3. POST APPROVAL PROCEDURES

Supersedes:	Version ~~2~~3
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3. Purpose

To describe the review procedures of the Jose R. Reyes Memorial Medical Center related to events reported to the IRB and PI submissions required by IRB during the conduct of the study. The period covered begins after approval has been granted by the IRB until the completion of the study at the IRB-approved site.

3.1. Review of Serious Adverse Events

3.1.1. **Purpose**

To describe the IRB review procedures for serious adverse events.

3.1.2. **Scope**

This SOP applies to the review of SAE and SUSAR reports submitted by investigators and sponsors to the Jose R. Reyes Memorial Medical Center IRB to comply with ICH GCP. The IRB reviews such reports to determine an appropriate action to protect the safety of participants in an approved study.

ICH-GCP E6 defines a serious adverse event (SAE) or a serious adverse drug reaction (ADR) as any untoward medical occurrence that at any dose

3.1.2.1. results in death,
3.1.2.2. is life-threatening,
3.1.2.3. requires hospitalization or prolongation of existing hospitalization,
3.1.2.4. results in persistent or significant disability or incapacity, or
3.1.2.5. results in a congenital anomaly or birth defect.

A suspected unexpected serious adverse reaction (SUSAR) is a serious event the nature and severity of which is not consistent with the applicable product information. In the case of an unapproved investigational product, the event is not consistent with the Investigator's Brochure (IB). In the case of a licensed product, the event is not consistent with the approved package insert or summary of product characteristics.

3.1.3. **Responsibilities**

The primary responsibility of the Jose R. Reyes Memorial Medical Center IRB is to conduct an appropriate review of SAE and SUSAR reports to ensure oversight over the safety of participants enrolled in the study.

The IRB should also make sure that researchers are made aware of its policies and procedures concerning SAE reporting.

The Jose R. Reyes Memorial Medical Center IRB sets up the necessary mechanisms to receive SAE and SUSAR reports from investigators and sponsors of researches that it has approved.

All onsite SAE and SUSAR would be reviewed by a full-board.

The primary responsibility of the Jose R. Reyes Memorial Medical Center IRB is to receive and review SAE and SUSAR reports from its ~~own~~ site and to take the necessary action to ensure the safety of participants in the study.

In multicenter studies, the IRB also receives SAE and SUSAR reports from other sites within and outside the country. It is the responsibility of the Jose R. Reyes Memorial Medical Center IRB to be updated about safety issues related to studies that it has approved.

The Jose R. Reyes Memorial Medical Center IRB has the authority to suspend or terminate approval of research at its site when the safety of participants is no longer assured. When Jose R. Reyes Memorial Medical Center IRB takes such action, it is required to provide the reasons for its action and to promptly report such decision to the investigator, the institution, and relevant regulatory authorities.

3.1.4. Process Flow/Steps

	ACTIVITY	PERSPO	RESPONSIBILITY	
1	Report SAE and SUSAR	Investigators, Sponsors	Investigators, Sponsors	7 days
2	Receive SAE and SUSAR reports	Secretariat	Secretariat	1 day
3	Refer SAE Reports to appropriate IRB Members	Secretariat	Secretariat	1 day
4	Review/Monitor SAE and SUSAR reports and make a recommendation	Chair, Members & Secretariat	Chair, Members & Secretariat	7 days
5	Keep copies of all documents in the files	Chair, Members & Secretariat	Secretariat	1 day
6	Summarize and report to full board for appropriate action	Secretariat	Chair, Members & Secretariat	7 days
	Inform Investigator, sponsor & other officials about IRB decision, whenever it is necessary		Secretariat	

3.1.5. Detailed Instructions

3.1.5.1 The IRB should inform investigators that they are required to report SAEs and SUSARs to the IRB for all studies approved by the IRB within 7 days from the occurrence if the SAE/ SUSAR happened onsite and within 7days upon receiving notice of the SAE from the Sponsor for offsite SAE's SUSARs. They should use **Form 3.1** to report SAEs.

3.1.5.2 The JRRMMC IRB also requires the primary investigator to report any negativ events/unanticipated events or problems that cause harm to participants in non-clinical trial. They should use Form 3.1 to report it.

~~3.1.5.2~~3.1.5.2.1 The Jose R. Reyes Memorial Medical Center IRB Secretariat sha be responsible for receiving and distributing the SAE and SUSAR report within 5 working days to primary reviewers/ designated IRB members fo review. They should classify the SAE/ SUSAR reports according to the origin or sites where they happened: foreign site, local site, onsite.

3.1.5.3 Classification of SAE/ SUSAR according to site – The IRB reviewers should adopt appropriate response depending on the site where the SAE/ SUSAR happened.

3.1.5.3.1. For multicenter, international studies, the trend of occurrence of SAE/ SUSAR in study sites in foreign counties and other local sites shall be noted.

3.1.5.3.2. For multicenter, national studies, the nature (related or expected) of the SAE/ SUSAR shall be noted.

3.1.5.3.3. For SAEs that occur onsite, the Jose R. Reyes Memorial Medical Center IRB should analyze the investigator/ sponsor assessment (related, unexpected) and may need to recommend some form of action to the investigator to ensure the safety of participants. The designated IRB members should inform the Chair about their recommendation for appropriate IRB action during the meeting.

3.1.6 Criteria for the review

To review SAE reports, designated ERC members should use the same form (**Form 3.1**) filled up by the principal investigator and fill up Section 2 that recommends appropriate action to be done by the IRB. The review procedures are as follows:

3.1.6.1. Assessment of the SAE is unlikely or unrelated to the study drug or article: The report is forwarded to the Chair for review and determination if the report should be reviewed at the convened meeting by full Board.

3.1.6.2. Assessment of the SAE is definitely, possibly, or probably related to the study drug or article: The report is added to the agenda for review at a convened meeting by full Board.

3.1.6.3. Assessment of the SAE is unexpected/unanticipated and definitely, possibly, or probably related to the study drug or article: The report is added to the agenda for review at a convened meeting by full Board.

~~3.1.7~~ ***SAE and SUSAR are discussed and reviewed during Jose R. Reyes Memorial Medical*** Center IRB meetings for appropriate action.

3.1.7 Review and discuss:

3.1.7.1. After reviewing the report and the recommendation by designated IRB members, the Chair presides over the board discussion of the SAEs and similar adverse experiences or advisories.

3.1.7.2. If appropriate to the discussions, the Chair or another Board member may call for a consensus on whether to:

3.1.7.2.1. Request an amendment to the protocol or the consent form.
3.1.7.2.2. Request further information.
3.1.7.2.3. Suspend or terminate the study
3.1.7.2.4. Take note and no further action is needed.

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3.1.8. Inform the investigator when necessary about the IRB decision and keep a record in the IRB files.

3.1.8.1. If any of the above actions are taken, the Jose R. Reyes Memorial Medical Center IRB secretariat notifies the investigator of the action taken within 7-14 days after the meeting.

3.1.8.2. If the Jose R. Reyes Memorial Medical Center IRB takes no action, a notation is made in the minutes and the study is allowed to continue.

3.1.8.3. The Jose R. Reyes Memorial Medical Center IRB secretariat member drafts a formal letter to the investigators or the clinical trial office to notify them of the action they should take according to the Jose R. Reyes Memorial Medical Center IRB decision.

3.1.8.3.1. The Chair approves, signs and dates the letter.
3.1.8.3.2. The letter is sent and the delivery date is recorded.

SERIOUS ADVERSE EVENT REPORT FORM (FORM 3.1)

Whenever there is any SAE event in any research approved by the Jose R. Reyes Memorial Medical Center IRB, it has to be reported by the principal investigator (PI) to the IRB. Section 1 of this form should be filled up by the PI.

SECTION 1

Principal Investigator:	

Study Title:		**Protocol No.:**	

Name of the study medicine/device:	**Report Date:**
	☐ **Initial** ☐ **Follow-up**
	Onset Date:

Sponsor:	**Date of first use:**
Title of the Report	**Date of the report**

Subject's initial/number: _____ **Age:** _____ ☐ **Male** ☐ **Female**

Subject's history:	**Laboratory findings:**

SAE:	**Treatment:**
	Outcome: ☐ **Resolved** ☐ **On-going**

Seriousness:	**Relation to**

☐ Death	☐ Life Threatening	☐ Drug	☐ Device	☐ Study

☐ Hospitalization:
- ☐ Initial
- ☐ Prolonged

☐ Disability/Incapacity

☐ Congenital Anomaly

☐ Others

☐ Not related

☐ Possibly

☐ Probably

☐ Definitely related

☐ Unknown

Note: PI should attach standard SAE report form to this IRB form.

