MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

SERIOUS ADVERSE EVENT REPORT
REVIEWER'S RECOMMENDATION FORM
(Form 3.1B) ONSITE REPORT

TO THE SECRETARIAT: *ATTACH THIS FORM TO FORM 3.1A BEFORE DISTRIBUTING TO THE REVIEWERS, SAE SUBCOMMITTEE CHAIR AND SAE SUBCOMMITTEE MEMBERS.*

TO THE SAE SUBCOMMITTEE CHAIR OR MEMBER: *PUT A (√) MARK ON THE APPROPRAITE TICK BOX. INDICATE THE NEEDED INFORMATION ON THE SPACE PROVIDED, IF APPLICABLE. PRINT NAME, SIGN AND DATE THIS FORM. PLEASE DO NOT USE PENCIL IN ACCOMPLISHING THIS FORM.*

Recommendation

- ☐ Request an amendment to the: ☐ Protocol ☐ Consent Form
- ☐ Request further information _
- ☐ Suspension of:
  - ☐ Enrolment of new research participants until further review of the IRB
  - ☐ A trial-related procedures (except those intended for safety and well-being of the participant) until further review by the IRB
- ☐ Termination of the study
- ☐ Take note and continue monitoring
- ☐ Site Visit

Name of SAE Subcommittee Chair/ Member	Signature	Date (MMM/DD/YYYY)

TO THE PRINCIPAL INVESTGATOR: *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PRINT NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION.*

Date of Submission (MMM/DD/YYYY)		**IRB Protocol Number**	
Sponsor		**Sponsor's Protocol Number**	
Principal Investigator		**Co-investigator(s)** (if any)	
Principal Investigator's Contact Number		**Principal Signature**	
Date of Initial Approval of Protocol (MMM/DD/YYYY)			
Protocol Title			

TO THE PRINCIPAL INVESTIGATOR: *ON THE FIRST COLUMN, SPECIFY THE AMENDMENTS FOR APPROVAL. PROVIDE A COMPARISON BETWEEN THE ORIGINALLY APPROVED VERSION AND THE NEW VERSION FOR APPROVAL. ON THE SECOND COLUMN, SPECIFY THE REASON FOR THE AMENDMENT. YOU MAY ADD MORE ROWS OR EXTRA PAGES, AS NEEDED.*

TO THE REVIEWER/ INDEPENDENT CONSULTANT: *IF THE AMENDMENT IS APPROVED, PUT A (√) MARK ON THE THIRD COLUMN. KINDLY STIPULATE ON THE FOURTH COLUMN YOUR COMMENTS OR OTHER CLARIFICATIONS, IF NEEDED. PLEASE DO NOT USE PENCIL IN ACCOMPLISHING THIS FORM.*

List of Amendments (*originally approved version versus the new version)*		**Reason**	**Primary Reviewers only**	
Original Version	**New Version**		**Approval**	**For Review** ***(Specify comments.)***
1.				
2.				
3.				
4.				
5.				

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

TO THE REVIEWER/ INDEPENDENT CONSULTANT: *PUT A (✓) MARK ON THE APPROPRIATE TICK BOX. PRINT NAME, SIGN AND DATE THIS FORM. PLEASE DO NOT USE PENCIL IN ACCOMPLISHING THIS FORM.*

Type of Review
☐ Expedited ☐ Full board **Date of Meeting Presented:** _____ (MMM/DD/YYYY)

Primary Reviewer's Recommendation
☐ Approval ☐ Major modification to the protocol ☐ Minor modification to the protocol ☐ Disapproval
☐ Others: _____

Name of Primary Reviewer	**Signature**	**Date** (MMM/DD/YYYY)

**If IRB approval of your study has expired, you must also complete the Expired Study Report Form.*
**If you plan on closing your study, do not complete this form. Please complete the Final Study Report/Study Closure Form.*

TO THE PRINCIPAL INVESTIGATOR: *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PRINT, DATE AND SIGN THIS FORM BEFORE SUBMISSION. CLEARLY TYPE ALL PORTIONS OF THIS FORM.*

Date of Submission (MMM/DD/YYYY)		**IRB Protocol Number**	

Protocol Title	

Expiration Date of Study Approval (MMM/DD/YYYY)	

Sponsor		**Sponsor's Protocol Number**	

Principal Investigator	

Department	

Telephone Number	**Mobile Number**	**Mailing Address**	**Email Address**

Additional Contact: If additional information is needed, specify the contact person if other than the PI (e.g., study coordinator)		**Email Address/ Contact No.**	

STUDY PERSONNEL

Co-Investigator(s):	

Other Study Personnel (i.e., research coordinators, data managers, etc.	

