects are properly consented prior to performing any procedures or interventions solely performed for research purposes
* Establishes safeguards to protect Protected Health Information (PHI) during the screening and enrollment process. This includes use of a waiver of HIPAA authorization for identifying potential subjects
* Delegates recruitment, screening and enrollment activities to other research team members, as appropriate.

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*[Optional: Insert any additional details regarding the responsibilities of the Principal Investigator/Designee]*

**Study Coordinator/Designee**

An individual filling the role of Study Coordinator (SC) is generally responsible for the recruitment and screening of research subjects. A person filling the role of the SC/Designee is responsible for the following activities:

* Creates and utilizes recruitment materials in accordance with the research protocol and IRB requirements
* Performs screening and enrollment activities in accordance with the research protocol and IRB requirements
* Creates and manages tracking tools such as screening and enrollment logs, etc.
* Screens potential subjects for eligibility
* Ensures informed consent is obtained and documented according to the research protocol and IRB requirements
* Enrolls eligible subjects
* Records, tracks and manages the enrollment status of subjects including withdrawals or discontinuation of clinical trial participation

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional details regarding the responsibilities of the Study Coordinator/Designee]*

**Additional Roles and Responsibilities**  **☐ N/A**

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional role(s) and responsibilities that apply to this SOP]*

1. **PROCEDURE**

**Recruitment Materials Creation**

*[Describe the process that is used to create, review and approve the recruitment materials]*

**Recruitment Materials Approval**

*[Describe the mechanisms used to ensure appropriate approval of advertisements and other necessary recruitment materials provided to potential research subjects]*

**Recruitment Procedures**

*[Describe the recruitment methods and procedures for identifying potential clinical trial subjects]*

 **Screening Procedures**

*[Describe the screening methods and procedures for identifying potential clinical trial subjects]*

**Enrollment Procedures**

*[Describe the subject enrollment process and documentation of subjects’ signed informed consent and eligibility]*

**Storage and Tracking of Eligibility Documentation**

*[Describe the process for managing and storing the documentation that verifies eligibility and completion of the informed consent process i.e. pregnancy test results, labs]*

**Screening and Enrollment Tracking Procedures**

*[Define tracking mechanisms for identification of clinical trial subjects which limit the possibility of repeat requests for screening, i.e. screening and enrollment log(s) and/or retention log(s)]*

**Additional Procedures** **☐ N/A**

*[Optional: Insert any additional relevant procedures. Provide enough detail to ensure the procedure is consistently carried out, without providing so much detail that violations occur due to normal or expected variations in the work.]*

1. **REFERENCES**

Good Clinical Practice Guidance Document:

<http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf>

FDA - Screening Tests Prior to Study Enrollment - Information Sheet:

http://www.fda.gov/RegulatoryInformation/Guidances/ucm126430.htm

University of Michigan Medical School - HIPAA Authorization Waiver:

[*http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/privacy-board/request-waiver-hipaa-authorization#authorization*](http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/privacy-board/request-waiver-hipaa-authorization#authorization)

University of Michigan Medical School - Evaluation, Screening and Diagnostic Testing for Determination of Clinical Trial Eligibility:

<http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/guidance/eligibility-screening>

U.S. Department of Health & Human Services - The HIPAA Privacy Rule:

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/research/research.pdf>

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional SOP references]*

1. **APPENDICES**

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional SOP appendices]*