SECTION 2 (to be filled up by the designated IRB representative)

Document Receipt by the IRB

Name (IRB Secretariat)	Signature	Date

Reviewer/s Recommendations

Reviewer's Name:	Signature	Date

Changes to the protocol recommended ☐ No ☐ Yes
Comments:

Changes to the informed consent form recommended? ☐ No ☐ Yes
Comments:

IRB Final Action:

- ☐ Request an amendment to the protocol or the consent form.
- ☐ Request further information.
- ☐ Suspend or terminate the study
- ☐ Take note and no further action is needed.
- ☐ Others:

Type of review:

- ☐ Expedited review
- ☐ Full board review

Date of meeting _____

~~Name of IRB Chair:~~	~~Signature~~	~~Date~~

~~3.2.~~ 3.2. Review of Amendments

3.2.1. Purpose

To describe the IRB review procedures for amendments of the protocol and related documents

3.2.2 Scope

This SOP applies to previously approved study protocols and related documents that are being amended later and submitted for approval by the Jose R. Reyes Memorial Medical Center IRB. Any amendment of the study related documents may not be implemented until reviewed and approved by the IRB.

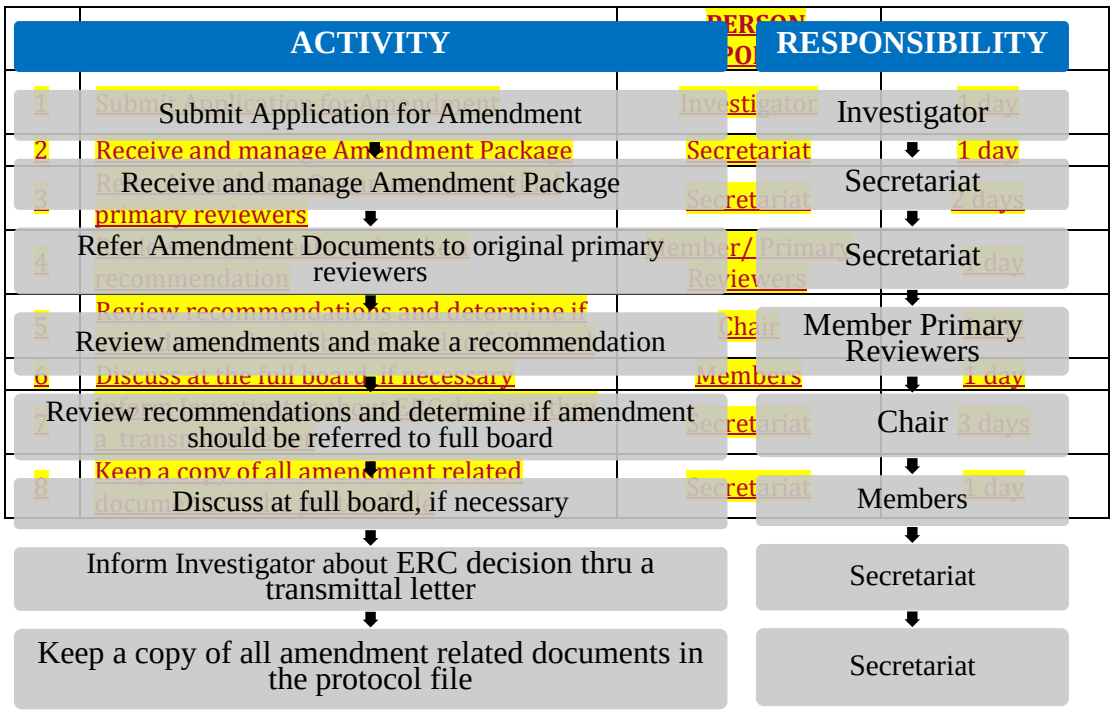
3.2.3 Responsibility

It is the responsibility of the IRB Secretariat to manage protocol amendment package submitted by the PI.

It is the responsibility of the original primary reviewers to review the amendments and recommend appropriate action. If the original reviewers are no longer available, the Chair may assign another member to review the amendment.

It is the responsibility of the IRB Chair to determine whether the amendment goes to expedited or full board review after reviewing the recommendations of the member assigned. The IRB approves the final decision for amendments submitted by the PI to the IRB.

3.2.4 Process Flow/Steps



3.2.5. Detailed Instructions

3.2.5.1. The IRB should properly inform investigators to submit an amendment application whenever there is any change regarding the composition of the study team, the study site, and the protocol-related documents for approvals previously granted by the IRB.

3.2.5.2. The IRB Secretariat checks the completeness of the amendment package submitted by the Investigator. **Use Form 2.1 and Form 3.2.**

3.2.5.3. The IRB Secretariat refers the amendment package to the original primary reviewers or ~~to~~ the members assigned by the Chair.

3.2.5.4. The primary reviewers check the amended documents and compare them with the previously IRB-approved documents in the protocol files. They check if the amendments would alter the risk/ benefit ratio of the study to make appropriate recommendations using **Form 3.2.** Amendments that may potentially alter the risk/ benefit ratio of a study are referred to a full-board for discussion. Research protocols with minor amendments would go to expedited review.

~~3.2.5.4.~~

3.2.5.5. Protocol amendment which increase risk to study participants may include, but is not limited to the following:

3.2.5.5.1 a change in study design
3.2.5.5.2. additional treatments or the deletion of treatments
3.2.5.5.3. any change in the inclusion/exclusion criteria
3.2.5.5.4. change in method of drug intake or route of drug intake (e.g. oral changed to intravenous)
3.2.5.5.5. significant change in the number of subjects (increase or decrease in sample size that alters the fundamental characteristics of the study)
3.2.5.5.6. significant decrease or increase in dosage amount

3.2.5.6. Criteria for Full Board Review of ~~Resubmissions/~~ Amendments~~/ Reports~~

3.2.5.6.1. Major revisions of the protocol and informed consent after initial review
3.2.5.6.2. Amendments that involve major changes from previously approved protocol or consent form (major changes in the inclusion/ exclusion criteria, safety issues, etc.)
3.2.5.6.3. Major amendments that change the risk/ benefit ratio
3.2.5.6.4. Major protocol violations

3.2.5.7. ~~Resubmissions/~~Amendment~~/~~ Reports which meet the following criteria may ~~qual~~qualify for Expedited Review

3.2.5.7.1. Administrative revisions, such as correction of typing errors.
3.2.5.7.2. Addition or deletion of non-procedural items, such as the addition of study personnel names, laboratories, etc.
3.2.5.7.3. The research activity includes only minor changes from previously approved protocol.
3.2.5.7.4. Minor protocol amendments that do not change the risk/-benefit assessment.

3.2.5.8 If only minor changes are involved in the amendment, the reviewers' recommendation become the basis for the final decision of the IRB and a letter granting approval is prepared by the IRB Secretariat and approved by the Chair.

3.2.5.9 If major changes are involved in the amendment (alters the risk/ benefit ratio of the study), the amendment is referred to full board after review by the primary reviewers. The members discuss the issues related to the amendments to arrive at a decision.

3.2.5.10 Decision regarding an amendment presented at full board may be any of th following:

3.2.5.10.1 Approved. This means that the investigator can proceed with the study.
3.2.5.10.2 Disapproved. The amendment should not be carried out hence the stud may be stopped in the site.
3.2.5.10.3 Modification required. Upon complying with the recommended revision, th study may proceed.
3.2.5.10.4 Additional information required

3.2.5.11 The Secretariat prepares a communication letter to inform the investigators abou the board decision. The Secretariat forwards the letter to the investigators fo proper action.

3.2.5.12 The Secretariat keeps a copy of all amendment related documents in the protoco files.

PROTOCOL AMENDMENT REVIEW (FORM 3.2)

IRB Protocol No.	Sponsor Protocol No	Date of submission

Date of approval

Title	

Principal Investigator	Sponsor	Contact Number

(use additional sheets if necessary)

List of Amendments	Reasons
1.	
2.	
3.	

Comments of Primary Reviewers	

IRB Decision	Name of Chair	Date

Signature

3.3. Review of Progress ~~and Final~~ Reports

3.3.1. Purpose

To describe the IRB review procedures for progress ~~and final~~ reports

3.3.2. Scope

This SOP provides instructions for the review of progress reports that are required by the Jose R. Reyes Memorial Medical Center IRB to be submitted by the PI to monitor the safety of participants enrolled in a study. The annual progress report becomes the basis for continuing review of protocols whose approval needs to be renewed every year. ~~This SOP also aims to provide instructions for the review of final reports that are submitted by the PI after completion of subject enrollment and all follow up procedures.~~

This SOP applies to conducting any continuing review of study protocols involving human subjects at intervals appropriate to the degree of risk but not less than once a year. Depending upon the degree of risk to the participants, the nature of the studies, and the vulnerability of the study participants and duration of the study, the IRB may choose to review or monitor the protocols more frequently.