Have there been any changes in study personnel not previously reported to the IRB? Indicate the changes below and when:

PROTOCOL SUMMARY

Summary of Study: Attach current protocol with version date.

A. What is you research question (hypothesis?)

B. Describe the Design

C. What will the subjects be asked to do? What will be done to the subjects?

D. Describe the risks to the subjects:

E. Describe the potential benefits to subjects or others, if any:

PROJECT STATUS (Check all that apply)

☐ **A. Active – Open to Enrolment**

- ☐ No enrolment to date
- ☐ Participant enrolment has begun
- ☐ Specimen collection or chart review occurring

☐ **B. Active – Closed to Enrolment**

- ☐ Treatment and/or active follow-up continues
- ☐ Long term follow-up of subjects as patients (e.g., following for survival)
- ☐ Data analysis only

☐ **C. Study Closed Prior to Completion**
Do not complete this form. Please complete the Final Study Report/ Study Closure Form

☐ **D. Study Completed** (***Enrolment, treatment, data collection, follow-up, and data analysis are complete.)***
Do not complete this form. Please complete the Final Study Report/ Study Closure Form.

SPONSOR/ FUNDING SOURCE

Is this research funded at this time?	☐ **No**	☐ **Yes**	
Has the sponsor/ funding source changed since the last review?	☐ **No**	☐ **Yes**	**If YES, please attach the Sponsor/ Funding Information*

DRUG AND DEVICE STUDIES

A. Since the last continuing review, has your study site been inspected by the FDA?	☐ **No**	☐ **Yes**	
If YES, did the site receive Inspectional Observations?	☐ **No**	☐ **Yes**	**If YES, please attach a copy of Inspectional Observations and your response to FDA*
B. Is the Principal Investigator the holder of the IND or IDE?	☐ **No**	☐ **Yes**	**If YES, provide a copy of the most recent IND/ IDE report submitted to the FDA.*

ENROLLMENT

Has enrolment been lower than anticipated?	☐ **No** ☐ **Yes**	**If YES, explain the reasons for low or no enrolment and, if relevant, what steps were or will be taken to increase enrolment:**	

CUMULATIVE SUMMARY OF SUBJECTS ENROLLED TO DATE

(For studies involving record and/or specimen review only, skip and complete Section B)
(For study designs utilizing multiple consent forms, this table may be replicated).

1. Number of subjects accrued	
2. Number of subjects currently active/ on study *(For example, subjects receiving study interventions/ interactions or long-term follow-up)*	
3. Number of subjects completed *(Without events leading to early termination/ withdrawal from the study)*	
4. Number of subjects who voluntarily withdrew consent after enrolling *(For example, after signing the consent form, the subject changes his/her mind and decided not to participate or to stop participating after completing some of the study procedures)*	
Explanation	
5. Number of subjects terminated/ withdrawn from the study by the investigator due to adverse event(s) *For example, subject met toxicity drop point or experienced a serious adverse event.*	
Explanation	
6. Number of subjects terminated/ withdrawn from the study by the investigator due to other reasons *For example, non-compliance with the protocol, pregnancy, etc.*	
Explanation	
7. Number of subjects lost to follow-up	
Explanation	

8. Number of subjects who are no longer participating for reasons other than those above	
Explanation	
9. Total of item nos. 2 to 8 *(should be equal to item no. 1)*	
10. Number of subjects approved at Makati Medical Center	

RECORDS AND SPECIMENS

A. Number of specimens and/or records approved by the IRB:	

B. Did you review medical records, patient charts, radiographs or other patient information for this study?	☐ **No** ☐ **Yes**	**No. of records reviewed to date:**	
C. Did you analyze specimens (e.g., archival tissue, blood, blood products, or body fluids) for this study?	☐ **No** ☐ **Yes**	**No. of specimen analyzed to date:**	

PROGRES REPORT: (Complete all sections in sufficient detail to assess current risk/ benefit)

The primary purpose of continuing review is to re-assess the risk-benefit ratio at intervals appropriate to the degree of risk associated with the study procedures, but not less than once per year. At the time of continuing review, the IRB must ensure that the regulatory criteria for IRB approval continue to be satisfied. Please answer the following questions so that both you and the IRB can determine whether any new information has emerged, either from the research itself or from other sources that could alter the IRB's previous determinations, particularly with respect to risk to subjects.

