[SITE NAME]

STANDARD OPERATING PROCEDURE

Title:		No.: ISCORE-RC-118.00	
Institutional Review Board (IRB) Communication		Page 1 of 4	
		Date of Issuance: dd, month, yyyy	Date Effective: dd, month, yyyy
		Supersedes:	
Prepared by:	Reviewed by:	Approved by:	

Purpose:
This standard operating procedure (SOP) describes the operational guidelines followed by the [Site Location], [Site Name], [Site Institution] and affiliated health systems regarding communications with the Institutional Review Board (IRB).

Scope:
This SOP describes the guidelines and various methods for communication with the Institutional Review Board (IRB) of record and [Site Institution] IRB during a clinical trial to ensure protection of subjects' rights, safety and confidentiality and to ensure that the studies are carried out according to protocol, written procedures and regulatory guidelines.

Materials:
NA

Responsibility:
This SOP applies to the [Site Institution(s)] and associated clinical departments actively engaged in clinical research involving human subjects.

Definition:

Institutional Review Board (IRB):

An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure 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.

Procedure

1. General Communication Guidelines

    a. Effective communication between the IRB and the clinical research staff is vitally important to ensure that clinical research is maintained ethically and performed according to regulatory guidelines.

    b. Individuals should be delegated by the Principal Investigator (PI) to prepare, compile and manage regulatory correspondence with the IRB.

    c. Any comments or revisions and/or clarifications requested from the IRB at any time during the study shall be addressed within a timely manner. Any changes to documents should be provided to the sponsor for approval, if applicable, prior to returning the documents to the IRB.

    d. The IRB of record and/or the [Site Institution] IRB may have online portals to be used for communications and/or specific forms to be completed at different stages of the study. Verify with the IRB policies for specific requirements.

2. Determine the IRB of Record
    a. [Site Institution] IRB
    b. Central IRB (e.g., WIRB, Advarra)
    c. IRB at another Institution (e.g., using SMART IRB, IRBEx platforms)

    Note: When a central IRB is utilized, [Site Institution] IRB requires an administrative review of the study. Refer to [Site Institution] IRB for additional guidelines on requirements.

3. Pre-Study Communications

    a. Initiate the protocol submission in the [Site Institution IRB System] system and obtain a [Site Institution] IRB protocol number. This number will need referenced during the IRB submission and/or to the IRB of record.

    b. According to the Good Clinical Practice (GCP) guidelines, the following documents, as applicable should be submitted to the IRB for initial review:

        - Trial protocol/protocol amendment
        - Written informed consent form(s) and a description of the informed consent process
        - Subject recruitment materials, e.g., advertisements
        - Written information to be provided to subjects
        - Investigator's brochure and any available safety information
        - Information about payments and compensation available to subjects
        - The investigator's current curriculum vitae (CV) and/or other documentation evidencing qualification; and
        - Any other documents that the IRB may need to fulfill its responsibilities.

    c. Submit the application to the IRB of record for review.

d. According to the ICH GCP guidelines, the investigator/institution should have written and dated approval from the IRB for the trial protocol, informed consent form and other required documents at this investigative site before initiating a trial.

e. Upon receipt of an approval letter from the IRB of record, ensure that the documentation is accurate and provide copies to the sponsor, as applicable.

f. For central IRB approvals, complete the [Site Institution] IRB submission within local IRB system. [Site Institution] IRB acknowledgement should be received prior to execution of the study.

g. File all communication within the appropriate study file.

4. During the Study

a. Report proposed changes or modifications to the IRB of record for all approved research studies, such as, but not limited to:
   - Protocol amendments
   - Informed Consent revision
   - Revisions to the investigator brochure
   - Revisions to information provided to the subjects

   Obtain documentation of IRB approval of amendments and revisions to study-related documents prior to implementation except to eliminate apparent immediate hazard to subjects. Reconsent subjects as recommended by the IRB of record.

b. Report per the IRB of record and protocol requirements:
   - Promptly report unanticipated problems involving risks to subjects or others
   - Unanticipated adverse device effects (UADE)
   - Serious Adverse Events (SAEs)
   - Major Deviations
   - Safety Reports

c. Submit Continuing Reviews and or periodic reports as determined by the IRB of record, such as
   - Summary of unanticipated problems (SAEs)
   - Deviations
   - Other study-related serious events

d. Certain events may also need to be reported to the [Site Institution] IRB, according to their requirements, for when they are not the IRB of record.

e. File all communication within the appropriate study file.

5. Study Completion

a. Once the close out visit has been completed, notify the IRB of record and [Site Institution] IRB to provide documentation as required, such as, but not limited to:
   - Number of enrolled subjects

- Reason for closure

b. File all communication within the appropriate study file.

7. Sponsor audits/Regulatory inspections

a. Notify the IRB of record and [Site Institution] IRB in the event of notification for a sponsor audit and/or a regulatory inspection.

References

International Conference on Harmonisation; Good Clinical Practice Consolidated Guidelines, ICH E6

History of Revisions to SOP

Effective Date	Nature of Revision
dd, month, yyyy	