This SOP describes the follow-up of progress ~~and final reports~~ by the IRB Secretariat and the review of such reports submitted by the PI by designated members of the IRB in compliance with ICH-GCP requirements. All post-approval reports shall be designated to either expedited or full board review.

3.3.3. Responsibility

It is the responsibility of the Jose R. Reyes Memorial Medical Center IRB Secretariat to remind investigators to submit the progress ~~and final reports~~ one month before its due date, to forward the reports to the primary reviewers for review comments, to communicate with the investigators if there is a need for further information or action and to submit to full board a list of progress and final reports for approval.

It is the responsibility of the primary reviewers to review the reports to check the completeness of the information and ensure that the data are ~~in accordance with~~following the protocols and other related documents approved by the IRB.

It is the responsibility of the Vice-Chair to deem if the post-approval study is for expedited or full board review. If the progress reports of more than minimal risk protocols should go on full board and progress reports of low-risk protocols should go to the expedited review.

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~~3.3.4.~~ Process Flow/Steps

ACTIVITY	RESPONSIBILITY
Remind PIs to submit progress or final report one month before due date	Secretariat
Submit progress or final report on or before due date	Investigators
Check completeness of information in the report and forward to the primary reviewers for assessment/comments	Secretariat
Review the progress or final report if it is in accordance with the approved protocol and related documents	Primary Reviewers
Recommend approval or require more information or other action from the PI	Primary Reviewers
Discuss at full board and make a decision	Secretariat
Report approval/ other recommendations to full board	Members, Secretariat
Communicate ERC decision to PI	Secretariat

3.3.4.

No.	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Remind PIs to submit progress report one month before the due date	Secretariat	1 day
2	Submit progress report on or before due date	Investigators	
3	Check completeness of information in the report and forward to the primary reviewers for assessment/comments	Secretariat	1 day
4	Review the progress report if it is in accordance with the approved protocol and related documents	Primary Reviewers	7 days
5	Discuss at full-board and make a decision	Members	1 day
6	Report approval/other recommendations to full-board	Members	1 day
7	Communicate ERC decision to PI	Secretariat	1 day

3.3.5. Detailed Instructions

3.3.5.1. Submission and management of ~~Final~~ Progress Reports

3.3.5.1.1. The Secretariat checks the database and tracks due dates of progress ~~or final~~ reports of Study Protocols approved by the Jose R. Reyes Memorial Medical Center IRB.
~~3.3.5.1.1.~~

3.3.5.1.2. The Secretariat prepares and sends a reminder letter/notice addressed to the PI one month before the due date of the report.

~~3.3.5.1.2.~~

3.3.5.1.3. The Secretariat reviews the completeness of the submitted report based on the items in **Progress Report Form 3.3** ~~and **Final Report Form 3.4**~~ and forwards the report to the ~~primary reviewers~~Vice-Chair.

~~**3.3.5.2**~~3.3.5.2. Review of ~~Progress/Final Reports~~Progress Reports

3.3.5.2.1. The primary reviewers conduct continuing review of the progress~~/final~~ report if they are in accordance with the protocol and related documents approved by the IRB.

3.3.5.2.2. The primary reviewers refer to the protocol file to check compliance with approval given by the IRB during initial review and upon submission of amendments.

3.3.5.2.3. The primary reviewers recommend approval of the progress/ final report if there is no deviation or violation of IRB approvals.

3.3.5.2.4. If there is any deviation or violation of approvals given by the IRB, the primary reviewers recommend that appropriate action be taken by the PI (i.e., explanation of deviation or violation for final reports,). This will be presented to full board.

3.3.5.2.5. Approval or other recommendations by the primary reviewers of progress/ final report is reported to the board meeting by the Secretariat.

3.3.5.2.6. Approval of the annual progress report is necessary to renew the initial approval of the protocol and allow the investigator to continue the conduct of research. Approval of the final report enables the IRB Secretariat to close the protocol files.

3.3.5.2.7. Related issues or recommendations related to progress/ final reports are included in the agenda for discussion during the board meeting in order to arrive at a decision for appropriate action.

3.3.5.2.8. The Secretariat takes note of the decision and/or discussion during the board meeting in the meeting minutes and communicates with the PI if further action is required.

3.3.5.3. Communicating Jose R. Reyes Memorial Medical Center IRB decisions for Progress Reports

3.3.5.3.1. The IRB Secretariat notifies the investigator of IRB decision whether approved or disapproved.
3.3.5.3.1.

3.3.5.3.2. After reviewing the progress report and found to be compliant with the approved protocol, the IRB accepts the annual progress report and notifies the investigator about the renewal of approval of the protocol and related documents to enable the PI to continue the conduct of the research.
3.3.5.3.2.

3.3.5.3.3. After reviewing the final report and found to be compliant to the approved protocol, the IRB accepts the Final Report and considers the study as completed.
3.3.5.3.3.

3.3.5.3.4. The IRB Secretariat keeps a copy in the protocol files of the progress/final report signed by the Primary Reviewers and the Chair or Member-Secretary.

3.3.5.3.5. The IRB Secretariat marks the folder of the completed protocol and archives the entire study protocol.
~~3.3.5.3.5.~~

3.3.5.3.6. For disapproved progress report and/or final report because of failure to comply the previously approved protocol, the investigator will not be able to proceed with the study or publish the study results unless he applies for continuing review and upon complying with the SOP's of the JRRMMC IRB regarding Post Approval procedures as applicable in his case.

~~———~~Review of Final Reports

3.4.

3.3.1. Purpose

To describe the IRB review procedures for submission of final reports

3.3.2. Scope

This SOP provides instructions for the submission of final report that are required b
the Jose R. Reyes Memorial Medical Center IRB. Principal investigators have th
responsibility of informing the IRB when a study has been completed. If a study
completed and not closed, the IRB may not approve a new study until the complete
study is closed. A study is considered to be open and active until the investigator ha
submitted a physical and electronic version of the Final Report to the IRB. When Fina
Reports are submitted, an administrative review will be conducted by the IRB staff. IR
Chair/IRB Secretary will review the form and report the closure of study to the IRI
This SOP describes the final reports by the IRB Secretariat and the review of suc
reports submitted by the PI by designated members of the IRB in compliance with ICH
GCP requirements.

3.3.3. Responsibility

It is the responsibility of the Primary Investigator to submit a final report to the IR
upon completion of the study. Studies would be considered eligible for closure once th
following is complete: 1. enrollment of subjects is closed, 2. subjects have completed a
research-related interventions, 3. data collection is complete, 4. data are de-identified
for example data are being maintained in such a way that identifiers are separated fro
the coding system, or data is in a secure location, and 5. there is no additional researc

beyond the original intent planned for these data. *For the purposes of submitting the IRB final report, the study will be considered complete if only data analysis using de-identified data remains. If identifiers remain on the data, researchers must request continuing review. Note that it is the continued responsibility of the research team to maintain the confidentiality of the data. Please complete a final report form and submit it to the IRB so the study file may be closed. It is the responsibility of the primary reviewers to review the reports to check completeness of information and ensure that the data are in accordance with the protocols and other related documents approved by the IRB.

3.3.4. Flow chart

No.	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Submission of final report on or before due date	Investigators	1 day
2	Check completeness of information in the report and forward to the primary reviewers for assessment/comments	Secretariat	1 day
3	Review the final report if it is in accordance with the approved protocol and related documents	Reviewer	1 day
4	Accepts the final report and considers the study as completed	Board	
5	Communicate ERC decision to PI	Secretariat	1 day
6	Files and attached to the main protocol	Secretariat	1 day

3.3.5. Detailed Instructions

3.3.5.1. Submitting a Final Report in e-Protocol

3.3.5.1.1. To submit a final report, you may submit it through e-mail at jrrmmc.irb@gmail.com.

3.3.5.1.2. You may get the Final Report Form at the website, under downloads.

3.3.5.1.3. Fill out all of the information on the form.

3.3.5.1.4. Submit the form together with the Final Protocol.

3.3.5.2. Submitting of Hard Copy of Final Report

3.3.5.2.1. The primary reviewers conduct review of final report if they are in accordance with the protocol and related documents approved by the IRB.

3.3.5.2.2. The primary reviewers refer to the protocol file to check compliance

with approval given by the IRB during initial review and upon submission of amendments.

3.3.5.2.3. The primary reviewers recommend approval of the final report if there is no deviation or violation of IRB approvals.