A. Unanticipated problems

1. Since the last IRB review, have any serious, unexpected adverse events occurred that were considered related to participation in the research that have not been previously reported to the IRB?	☐ **No**	☐ **Yes**	**If YES, please attach Unanticipated Problem Report describing any previously unreported unanticipated event.*
2. Since the last IRB review, have any other unanticipated problems involving risks to subjects or others occurred, for example, medication or laboratory errors, loss or unintended disclosure of confidential information, investigator suspension or termination?	☐ **No**	☐ **Yes**	**If YES, please attach Unanticipated Problem Report describing any previously unreported unanticipated event.*

B. PROTOCOL DEVIATIONS/ VIOLATIONS

Since the last IRB review, have any protocol deviations/ violations involving risks to subjects or others occurred that have not been previously reported to the IRB?	☐ **No**	☐ **Yes**	**If YES, please attach the IRB Protocol Deviation/ Violations Report Form (Form 3.5)*

C. COMPLAINTS ABOUT THE RESEARCH

Since the last IRB review, have any subjects or others complained about the research?	☐ **No**	☐ **Yes**	**If YES, please provide a summary of the complaints and how they were resolved.*

D. PROGRESS REPORT AND INTERIM FINDINGS

1. Provide a brief general summary of the progress of the study.

2. Has there been an interim analysis or are there any interim findings to report?	☐ **No**	☐ **Yes**	**If YES, please provide results of interim analysis or a summary of any findings to date.*

E. DATA AND SAFETY MONITORING

Is this a trial subject oversight by a Data Safety and Monitoring Board (DSMB), Data Monitoring Committee (DMC), other similar body (e.g., coordinating or statistical center), or group whose responsibilities include review of adverse events and interim findings?	☐ **No**	☐ **Yes**	**If YES, indicate the type of monitoring plan below, and attach a copy of the most recent report or communication.* ☐ *DSMB/ DMC/ DSMC* ☐ *Monitor/ monitoring group* ☐ *Coordinating or statistical center*

F. OTHER INFORMATION RELEVANT

Since the last IRB review, have there been major advances, changes in standards or care, drug approvals, device recall, new black box warning, or key publications in major peer-reviewed journals which would alter the risk/ benefit assessment of this study?	☐ **No**	☐ **Yes**	**If YES, please provide a summary of relevant information. Provide the key references and interpretation/ commentary.*

G. INVESTIGATOR'S ASSESSMENT OF RISKS AND BENEFITS

1. Since the last IRB review, have the risks to subjects changed?	☐ **No**	☐ **Yes**	**If YES, please provide a summary of the changes in the risks to subjects.*
2. Since the last IRB review, has the magnitude of benefit or likelihood of benefit to subjects changed?	☐ **No**	☐ **Yes**	**If YES, please provide a summary of the changes in the anticipated benefits.*
3. Do the risks to subjects continue to be reasonable in relation to anticipated benefits, if any, to subjects and to the importance of the knowledge that may reasonably be expected to result?	☐ **No**	☐ **Yes**	**If NO, explain below.*

H. PROPOSED MODIFICATIONS/AMENDMENTS/ CHANGES TO THE RESEARCH

Are any changes to the research being proposed at this time?	☐ **No**	☐ **Yes**	**If YES, please attach the Protocol Amendment Review Form (Form 3.2) detailing proposed changes. ***

*****NB: The IRB must approve all changes to protocols and consent forms and other study documents (e.g., questionnaires, recruitment letters, advertisements, etc.) prior to implementation.***

ATTACHMENTS:
Attach the following:

- ☐ **Research Protocol**: Current dated version of the protocol (Provide highlighted or strikeout copy of any changes proposed with this continuing review submission, if applicable.)
- ☐ **Investigator Financial & Other Personal Interests Disclosure Form** for each investigator and key study personnel
- ☐ **Research Consent Forms**: Copy of most recent IRB-approved consent forms showing the IRB-approval stamp
- ☐ **Research Consent Forms**: Consent forms for re-approval without IRB-approval stamp (if changes are proposed, include one copy with proposed changes highlighted and one copy without proposed changes highlighted).
- ☐ **For multi-center trials -** Please attach any relevant multi-center reports

PRINCIPAL INVESTIGATOR'S ASSURANCES
I have followed all applicable policies and procedures of Makati Medical Center, national and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

