***Screening and Enrollment of Subjects***

1. **PURPOSE**

This Standard Practice Guideline (SPG) describes the process used too 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 Standard Practice Guideline (SPG) 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 SPG.

**(MANDATORY LANGUAGE)**

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

1. **POLICY**

**Good Clinical Practice (ICH GCP)**

This Standard Practice Guideline aligns with the Good Clinical Practice (ICH GCP) guidelines established by the International Council 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(s)** (if applicable)

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**

**(MANDATORY LANGUAGE)**

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

1. **DEFINITIONS**

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

(this definition is listed in section 8.1 of the eresearch application)

GOOD CLINICAL PRACTICE (ICH 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. (ICH -GCP R2 definition)

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.

(IRB definition)

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 (ICH-GCP R2 definition)

INTERNATIONAL COUNCIL 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): Individually identifiable health information held or maintained by covered entities, or by business associates acting for the covered entity. PHI is subject to HIPAA Privacy Rule protections. HIPAA Privacy Rule permits researchers to access and use PHI when necessary to conduct research, with certain restrictions.

(IRB definition)

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. (IRB definition)

SCREENING: For purposes of this SPG, 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.

Note: Some of the definitions above were obtained from the IRBMed Glossary. These definitions were current as of 01-Oct-2022 and are subject to change. Please see the [IRBMed Glossary](https://research.medicine.umich.edu/office-research/institutional-review-boards-irbmed/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 Practice Guideline 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 ultimately *responsible* 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.

**(MANDATORY LANGUAGE)**

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

**Study Coordinator(s)/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 recruitment materials in accordance with the IRB approved research protocol
* Utilizes IRB approved recruitment materials
* 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 IRB approved research protocol
* 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 SPG]*

1. **PROCEDURE**

**Recruitment Materials Creation**

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

**Recruitment Materials Approval by IRB**

*[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**

Food and Drug Administration (FDA) - Screening Tests Prior to Study Enrollment - Information Sheet:

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

FDA Title 21 CFR 56.107 - IRB Membership:

<http://www.ecfr.gov/cgi-bin/text-idx?SID=bb57308bb4dc8b040a14f34184e28ce9&mc=true&node=se21.1.56_1107&rgn=div8>

FDA Title 21 CFR 56.109 - IRB review of research:

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=bb57308bb4dc8b040a14f34184e28ce9&mc=true&n=pt21.1.56&r=PART&ty=HTML#se21.1.56_1109>

FDA Title 21 CFR 56.111 - Criteria for IRB approval of research:

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=bb57308bb4dc8b040a14f34184e28ce9&mc=true&n=pt21.1.56&r=PART&ty=HTML#se21.1.56_1111>

FDA Title 21 CFR 312.33 - Annual Reports:

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=dd0ce9060f6135c6ffc5fbc8e5189fef&mc=true&n=pt21.5.312&r=PART&ty=HTML#se21.5.312_133>

FDA Title 21 CFR 312.64 - Investigator Reports:

<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=dd0ce9060f6135c6ffc5fbc8e5189fef&mc=true&n=pt21.5.312&r=PART&ty=HTML#se21.5.312_164>

International Council for Harmonisation:

<https://www.ich.org/>

<https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf>

University of Michigan Medical School - HIPAA Authorization Waiver:

<https://az.research.umich.edu/medschool/guidance/request-waiver-hipaa-authorization>

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

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

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

<https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/>

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional SPG references]*

1. **APPENDICES**

**(MANDATORY LANGUAGE)**

*[Optional: Insert any additional SPG appendices]*