3.3.5.2.4. If there is any deviation or violation of approvals given by the IRB, the primary reviewers recommend that appropriate action be taken by the PI (i.e., explanation of deviation or violation for final reports,). This will be presented to full board.

3.3.4.2.5. Approval or other recommendations by the primary reviewers of final report is reported to the board meeting by the Secretariat.

3.3.4.2.6. Related issues or recommendations related to final reports are included in the agenda for discussion during the board meeting in order to arrive at a decision for appropriate action.

3.3.4.2.7. After reviewing the final report and found to be compliant to the approved protocol, the IRB accepts the Final Report and considers the study as completed.

3.3.4.2.8. The IRB Secretariat keeps a copy in the protocol files of th final report signed by the Primary Reviewers and the Chair or Membe Secretary.

3.3.4.2.9. The IRB Secretariat marks the folder of the completed protocol and the entire study protocol.

3.5. Review of Protocol Violation/Protocol Deviation

3.5.1. Purpose

To describe the IRB review procedures for protocol violation/ deviation

3.5.2. Scope

This SOP provides instructions for taking action and maintaining records of variou types of protocol deviation or violations:

It includes investigators who fail to comply with the procedures in the approve protocol or to comply with national/international guidelines for the conduct of huma research, including those who fail to respond to the Jose R. Reyes Memorial Medica Center IRB's requests.

It also covers actions taken by the IRB related to protocol violation/ deviation report submitted by the PI related to any event at the site that is not in compliance with th protocol documents previously approved by the IRB.

It also includes the determination of the source of violation (primar investigator or patient) and adaptation of appropriate recommendations.

3.5.3. Responsibility

It is the responsibility of the IRB Secretariat to receive protocol violation/ deviation reports submitted to the IRB.

It is the responsibility of the board members or designated members to take action related to protocol violation/ deviation. All protocol deviation reports shall go to full-board review. The reviewer shall determine the source of the deviation/violation whether it is from the investigator or the patient and make necessary recommendations.

3.5.4. Process Flow/Steps

No.	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive protocol violation/deviation reports	Secretariat	1 day
2	Distribute to the assigned members to review	Member-Secretary	1 day
3	Include this in the Agenda of the Meeting.	Secretariat	1 day
4	Notify the Investigator	Secretariat	1 day
5	File copies of the duly-accomplished forms in the Study File Folder of the particular protocol	Secretariat	1 day

3.5.5. Detailed Instructions

3.5.5.1. The Secretariat receives protocol violation/deviation reports from investigators and other parties related to any event in the site that is not in compliance with the previously IRB-approved protocol and related documents. The protocol deviation report form (Form 3.5) should be used for this purpose. The Secretariat gets full information about the event and puts the report in the next full board meeting agenda. The deviation will be classified as major or minor revision related to its effect on scientific soundness and/or safety of patients.

3.5.5.2. Whenever protocol deviation / non-compliance / violation has been observed:

3.5.5.2.1. Ensure that the issues, as well as the details of non-compliance involving research investigators are included in the agenda of the Jose R. Reyes Memorial Medical Center IRB meeting.

3.5.5.2.2. Maintain a file that identifies investigators who are found to be non-compliant with national/international regulations or who fail to follow protocol approval stipulations or fail to respond to the Jose R. Reyes Memorial Medical Center IRB's request for information/action.

3.5.5.2.3. A site visit may be conducted to check the status of the research in support of decision to be made regarding approval of the study to continue.

3.5.5.2.4. The Jose R. Reyes Memorial Medical Center IRB may allow the investigator to continue with the study after an explanation has been submitted and measures to correct the deviation that is acceptable to the IRB.

3.5.5.2.5. The JRRMMC IRB may elect to suspend or terminate approval of current studies or refuse subsequent applications from the investigators cited. The JRRMMC IRB may recommend training, need for more information prior making the appropriate decision. Decision to suspend or terminate prior approval may be done for the following violations:

3.5.5.2.5.1. Breach of previously approved conduct of the research

3.5.5.2.5.2. Major changes, deviations or amendments to the approved protocol without another approval by the IRB.

3.5.5.2.5.3. Revisions in the informed consent form without approval by the IRB.

3.5.5.2.5.4. Decisions are recorded in the minutes.

3.5.5.3. Notification of the Jose R. Reyes Memorial Medical Center IRB's decision.

3.5.5.3.1 The IRB Secretariat records the JRRMMC IRB decision.
3.5.5.3.2 A notification letter is prepared by the Secretariat and approved and date by the Chair.
3.5.5.3.3 Make three copies of the notification letter.

3.5.5.3.3.1. Send the original copy of the notification to the investigator.
3.5.5.3.3.2. Send a copy to the Sponsor.
3.5.5.3.3.3. Third copy is kept on file.

3.5.5.4. Secretariat keep records on file.

3.6. Responding to Participant's Requests/Queries

3.6.1. Purpose

To describe the IRB procedures related to participant requests and queries.

3.6.2. Scope

This SOP applies to all queries and requests related to the rights and well-being of the research participants in studies approved by the Jose R. Reyes Memorial Medical Center IRB.

3.6.3. Responsibility

A designated member of the secretariat is responsible for receiving participant queries and requests related to their participation, refers relevant issues to the IRB Chair or members for the IRB to take appropriate action. The Secretariat keeps records of all action taken by the IRB.

3.6.4. Process Flow/Steps

No.	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive the request or query	Secretariat	1 day
2	Assess nature of the request and refer to appropriate person	Secretariat and Chair	1 day
3	Take action and refer to full board if necessary	Chair, Members	1 day
4	Communicate decision to person who made the query	Secretariat	2 days
5	File the documents	Secretariat	1 day

3.6.5. Detailed Instructions

3.6.5.1. Receive the request or query.

3.6.5.1.1. The Jose R. Reyes Memorial Medical Center IRB secretariat receives the inquiry or requests from research participants/patients or the community through various forms of communication (email, telephone call, letter, etc.)

3.6.5.2. Assess the nature of the request. If it is within the authority of the Secretariat, make an immediate reply to the request or query; or refer to the Chair or IRB member for appropriate action.

3.6.5.2.1. Record the request and information in the request record form **(Form 3.6)** and keep a copy in the files.

3.6.5.2. Take action. A designated IRB member takes appropriate action.

3.6.5.2.1. Investigate the fact.

3.6.5.2.2. Record information and any action or follow-up taken in the **Form 3.6**

3.6.5.2.3. Sign and date the form and forward to the Secretariat for filing.

3.6.5.2.4. If needed, take up the received query and the action taken during the full board meeting.

3.6.5.3. Report to the Jose R. Reyes Memorial Medical Center IRB about the action taken and the outcomes.

3.6.5.4. File the request document.

3.6.5.4.1. Keep the record form in the "response" file.

3.6.5.4.2. Keep a copy in the study file.

3.6.5.4.3. Store the file in the appropriately labeled shelf.

3.7. Site Visits

3.7.1 Purpose

To describe the IRB procedures related to the conduct of site visits

3.7.2 Scope

This SOP applies to any visit made in any study site, on behalf of the Jose R. Reyes Memorial Medical Center IRB, to check compliance with GCP and IRB approved protocol and related documents.

3.7.3 Responsibility

It is the responsibility of the Jose R. Reyes Memorial Medical Center IRB to perform or designate some members or qualified representatives to perform on its behalf on-site visit of the research projects it has approved.

The Jose R. Reyes Memorial Medical Center IRB members or Secretariat in consultation with the Chair may initiate an on-site evaluation of a study site for cause or for a routine audit.

3.7.4 Process Flow/Steps

No.	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Select study sites and inform the PI about the planned visit	Members and Secretariat	7 days
2	Check approval given by the IRB from the protocol files and collect relevant information about the study site	Members and/or IRB representative	
3	Check the onsite documents and compare with documents in the protocol files; interview PI and/or research staff	Members and/or IRB representative	5 days
4	Write a report and make a recommendation	Members and/or IRB representative	2 days
5	Present the findings to the Full Board which adopts an appropriate action	Members	1 day
6	Communicate board decision to the PI	Secretariat	1 day
7	PI implements board recommendation and reports action to the board	PI	
8	File copies of documents	Secretariat	1 day

3.7.5 Detailed Instructions

3.7.5.1 Selection of study sites

3.7.5.1.1 Review periodically the database files of the submitted/approved study protocols.

3.7.5.1.2 Select study sites needed to be monitored based on the following criteria:

3.7.5.1.2.1 New study sites or new PIs

3.7.5.1.2.2 Reports of remarkable serious adverse events

3.7.5.1.2.3 Big number of studies carried out at the study site
3.7.5.1.2.4 Frequent protocol submission for Jose R. Reyes Memorial Medical Center IRB review
3.7.5.1.2.5 Non-compliance or suspicious conduct
3.7.5.1.2.6 Frequently fail to submit final reports
3.7.5.1.2.7 Frequent protocol violations

3.7.5.2. Before the visit

The Jose R. Reyes Memorial Medical Center IRB representatives will:
Contact the site PI to notify them that they will be visiting them. Coordinate a time for the site evaluation visit.