☐ The research was performed as approved by the IRB under the direction of the Principal Investigator by appropriately trained and qualified personnel;

☐ Unanticipated problems were promptly reported to the IRB, as well as any other information necessary for appropriate oversight of the research;

☐ Research-related records (and source documents) will be maintained in a manner that documents the validity of the study and integrity of the data collected, while protecting the confidentiality of the data and privacy of participants;

☐ Study-related records will be retained and available for audit for a period of 15 years after the study has ended (or longer, according to sponsor or publication requirements) even if I leave the Makati Medical Center;

☐ IRB approval or exemption will be obtained before initiating any new research activities involving human subjects; and

☐ All co-investigators, research staff, employees, and students assisting in the conduct of the research will be informed of their obligations in meeting the above commitments.

I verify that the information provided in this Continuing Review Application is accurate and complete.

Name of the Principal Investigator	Signature	Date (MMM/DD/YYYY)

PROGRESS REPORT EVALUATION FORM (Form 3.3B)

TO THE INVESTIGATOR: *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED ON THE SPACE PROVIDED. PRINT NAME, DATE AND SIGN THIS FORM BEFORE SUBMISSION.*

Date of Submission (MMM/DD/YYYY)		**IRB Protocol Number**	
Sponsor		**Sponsor's Protocol Number**	
Principal Investigator		**Co-investigator(s)** (if any)	
Principal Investigator's Signature		**Principal Investigator's Contact No.**	
Protocol Title			
Date of Initial Approval of Protocol (MMM/DD/YYYY)			

TO THE PRINCIPAL INVESTIGATOR: *INDICATE THE LOCATION OF THE ASSESSMENT POINT (E.G. PAGE NO.) IN THE SECOND COLUMN. INDICATE **N/A** IF NOT APPLICABLE*
TO THE PRIMARY REVIEWER/ INDEPENDENT CONSULTANT: *IF YOU HAVE NO FURTHER COMMENTS, PUT A (√) MARK ON THE SPACE PROVIDED.OTHERWISE, SPECIFY THE ISSUES IN THE SPACE PROVIDED.PLEASE DO NOT USE PENCIL IN ACCOMPLISHING THIS FORM.*

ASSESSMENT POINT	***LOCATION***	**REVIEWER'S COMMENTS**	
		APPROVE/ SUFFICIENT/ NO FURTHER COMMENT **(put a check √ mark)**	FOR REVISION (specify issues)
1. The number of subjects accrued; (For multi-site studies, the number of subjects accrued at the local site and the number accrued study-wide, if available) a. Expected enrollment rate b. Actual enrollment rate c. Reason for the difference between the expected and actual enrolment rate d. Enrollment issues e. Number of subjects who withdrew f. Summary of reasons for withdrawal at local site			

2. A brief summary of any amendments to the research approved by the IRB since the IRB's initial review or the last continuing review.			
3. Any new and relevant information, published or unpublished, since the last IRB review, especially information about risks associated with the research			
4. A summary of any unanticipated problems. In many cases, such a summary could be a brief statement that there have been no unanticipated problems (i.e., adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document and Investigator's Brochure (if applicable);			
5. A summary of any subject withdrawals from the research since the last IRB review, and the reasons for withdrawal, if known;			

6. A summary of any complaints about the research from subjects enrolled at the local site since the last IRB review;			
7. The latest versions of the protocol and sample informed consent document(s) in use at the site;			
8. Any proposed modifications to the informed consent document or protocol;			
9. The current Investigator's Brochure, if any, including any modifications;			

10. Any other significant information related to subject risks, such as the most recent report, if any, from data safety monitoring board (DSMBs); (Additionally, it may be useful for sponsors to ensure that IRBs are informed when DSMBs have met, even when no problems have been identified and the DSMBs has recommended continuation of the study as designed. This information can be transmitted either by the investigator or directly by the sponsor);			
11. Aggregate information about relevant regulatory actions occurring since the last review that could affect safety and risk assessments (e.g., withdrawal or suspension from marketing in any country on the basis of safety, reports of recalls and device disposition.)			
12. Development Safety Update Report (DSUR) Executive Summary, if available.			
13. Changes in the investigator's situation or qualifications (e.g., suspension of hospital privileges, medical license, involvement in numerous clinical trials, renewal of GCP training, etc.)			

