[SITE NAME]

STANDARD OPERATING PROCEDURE

<table>
<tr><td colspan="2">Title:</td><td colspan="2">No.: ISCORE-RC-124.00</td></tr>
<tr><td colspan="2" rowspan="2">Clinical Research Participant Recruitment</td><td colspan="2">Page 1 of 4</td></tr>
<tr><td>Date of Issuance:
dd, month, year</td><td>Date Effective:
dd, month, year</td></tr>
<tr><td colspan="2"></td><td colspan="2">Supersedes:</td></tr>
<tr><td>Prepared by:</td><td>Reviewed by:</td><td colspan="2">Approved by:</td></tr>
</table>

Purpose:
[Site Name] is committed to supporting clinical trials and strives for these to be conducted to a high-quality standard. The purpose of this SOP is to define the process for clinical research participant recruitment at [Site Name] campus.

Scope:
This SOP applies to all personnel involved in the conduct of clinical research involving human subjects at [Site Name] institutions and associated clinical departments.

Materials:
Attachment 1- [Site's EMR system] message template

Responsibility:

This SOP applies to all the clinical research departments and [Site Name] Institutions actively engaged in clinical research involving human subjects.

By adhering to this SOP, members of the clinical research team and [Site Name] can help ensure that the rights and wellbeing of the subjects participating in clinical trials are protected, the trial data is credible and that the trial is conducted in compliance with the approved protocol and applicable regulatory requirements.

Definition:
HIPAA Authorization Waiver: A waiver provided by the IRB that permits use and/or disclosure of PHI for research purposes, without obtaining subject authorization.

Procedure:

1. **Development of a Recruitment Plan**

   After identification of the target population for trial recruitment, the Principal Investigator and study team will develop an appropriate screening and recruitment plan. This plan must follow the strategies outlined in section 2 below, depending on the applicable scenario.

   [Site Name/Hospital] and associated entities have sole discretion in the disclosure of PHI to researchers to aid in study screening and recruitment.

   PHI may be used for screening for IRB-approved research by [Site Name] investigators/Research Teams only if one of the following is met:
   - A HIPAA Authorization Waiver (Partial or Full) has been approved for the study
   - There is an IRB-approved recruitment protocol that describes the access to PHI for research screening and recruitment
   - The potential research subject has provided written HIPAA authorization

   All screening and recruitment plans must be outlined in detail in the IRB submission materials for review and approval prior to implementation. If at any time additional or alternative strategies need to be implemented, these strategies must be described and submitted to the IRB for review and approval prior to implementation.

   All screening activities will be recorded and maintained by the research team. Investigators are responsible for the security of patient information used for research and must comply with the privacy and security requirements outlined in institutional policies. It is expected the research team to also comply with the requirements.

2. **Recruitment**

a) Without an Existing Patient Care Relationship

If an investigator or research team member does not have an existing patient care relationship with a potential subject, the investigator or research team member may be permitted to access patient information of potential subjects for recruitment purposes ONLY by one of the following processes:

• Obtaining HIPAA authorization waiver for recruitment purposes from the IRB before accessing clinical patient information to identify or recruit potential research subjects to that specific IRB approved study.

• Through an IRB-approved recruitment plan that describes how research team members will access the patient information of potential subjects for screening and recruitment purposes.

The research team will not initiate contact with potential study participants until either a provider has

referred the patient to the research team, or the patient has contacted the research team directly. When participants self-refer and do not have their medical history contained within the [Site Name/Hospital] EMR, the research team will act to obtain medical history from the patient's primary provider, documenting all such efforts.

[Update to reflect Site's EMR System if not EPIC]

i) EPIC Mychart: The use of MyChart to send messages to potential subjects is one method that may be acceptable. Once the IRB approves MyChart as a tool, the IRB approval with message to participant (see Attachment for template) will be provided to [Site Name] for verification. Once verified, the EPIC team will create the message according to specifications. Patients may be contacted through Mychart if they meet study criteria based on discrete inclusion and exclusion criteria available in medical records. Once setup by the EPIC team, the messages would automatically be delivered to potentially eligible EPIC patients that have not opted out of being contacted for potential research participation through Mychart, with action buttons within the message itself to indicate whether they are interested or not in being directly contacted by the research team for a particular study.

Note: MyChart messages should not be created by research team members themselves when a patient care relationship does not exist.

ii) Best Practice Advisory (BPA): BPA is a functionality available in EPIC to assist in patient recruitment where care providers are alerted to patients in clinic that meet eligibility criteria. When approved by the IRB as a recruitment method, a BPA could be setup by the EPIC team. The alerted provider may then provide information about the research to the patient or alert the research team of the referral if patient is interested or send a Mychart request to the patient. This method may be considered for studies that require real-time recruitment.

b) With an Existing Patient Care Relationship

If the investigator is a credentialed clinical care staff member and has an existing patient care relationship with a potential subject, then the investigator and members of the research team (under the direct supervision of the investigator) may access patient information for identifying and contacting potential subjects for the protocol according to the recruitment plan that has been approved by the IRB. This may include the use of a MyChart message created by research team members, see attachment for template message.

When possible, a member of the clinical care team that has an existing patient care relationship with the potential subject should introduce research team members that may not be members of the clinical team or clinical care employees to the patient and bridge the gap between clinical care and discussion of possible research study participation.

History of Revisions to SOP

Effective Date	Nature of Revision
dd, month, yyyy	New SOP