3.7.5.2.1. Make the appropriate travel arrangements if necessary or the study site outside the institution.
3.7.5.2.2. Review the Jose R. Reyes Memorial Medical Center IRB files for the study and site.
3.7.5.2.3. Make appropriate notes as guide during the visit.
3.7.5.2.4. Copy some parts of the files for comparison with the site files.

3.7.5.3. During the visit

Using the Site visit checklist **(Form 3.7)**, the Jose R. Reyes Memorial Medical Center IRB representatives will:

3.7.5.3.1. Review the informed consent document to make sure that the site is using the most recent version.
3.7.5.3.2. Review the investigator records and compare with documents in the protocol files submitted initially in the IRB.
3.7.5.3.3. Review randomly the subject files to ensure that subjects are signing the correct informed consent. Check if the files are orderly and confidentiality is maintained.
3.7.5.3.4. Debrief the PI about site visit findings and comments.
3.7.5.3.5. Get immediate feedback.

3.7.5.4. After the visit

The Jose R. Reyes Memorial Medical Center IRB representative will:

3.7.5.4.1. Write a report/comment (**use Form 3.5**) within 1 week describing the findings during the audit.
3.7.5.4.2. Forward a copy of the site visits to the Secretariat for inclusion in the next board meeting.
3.7.5.4.3. Send a copy of the report to the site for their files, and
3.7.5.4.4. Place the report in the correct site files.

3.7.5.5. Present the site findings to the Full Board.

3.7.5.5.1. Present the site visit report to the Full Board.
3.7.5.5.2. Board makes a decision about appropriate action:

3.7.5.5.2.1. Uphold current approval
3.7.5.5.2.2. Suspend approval (Refer to SOP 3.5.5.2.5 under Protocol Deviation/Non-compliance)

3.7.5.6. Secretariat communicates the board decision to the PI for appropriate action.

3.7.5.7. PI follows board recommendation and reports to the IRB.

3.7.5.8. Secretariat reports PI's action to the board.

3.7.5.9. Secretariat keeps a copy of the files.

3.8. Early Protocol Termination

3.8.1. Purpose

To describe the IRB procedures related to early termination of protocol implementation

3.8.2. Scope

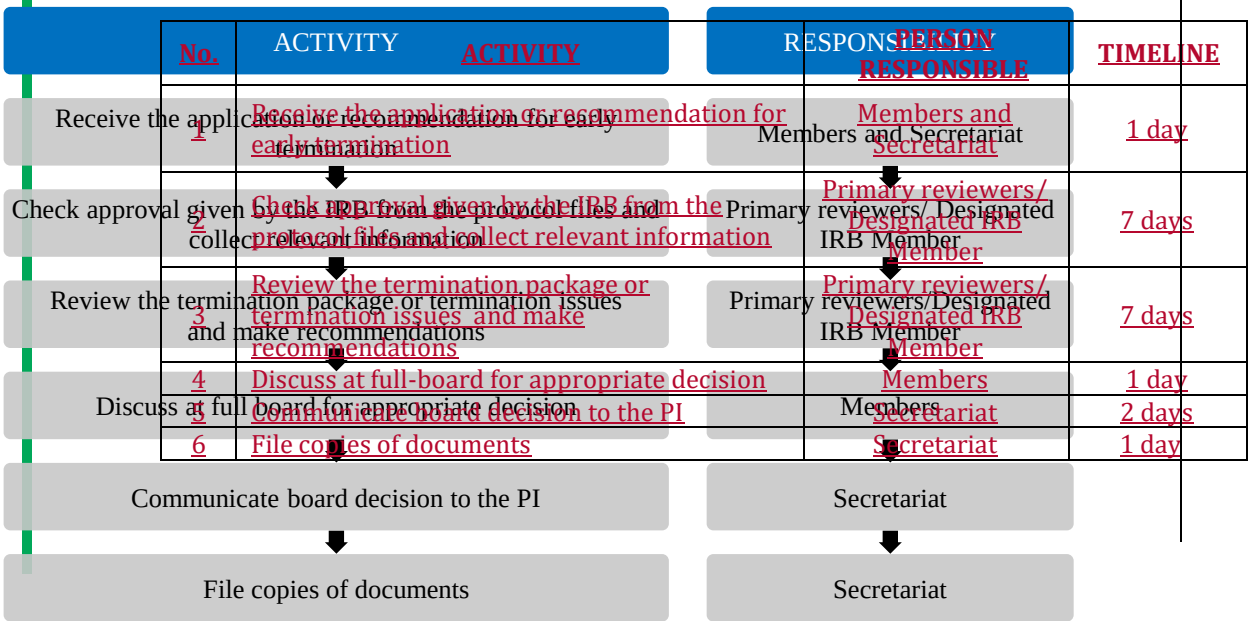
This procedure describes how the IRB proceeds and manages the premature or early termination of a protocol when subject enrollment is discontinued before the scheduled end of the study. Protocols are usually terminated at the recommendation of the Data Safety Monitoring Board (DSMB), the Scientific Director, sponsor, PI, by the IRB itself or other authorized bodies

3.8.3. Responsibility

It is the responsibility of the IRB to act on any early protocol termination application. It is also the responsibility of the IRB to withdraw approval for any previously approved protocol when the safety or benefit of the study participants is doubtful or at risk. All applications are reviewed at a full-board for appropriate action.

The Secretariat is responsible for the receipt and management of the termination documentation. The primary reviewers review the reasons for early termination and make a recommendation to a full-board.

3.8.4. Process Flow/Steps



No.	ACTIVITY	RESPONSIBLE PERSON	TIMELINE
1	Receive the application or recommendation for early termination	Members and Secretariat	1 day
2	Check approval given by the IRB from the protocol files and collect relevant information	Primary reviewers/ Designated IRB Member	7 days
3	Review the termination package or termination issues and make recommendations	Primary reviewers/ Designated IRB Member	7 days
4	Discuss at full-board for appropriate decision	Members	1 day
5	Communicate board decision to the PI	Secretariat	2 days
6	File copies of documents	Secretariat	1 day

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3.8.5. Detailed Instructions

3.8.5.1. Receive application or recommendation for early study termination.

3.8.5.1.1. Receive recommendation and comments from the Sponsor, DSMB, IRB members, Scientific Director, or other authorized bodies for study protocol termination.

3.8.5.1.2. Inform the principal investigator to prepare and submit a protocol termination package.

3.8.5.1.3. Receive the study protocol termination package prepared and submitted by the principal investigator.

3.8.5.1.4. Check the completeness of the contents of the package to include the Study Termination **(Form 3.8).**

3.8.5.1.5. The request for termination memorandum should contain a brief written summary of the protocol, its results, and accrual data.

~~3.7.1.1.~~

3.8.5.2. Check approval given by the IRB from the protocol files and collect relevant information.

3.8.5.3. Review the termination package or termination issues and make recommendation. The primary reviewers review the safety data. It is important for the termination package to contain a plan to follow up the participants who are still active in the study.

3.8.5.4. Discuss at a full board for appropriate decision.

3.8.5.4.1. For recommendations for early termination coming from the sponsor or study team, the IRB approves.

3.8.5.4.2.

3.7.5.4.2. If there is a recommendation regarding early termination after noting protocol deviations/ non-compliance and supported by site visit findings, this will be discussed and approved during a full board meeting.

Sponsor:	Date of first use:
Title of the Report	Date of the report

3.8.5.5. Communicate the IRB decision to the PI.

3.8.5.6. Keep the files in the Inactive File Folders.

SERIOUS ADVERSE EVENT REPORT FORM (FORM 3.1)

Whenever there is any SAE event in any research approved by the Jose R. Reyes Memorial Medical Center IRB, it has to be reported by the principal investigator (PI) to the IRB. Section 1 of this form should be filled up by the PI.

