PM-302 REVISION HISTORY

Date of Revision	Page(s)/Section(s) Revised	Revision Explanation
01AUG2011		
04APR2017		
31OCT2017	All	Cosmetic Only
26MAR2019	All	Minor corrections and updates.

PM-302 STANDARD OPERATING PROCEDURE FOR INTERACTIONS WITH THE INSTITUTIONAL REVIEW BOARD

I. INTRODUCTION AND PURPOSE

The primary responsibility of the Institutional Review Board (IRB) is to protect the rights and welfare of research subjects. Federal regulations require that the IRB ensure that certain criteria for approval of research are met prior to approving a study. The principal investigator must provide the IRB with the information necessary to permit an informed decision on whether to approve, disapprove, or to require modifications prior to approval.

By signing the Form FDA 1572, the principal investigator ensures that the IRB reviewing the research complies with the regulations. Additionally, the principal investigator agrees to inform the IRB of any changes to the protocol and any materials used to recruit subjects, as well as any additional risks to subjects associated with the investigational article.

This SOP describes how this site communicates with the IRB throughout the research process in order to ensure compliance with the regulations and to protect the safety and well-being of study subjects.

2. SCOPE

This SOP applies to the interactions with the IRB responsible for all research carried out at this site subject to investigational new drug (IND) regulations for drugs and biologics during all phases of development.

3. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.32	IND safety reports
21 CFR 312.53	Selecting investigators and monitors
21 CFR 312.54	Emergency research
21 CFR 312.66	Assurance of IRB review
21 CFR 50	Protection of Human Subjects
21 CFR 56	Institutional Review Boards
45 CFR 46	Protection of Human Subjects

4. REFERENCES TO OTHER APPLICABLE SOP'S

GA-102	Responsibilities of the Research Team
SS-201	Assessing Protocol Feasibility
PM-301	Site-Sponsor/CRO Communications
PM-303	Regulatory Files and Subject Records
SM-401	Informed Consent Development and Implementation
SM-404	Adverse Event Reporting

5. ATTACHMENTS

A. Checklist for IRB Submission
B. Reporting IND Safety Reports to the IRB

6. RESPONSIBILITY

This SOP applies to those members of the clinical research team involved in communicating with the IRB to ensure appropriate management of all clinical trial activity. This includes the following:

- Principal investigator
- Subinvestigator
- Research coordinator

7. DEFINITIONS

The following definitions from the Code of Federal Regulations and the International Conference on Harmonisation, Good Clinical Practice: Consolidated Guideline apply to this SOP.

Approval in relation to Institutional Review Boards (IRBs): The affirmative decision of the IRB that the clinical trial has been reviewed and may be conducted at the institution site within the constraints set forth by the IRB, the institution, good clinical practice (GCP), and the applicable regulatory requirements.

Informed Consent: A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.

Institutional Review Board (IRB): An independent body constituted of medical, scientific, and nonscientific members, whose responsibility it 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 trials, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

Protocol: A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guideline, the term protocol refers to protocol and protocol amendments.

Protocol Amendment: A written description of a change(s) to or formal clarification of a protocol.

Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR): Any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect or requires medical or surgical interventions to prevent any of the above outcomes.

Well-being of the trial subjects: The physical and mental integrity of the subjects participating in a clinical trial.

8. PROCESS OVERVIEW

A. Documenting IRB compliance

B. Communicating with the IRB at study start-up
C. Communicating with the IRB while the study is ongoing
D. Communicating with the IRB when the study is over

9. PROCEDURES

A. DOCUMENTING IRB COMPLIANCE

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Research coordinator	Ensure that the IRB is duly constituted and compliant with federal and state regulations. Request a copy of the IRB membership list and the general assurance number (if available).

A. COMMUNICATING WITH THE IRB AT STUDY START-UP

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
PI Research coordinator	Using the IRB procedure manual (if available) and the appropriate form, complete the initial IRB submission. Include all attachments as directed, e.g., the protocol, investigator's brochure, informed consent form, and advertisements (Attachment A, IRB Checklist of Application Material). Submit the package for the next scheduled meeting.
Research coordinator	Obtain documentation of full IRB approval for the protocol and informed consent form prior to study start. Copy sponsor/CRO on correspondence. Maintain all documents in the appropriate study files.

B. COMMUNICATING WITH THE IRB WHILE THE STUDY IS ONGOING

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research coordinator	Notify the IRB of any changes to the protocol and/or informed consent and of new information from the sponsor on the test article. Submit periodic report form for renewal of protocol as requested (Attachment D, Periodic Report to the IRB). Obtain documentation of IRB approval of amendments and revisions to study-related documents, such as advertisements, prior to implementation except to eliminate apparent hazard to subject safety. Copy sponsor/CRO on correspondence.
Research coordinator Support staff	Notify the IRB promptly of all serious or alarming events occurring during the approval period for the ongoing study (Attachment B, Serious Adverse Event Report). Promptly submit to the IRB all IND Safety Reports received from the sponsor (Attachment C, Reporting IND Safety Reports to the IRB). Report all routine AEs to the IRB as part of the periodic or annual reporting requirements.

	Maintain all documents in the appropriate study files.

C. COMMUNICATING WITH THE IRB WHEN THE STUDY IS OVER

RESPONSIBILITY	DESCRIPTION OF PROCEDURE
Research Coordinator	Notify IRB of study closure via IRB's standard reporting form. This should be done the same day as the close-out visit.

ATTACHMENT A

CHECKLIST FOR IRB SUBMISSION

- ✓ Study summary
- ✓ Research protocol
- ✓ Investigator's brochure (if applicable)
- ✓ Proposed informed consent form
- ✓ Proposed patient information (instructions, diaries, etc.)
- ✓ Up-to-date curriculum vitae of principal investigator
- ✓ Up-to-date curriculum vitae of subinvestigator(s) or other staff listed on Form FDA 1572
- ✓ Copy of current medical license for principal investigator and subinvestigators (if applicable)
- ✓ Other supporting material (e.g., sample of any proposed advertising)
- ✓ Copy of Form FDA 1572 (if required)

ATTACHMENT B

REPORTING IND SAFETY REPORTS TO THE IRB

<Date>

<Name>

Chairperson

Institutional Review Board

<Hospital>

<City, State, Zip code>

RE: <Protocol Title>

Dear Chairperson:

Enclosed please find an IND Safety Report #_____, submitted to us by <sponsor> for the above referenced study. The federal regulations require that sponsors notify investigators of immediately reportable adverse events that have occurred worldwide in connection with the investigational drug. I am, in turn, notifying you of this event.

In my opinion, information contained in this IND Safety Report (does/does not) require a change to our approved informed consent form. (Enclose revised consent form when a change is being requested)

If you have any questions, please call.

Sincerely,

<Signature>

Copy: Study file