SECTION 1

Principal Investigator:			
Study Title:		Protocol No.:	
Name of the study medicine/device:		Report Date:	
		☐ Initial ☐ Follow-up	
		Onset Date:	

Subject's initial/number: _____ Age: _____ ☐ Male ☐ Female

~~SAE:~~

~~Treatment:~~

~~Outcome:~~ ☐ ~~Resolved~~ ☐ ~~On-going~~

Subject's history:

Laboratory findings:

~~Seriousness:~~

☐ ~~Death~~ ☐ ~~Life Threatening~~

☐ ~~Hospitalization:~~

☐ ~~Initial~~ ☐ ~~Prolonged~~

☐ ~~Disability/Incapacity~~

☐ ~~Congenital Anomaly~~

☐ ~~Others~~

~~Relation to~~

☐ ~~Drug~~ ☐ ~~Device~~ ☐ ~~Study~~

☐ ~~Not related~~

☐ ~~Possibly~~

☐ ~~Probably~~

☐ ~~Definitely related~~

☐ ~~Unknown~~

SAE:

Treatment:

Outcome: ☐ Resolved ☐ On-going

Seriousness:	Relation to

Note: PI should attach standard SAE report form to this IRB form.

☐ Death	☐ Life Threatening	☐ Drug	☐ Device	☐ Study
☐ Hospitalization:		☐ Not related		
☐ Initial	☐ Prolonged	☐ Possibly		
☐ Disability/Incapacity		☐ Probably		
☐ Congenital Anomaly		☐ Definitely related		
☐ Others		☐ Unknown		

Note: PI should attach standard SAE report form to this IRB form.

SECTION 2 (to be filled up by the designated IRB representative)

Document Receipt by the IRB

Name (IRB Secretariat)	Signature	Date

Reviewer/s Recommendations

Reviewer's Name:	Signature	Date

Changes to the protocol recommended ☐ No ☐ Yes
Comments:

Changes to the informed consent form recommended? ☐ No ☐ Yes
Comments:

IRB Final Action:

☐ Request an amendment to the protocol or the consent form.

☐ Request further information.

☐ Suspend or terminate the study

☐ Take note and no further action is needed.

☐ Others:

_____

Type of review:

☐ Expedited review

☐ Full board review

Date of meeting

_____

Name of IRB Chair :	Signature	Date

PROTOCOL AMENDMENT REVIEW (FORM 3.2)

Date of Submission	IRB Protocol No.	Sponsor Protocol No.

Principal Investigator	Email/Mobile No.	Sponsor

Title	

Study Site/s:		Date of Initial Approval	
		Type of Initial Review: (FB, Expedited, Exempted	

Items to be Amended	List of Amendments	Reasons

Signature of PI:	
Date:	

FOR REC USE:				
Assessment of Primary Reviewers	1. Type of amendments:			
		Minor		Major
	Comment/s:			
	2. Does the amendment decrease the risks to participants:			
		Yes		No
	Comment/s:			
	3. Does the amendment decrease the benefits to participants?			
		Yes		No
	Comment/s:			
	4. Is there favourable benefit/risk ratio?			
		Yes		No
	Comment/s:			

Recommendations:	Type of Review

	Approve
	Request for further
	information/modification
	Others

	Expedited
	Exempted
	Full Board

Name of Reviewer	Signature	Date

Final Decision	

IRB Chair	Signature	Date

PROGRESS REPORT (FORM 3.3)

IRB Protocol No.		Approval Date	
Protocol Title			
Investigator		Sponsor	

~~ACTION REQUESTED:~~

- ☐ ~~Renew - New participant accrual to continue~~
- ☐ ~~Renew - Enrolled participant follow up only~~
- ☐ ~~Terminate - Protocol discontinued~~

Any amendment since the last review? ~~(~~Describe briefly.~~)~~	☐ ~~No~~Yes	☐ No~~Yes~~
Any change in participant population, recruitment or selection criteria since the last review? ~~(~~Explain the changes.~~)~~	☐ ~~No~~Yes	☐ ~~Yes~~No
Any change in the Informed Consent process or documentation since the last review? ~~(~~Please explain.~~)~~	☐ ~~No~~Yes	☐ ~~Yes~~No
Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? Summarize.	☐ Yes	☐ No
	☐ Yes	☐ No

Any unexpected complication or side effect noted since the last review? Summarize.		
Were there protocol deviation/violation reports? Summarize. What corrective actions were taken?	☐ Yes	☐ No
Any new investigator that has been added to or removed from the research team since the last review? Please identify them and submit the CVs of new investigators.	☐ Yes	☐ No

Summary of recruitment~~protocol participants~~:

☐ Accrual ceiling set by IRB

☐ New participants accrued since last review
☐ Total participants accrued since protocol began
☐ No. of participants who are lost to follow-up~~Total participants accrued since protocol began~~
☐ No of participants withdrawn from the study
☐ No. of participants who experienced SAEs/SUSARs

~~Any new investigator that has been added to or removed from the research team since the last review? (Please identify them and submit the CVs of new investigators.)~~ ☐ ~~No~~ ☐ ~~Yes~~
~~1.~~

Are there any new collaborating sites that have been added or deleted since the last review? Please identify the sites and note the addition or deletion.	☐ Yes	☐ No

To be filled up by IRB

Assessment by the Primary Reviewer:

Questions:	Yes	No	Comments:
Do the risks to the study participants remain reasonable in relation to anticipated benefits?			
Are there new findings in the IB or literature (e.g., important toxicity or adverse event information) that need to be included in the informed consent?			
Is there need to revise the ICF?			
Is there need to re-consent subjects enrolled in the study?			
Are there concerns about conduct of the research team (e.g., suspension of medical license, frequent protocol violation, patient or third party complaints, etc.) or institutional commitment that may affect patient safety?			

Check the protocol file to ensure consistency of the progress report with actual reports (SAE, Protocol Deviation/Violation, etc.) submitted by the Principal Investigator.

Recommendations

☐ Approve

☐ Request further action. Specify.~~an amendment to the protocol or the consent form.~~

☐ Request further information. Specify.

☐ Others comments:

Type of review:

☐ Expedited review

☐ Full board review

Date of meeting:

~~Summary of protocol participants:~~

☐ ~~Accrual ceiling set by IRB~~

☐ ~~New participants accrued since last review~~

☐ ~~Total participants accrued since protocol began~~

~~Total participants accrued since protocol began~~

~~ACCRUAL EXCLUSIONS~~

- ☐ ~~None~~
- ☐ ~~Male~~
- ☐ ~~Female~~
- ☐ ~~Others (Specify)~~ _____

Primary Reviewers:	Signature:	Date:

Certified by:

Name of Member-Secretary:	Signature:	Date

~~*To be filled up by IRB*~~

~~Date received:~~		~~Received by:~~	
		~~Printed name:~~	~~77~~ 88
		~~Signature:~~	87 ~~76~~

~~Primary Reviewers:~~	~~Signature:~~	~~Date:~~

~~Recommendations~~

- ☐ ~~Approve~~

~~Type of review:~~

- ☐ ~~Expedited review~~

☐ Request an amendment to the protocol or the consent form.

☐ Request further information.

☐ Suspend or terminate the study

☐ Others:

_____

☐ Full board review

Date of meeting:

_____

Changes to the protocol recommended ☐ No ☐ Yes
Comments:

Changes to the informed consent form recommended? ☐ No ☐ Yes
Comments:

IRB Final Decision:	

Certified by:

Name of Member-Secretary:	Signature:	Date

FINAL REPORT (FORM 3.4)

IRB Protocol No.		Initial Approval Date	
Protocol Title			
Principal Investigator.			
Phone number:		E-mail address :	
Sponsor's Name			
Address:			
Phone number:		E-mail address :	

1. Study Arms:	
2. Summary of Recruitment:	
Accrual ceiling set by REC	
• New participants accrued since last review	
• Total number of participants accrued since protocol began	
• No. of participants who are lost to follow up	
• No. of participants withdrawn from the study	
• No. of participants who experienced SAEs/SUSARs	
3. Number of participants who completer the study:	
4. Amendments to the original protocol (including dates of approval):	
5. Summary of onsite SAEs reported:	
6. Summary of participants' complaints or grievances documented regarding conduct of study:	
7. Summary of benefits to participants:	
8. Summary of indemnifications of study related injury: (if applicable).	

9. If terminated early, specify reason for termination	

10. Progress reports submitted (with dates of approval):	
11. Duration of the study (months:	
12. Informed consent form used (with version no./date) and attach most recent version:	
13. Study objectives and summary of results:	

Study site(s):

Total Number of study participants :

No. of Study Arms

Number of participants who received the test articles:

Study materials:

Treatment form:

Study dose(s):

Duration of the study

Signature of PIResults: *(Use extra blank paper, if more*	

Date Submitted Date Received by the IRB	

~~Signature of P.I.~~	

Comments of the Primary Reviewer
(i.e. compliance with the terms of the approved protocol including post- approval review requirements, and overall assessment of risks against benefits in the conduct of study)

Recommendations

- ☐ Approve
- ☐ Request further action. Specify.~~an amendment to the protocol or the consent form.~~
- ☐ Request further information. Specify.
- ☐ Others comments:

Type of review:

- ☐ Expedited review
- ☐ Full board review

Date of meeting:

Primary Reviewers:	Signature:	Date:

3.4 Review of Protocol Violation/Protocol Deviation

3.4.1. Purpose

To describe the IRB review procedures for protocol violation/ deviation

3.4.2. Scope

This SOP provides instructions for taking action and maintaining records of various types of protocol deviation or violations:

It includes investigators who fail to comply with the procedures in the approved protocol or to comply with national/ international guidelines for the conduct of human research, including those who fail to respond to the Jose R. Reyes Memorial Medical Center IRB's requests.

It also covers actions taken by the IRB related to protocol violation/ deviation reports submitted by the PI related to any event at the site that is not in compliance with the protocol documents previously approved by the IRB.

It also includes the determination of the source of violation (primary investigator or patient) and adaptation of appropriate recommendations.

3.4.3. Responsibility

It is the responsibility of the IRB Secretariat to receive protocol violation/ deviation reports submitted to the IRB.
It is the responsibility or the board members or designated members to take action related to protocol violation/ deviation.

3.4.4 Process Flow/Steps

ACTIVITY	RESPONSIBILITY
Receive protocol violation/deviation reports	Secretariat
Distribute to the assigned members to review	Member-Secretary
Include this in the Agenda as full board review	Secretariat
Notify the Investigator	Secretariat
File copies of the duly accomplished forms in the Study File Folder of the particular protocol	Secretariat

~~3.4.5. Detailed Instructions~~

~~3.4.5.1. The Secretariat receives protocol violation/deviation reports from investigators and other parties related to any event in the site that is not in compliance with the previously IRB approved protocol and related documents. The protocol deviation report form (Form 3.5) should be used for this purpose. The Secretariat gets full information about the event and puts the report in the next full board meeting agenda. The deviation will be classified as major or minor revision related to its effect on scientific soundness and/or safety of patients.~~

~~3.4.5.2. Whenever protocol deviation / non-compliance / violation has been observed:~~

~~3.4.5.2.1. Ensure that the issues as well as the details of non-compliance involving research investigators are included in the agenda of the Jose R. Reyes Memorial Medical Center IRB meeting.~~

~~3.4.5.2.2. Maintain a file that identifies investigators who are found to be non-compliant with national/international regulations or who fail to follow protocol approval stipulations or fail to respond to the Jose R. Reyes Memorial Medical Center IRB's request for information/action.~~

~~3.4.5.2.3. A site visit may be conducted to check the status of the research in support of decision to be made regarding approval of the study to continue.~~

~~3.4.5.2.4. The Jose R. Reyes Memorial Medical Center IRB may allow the investigator to continue with the study after an explanation has been submitted and measures to correct the deviation is acceptable to the IRB.~~

~~3.4.5.2.5. The JRRMMC IRB may elect to suspend or terminate approval of current studies or refuse subsequent applications from the investigators cited. The JRRMMC IRB may recommend training, need for more information prior making the appropriate decision. Decision to suspend or terminate prior approval may be done for the following violations:~~

~~3.4.5.2.5.1. Breach of previously approved conduct of the research~~
~~3.4.5.2.5.2. Major changes, deviations or amendments to the approved protocol without another approval by the IRB.~~
~~3.4.5.2.5.3. Revisions in the informed consent form without approval by the IRB~~
~~3.4.5.2.6. Decisions are recorded in the minutes.~~

~~3.4.5.3. Notification of the Jose R. Reyes Memorial Medical Center IRB's decision.~~

~~3.4.5.3.1. The IRB Secretariat records the JRRMMC IRB decision.~~

~~3.4.5.3.2. A notification letter is prepared by the Secretariat and approved and dated by the Chair.~~

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~~3.4.5.3.3. Make three copies of the notification letter.~~

~~3.4.5.3.3.1. Send the original copy of the notification to the investigator.~~

~~3.4.5.3.3.2. Send a copy to the Sponsor.~~

~~3.4.5.3.3.3. Third copy is kept on file.~~

~~3.4.5.4. Secretariat keep records on file.~~

DEVIATION / NON-COMPLIANCE / VIOLATION REPORT (FORM 3.5)

IRB Protocol No.	Sponsor Protocol No.	Date of Submission

Study Title:			
Investigator		Contact No.:	
Sponsor:		~~Contact No.:~~Date of Submission	
Reported by		~~Contact No.:~~	
Protocol Deviation			
Corrective measures			

Please check the ones applicable :

☐ ~~PI~~ Deviation from protocol
☐ Major ☐ Minor

☐ Participant Non-Compliance
☐ Yes
☐ No
☐ N/A

~~Description:~~	
~~IRB Decision:~~	
~~Actions taken:~~	

~~Reported by:~~	~~Noted by (Secretariat)~~

Date:	Date:

Primary Reviewers:	Signature:	Date:

IRB Recommendations:

- ☐ Noted (no further action)
- ☐ Correction action needed
- ☐ Site visit needed
- ☐ Others please specify

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3.5. Responding to Participant's Requests/Queries

3.5.1. Purpose

To describe the IRB procedures related to participant requests and queries

3.5.2. Scope

This SOP applies to all queries and requests related to the rights and well-being of the research participants in studies approved by the Jose R. Reyes Memorial Medical Center IRB.

3.5.3. Responsibility

A designated member of the secretariat is responsible for receiving participant queries and requests related to their participation, refers relevant issues to the IRB Chair or members for the IRB to take appropriate action. The Secretariat keeps records of all action taken by the IRB.

3.5.4. Process Flow/Steps

ACTIVITY	RESPONSIBILITY
Receive the request or query	Secretariat
Assess nature of the request and refer to appropriate person	Secretariat and Chair
Take action and refer to full board if necessary	Chair, Members
Communicate decision to person who made the query	Secretariat
File the documents	Secretariat

3.5.5. Detailed Instructions

3.5.5.1. Receive the request or query.

3.5.5.1.1. The Jose R. Reyes Memorial Medical Center IRB secretariat receives the inquiry or requests from research participants/patients or the community through various forms of communication (email, telephone call, letter, etc.)

3.5.5.2. Assess the nature of the request. If it is within the authority of the Secretariat, make an immediate reply to the request or query; or refer to the Chair or IRB member for appropriate action.

3.5.5.2.1. Record the request and information in the request record form **(Form 3.6)** and keep a copy in the files.

3.5.5.3. Take action. A designated IRB member takes appropriate action.

3.5.5.3.1. Investigate the fact.

3.5.5.3.2. Record information and any action or follow-up taken in the **Form 3.6**

3.5.5.3.3. Sign and date the form and forward to the Secretariat for filing.

3.5.5.3.4. If needed, take up the received query and the action taken during the full board meeting.

3.5.5.4. Report to the Jose R. Reyes Memorial Medical Center IRB about the action taken and the outcomes.

3.5.5.5. File the request document.

3.5.5.5.1. Keep the record form in the "response" file.

3.5.5.5.2. Keep a copy in the study file.

3.5.5.5.3. Store the file in the appropriately labeled shelf.

REQUEST/ QUERY RECORD (FORM 3.6)

Date received:		Received by	

Request from :

- ☐ Telephone call Number _____
- ☐ Fax Number _____
- ☐ Mailed letter / Date _____
- ☐ E-mail / Date _____
- ☐ Walk-in/Date/Time _____
- ☐ Others, specify _____

Participant's Name:			
Contact Address:		Phone:	
Title of the Participating Study			
Starting date of participation :			
What are requested?			
Action taken:			
Outcome:			

Site Visits

3.6.1. Purpose

To describe the IRB procedures related to the conduct of site visits

3.6.2. Scope

This SOP applies to any visit made in any study site, on behalf of the Jose R. Reyes Memorial Medical Center IRB, to check compliance with GCP and IRB approved protocol and related documents.

3.6.3. Responsibility

It is the responsibility of the Jose R. Reyes Memorial Medical Center IRB to perform or designate some members or qualified representatives to perform on its behalf on-site visit of the research projects it has approved.

The Jose R. Reyes Memorial Medical Center IRB members or Secretariat in consultation with the Chair may initiate an on-site evaluation of a study site for cause or for a routine audit.

3.6.4. Process Flow/Steps

ACTIVITY	RESPONSIBILITY
Select study sites and inform the PI about the planned visit	Members and Secretariat
Check approval given by the IRB from the protocol files and collect relevant information about the study site	Members and/or IRB representative
Check the onsite documents (Investigator's records) and compare with documents in the protocol files; interview PI and/or research staff	Members and/or IRB representative
Write a report and make a recommendation	Members and/or IRB representative
Present the findings to the Full Board which adopts an appropriate action	Members
Communicate board decision to the PI	Secretariat
PI implements board recommendation and reports action to the board	PI
File copies of documents	Secretariat

3.6.5. Detailed Instructions

3.6.5.1. Selection of study sites

3.6.5.1.1. Review periodically the database files of the submitted/approved study protocols.

3.6.5.1.2. Select study sites needed to be monitored based on the following criteria:
3.6.5.1.2.1. New study sites or new PIs
3.6.5.1.2.2. Reports of remarkable serious adverse events
3.6.5.1.2.3. Big number of studies carried out at the study site
3.6.5.1.2.4. Frequent protocol submission for Jose R. Reyes Memorial Medical Center IRB review
3.6.5.1.2.5. Non-compliance or suspicious conduct
3.6.5.1.2.6. Frequently fail to submit final reports
3.6.5.1.2.7. Frequent protocol violations

3.6.5.2. Before the visit

The Jose R. Reyes Memorial Medical Center IRB representatives will:
Contact the site PI to notify them that they will be visiting them. Coordinate a time for the site evaluation visit.

3.6.5.2.1. Make the appropriate travel arrangements if necessary or the study site outside the institution.

3.6.5.2.2. Review the Jose R. Reyes Memorial Medical Center IRB files for the study and site.

3.6.5.2.3. Make appropriate notes as guide during the visit.

3.6.5.2.4. Copy some parts of the files for comparison with the site files.

3.6.5.3. During the visit

Using the Site visit checklist **(Form 3.7)**, the Jose R. Reyes Memorial Medical Center IRB representatives will:

Review the informed consent document to make sure that the site is using the most recent version.
3.6.5.3.1. Review the investigator records and compare with documents in the protocol files submitted initially in the IRB.
3.6.5.3.2. Review randomly the subject files to ensure that subjects are signing the correct informed consent. Check if the files are orderly and confidentiality is maintained.
3.6.5.3.3. Debrief the PI about site visit findings and comments.
3.6.5.3.4. Get immediate feedback.

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~~***3.6.5.4 After the visit***~~
~~The Jose R. Reyes Memorial Medical Center IRB representative will:~~
~~3.6.5.4.1. Write a report/comment (**use Form 3.5**) within 1 week describing the findings during the audit.~~
~~3.6.5.4.2. Forward a copy of the site visits to the Secretariat for inclusion in the next board meeting.~~
~~3.6.5.4.3. Send a copy of the report to the site for their files, and~~
~~3.6.5.4.4. Place the report in the correct site files.~~

~~***3.6.5.5. Present the site findings to the Full Board.***~~
~~3.6.5.5.1. Present the site visit report to the Full Board.~~
~~3.6.5.5.2. Board makes a decision about appropriate action:~~

~~3.6.5.5.2.1. Uphold current approval~~
~~3.6.5.5.2.2. Suspend approval (Refer to SOP 3.4.5.2.5 under Protocol Deviation/Non-compliance)~~

~~**3.6.5.6.** Secretariat communicates the board decision to the PI for appropriate action.~~

~~**3.6.5.7.** PI follows board recommendation and reports to the IRB.~~

~~**3.6.5.8.** Secretariat reports PI's action to the board.~~

~~**3.6.5.9.** Secretariat keeps a copy of the files.~~

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SITE VISIT REPORT (FORM 3.7)

IRB Protocol No.		Date of the Visit:	
Study Title:			
Principal Investigator/s:		Phone:	
Department:		Address:	
Sponsor		Address:	
Site Location		Reason/s for Visit	
Total number of expected subjects:		Total subjects enrolled:	

Are site facilities appropriate? Comment:

☐ Yes ☐ No

Are Informed Consents Recent? Comment:

☐ Yes ☐ No

Any adverse events found? Comment:

☐ Yes ☐ No

Any protocol non-compliance/violation? ☐ Yes ☐ No	Comment:	

Are all Case Record Forms up to date? ☐ Yes ☐ No	Comment:	

Are storage of data and investigating products locked? ☐ Yes ☐ No	Comment:	

How well are participants protected? ☐ Good ☐ Fair ☐ Not good	Comment:	

Any outstanding tasks or results of visit? ☐ Yes ☐ No	Give details:	

Study Team Members:		

Duration of visit: (hours)		Start:		Finish:	

Completed by:		Date:	

~~3.7. Early Protocol Termination~~

~~3.7.2.3.1.1. Purpose~~

~~To describe the IRB procedures related to early termination of protocol implementation~~

~~3.7.3.3.1.1. Scope~~

~~This procedure describes how the IRB proceeds and manages the premature or early termination of a protocol when subject enrollment is discontinued before the scheduled end of the study. Protocols are usually terminated at the recommendation of the Data Safety Monitoring Board (DSMB), the Scientific Director, sponsor, PI, by the IRB itself or other authorized bodies~~

~~3.7.4.3.1.1. Responsibility~~

~~It is the responsibility of the IRB to act on any early protocol termination application. It is also the responsibility of the IRB to withdraw approval for any previously approved protocol when the safety or benefit of the study participants is doubtful or at risk. All applications are reviewed at full board for appropriate action.~~

~~The Secretariat is responsible for the receipt and management of the termination documentation. The primary reviewers review the reasons for early termination and make a recommendation to full board.~~

~~3.7.5.3.1.1. Process Flow/Steps~~

ACTIVITY	RESPONSIBILITY
Receive the application or recommendation for early termination	Members and Secretariat
Check approval given by the IRB from the protocol files and collect relevant information	Primary reviewers/ Designated IRB Member
Review the termination package or termination issues and make recommendations	Primary reviewers/Designated IRB Member
Discuss at full board for appropriate decision	Members
Communicate board decision to the PI	Secretariat
File copies of documents	Secretariat

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~~3.7.6.3.1.1. Detailed Instructions~~

~~3.7.5.1 Receive application or recommendation for early study termination.~~

~~3.7.6.1.1.3.1.1.1.1. Receive recommendation and comments from the Sponsor, DSMB, IRB members, Scientific Director, or other authorized bodies for study protocol termination.~~

~~3.7.6.1.2.3.1.1.1.1. Inform the principal investigator to prepare and submit a protocol termination package.~~

~~3.7.6.1.3.3.1.1.1.1. Receive the study protocol termination package prepared and submitted by the principal investigator.~~

~~3.7.6.1.4.3.1.1.1.1. Check the completeness of the contents of the package to include the Study Termination (Form 3.8).~~

~~3.7.6.1.5.3.1.1.1.1. The request for termination memorandum should contain a brief written summary of the protocol, its results, and accrual data.~~

~~3.7.6.2.3.1.1.1. Check approval given by the IRB from the protocol files and collect relevant information.~~

~~3.7.6.3.3.1.1.1. Review the termination package or termination issues and make recommendation. The primary reviewers review the safety data. It is important for the termination package to contain a plan to follow up the participants who are still active in the study.~~

~~3.7.6.4.3.1.1.1. Discuss at full board for appropriate decision.~~

~~3.7.6.4.1.3.1.1.1.1. For recommendations for early termination coming from the sponsor or study team, the IRB approves.~~

~~3.7.5.4.2. If there is a recommendation regarding early termination after noting protocol deviations/ non-compliance and supported by site visit findings, this will be discussed and approved during a full board meeting.~~

~~3.7.6.5.3.1.1.1. Communicate the IRB decision to the PI.~~

~~3.7.6.6.3.1.1.1. Keep the files in the Inactive File Folders.~~

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~~S~~EARLY STUDY TERMINATION (FORM 3.8)

IRB Protocol No:		Sponsor Protocol No.	
Protocol Title:			
Principal Investigator:			
Phone :		E-Mail:.	
Department:			
Sponsor:			
IRB Approval Date:		Date Of Last Report:	
Starting Date:		Termination Date:	
No. of Participants:		No. Enrolled:	

Summary of Results	
Accrual Data: • How many have completed the study? • How many are still active?	

• What are the plans for those who are still active in the study?	

Signature of PI Date Submitted Date Received by the IRB	

Comments of the Primary Reviewer
(i.e. compliance with the terms of the approved protocol including post- approval review requirements, and overall assessment of risks against benefits in the conduct of study)

Recommendations
- ☐ Approve
- ☐ Request further action. Specify.
- ☐ Request further information. Specify.
- ☐ Others comments:

Type of review:
- ☐ Expedited review
- ☐ Full board review

Date of meeting:

Primary Reviewers:	Signature:	Date:

~~P.I. Signature:~~		~~Date:~~	