14. Changes in the acceptability of the proposed research in terms of institutional commitments (e.g., personnel and financial resources, adequacy of facilities) and regulations, applicable state and local law, or standards of professional conduct of practice.			
15. Study start data and expected duration			

TO THE PRIMARY REVIEWER/ INDEPENDENT CONSULTANT: *PUT A (✓) ON THE APPROPRIATE TICK BOX. PRINT NAME, SIGN AND DATE THIS FORM.PLEASE DO NOT USE PENCIL IN ACCOMPLISHING THIS FORM.*

Reviewer's Recommendation:

- ☐ Uphold original approval with no further action
- ☐ Approval pending
  - ☐ Request additional information
  - ☐ Recommend modification
- ☐ Recommend suspension of:
  - ☐ Enrolment of new subjects
  - ☐ Research procedures in currently enrolled subjects
  - ☐ The entire study
- ☐ Termination of approval
- ☐ Others (specify): _____ _____

Primary Reviewer's Name	Signature	Date (MMM/DD/YYYY)

TO THE PRINCIPAL INVESTIGATOR: *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PRINT, DATE AND SIGN THIS FORM BEFORE SUBMISSION.*

Date of Submission (MMM/DD/YYYY)		**IRB Protocol Number**	
Sponsor		**Sponsor's Protocol Number**	
Principal Investigator		**Co-investigator(s)** (if any)	
Principal Investigator's Signature		**Principal Investigator's Contact Number**	
Protocol Title			
Date of Initial Approval of Protocol (MMM/DD/YYYY)			
Study site(s):		**No. of Study Arms**	

A. CUMULATIVE SUMMARY OF SUBJECTS ENROLLED TO DATE

(For studies involving record and/or specimen review only, skip and complete Section B)
(For study designs utilizing multiple consent forms, this table may be replicated).

11. Number of subjects accrued	
12. Number of subjects currently active/ on study *(For example, subjects receiving study interventions/ interactions or long-term follow-up)*	
13. Number of subjects completed *(Without events leading to early termination/ withdrawal from the study)*	
14. Number of subjects who voluntarily withdrew consent after enrolling *(For example, after signing the consent form, the subject changes his/her mind and decided not to participate or to stop participating after completing some of the study procedures)*	
Explanation	
15. Number of subjects terminated/ withdrawn from the study by the investigator due to adverse event(s) *For example, subject met toxicity drop point or experienced a serious adverse event.*	

Explanation	

16. Number of subjects terminated/ withdrawn from the study by the investigator due to other reasons *For example, non-compliance with the protocol, pregnancy, etc.*	

Explanation	

17. Number of subjects lost to follow-up	

Explanation	

18. Number of subjects who are no longer participating for reasons other than those above	

Explanation	

19. Total of item nos. 2 to 8 *(should be equal to item no. 1)*	

20. Number of subjects approved at Makati Medical Center	

B. RECORDS AND SPECIMENS

D. Number of specimens and/or records approved by the IRB:	

E. Did you review medical records, patient charts, radiographs or other patient information for this study?	☐ **No** ☐ **Yes**	**No. of records reviewed to date:**	

F. Did you analyze specimens (e.g., archival tissue, blood, blood products, or body fluids) for this study?	☐ **No** ☐ **Yes**	**No. of specimen analyzed to date:**	

Duration of the Study (Date Initiated and Completed) (MMM/DD/YYYY)	

Objectives	

Summary of Results:

TO THE PRIMARY REVIEWER/ INDEPENDENT CONSULTANT: *PUT A (√) MARK ON THE APPROPRIATE TICK BOX. SPECIFY ON THE SPACE PROVIDED OTHER COMMENTS, IF APPLICABLE.*

Comments/ Recommendations of the Primary Reviewer

☐ Acknowledged

☐ Request for further information

_____ _____

☐ Recommend further action

_____ _____

☐ Others

_____ _____

Primary Reviewer's Name	Signature	Date (MMM/DD/YYYY)

Date of IRB meeting the report was presented (MMM/DD/YYYY)	

DEVIATION/ NON-COMPLIANCE/ VIOATION REPORT (Form 3.5)

TO THE PRINCIPAL INVESTIGATOR: *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PUT A (√) MARK ON THE APPROPRIATE TICK BOX. PRINT, DATE AND SIGN THIS FORM BEFORE SUBMISSION.*

Date of Submission (MMM/DD/YYYY)		**IRB Protocol Number**	
Sponsor		**Sponsor's Protocol Number**	
Principal Investigator		**Co-investigator(s)** **(if any)**	
Principal Investigator's Signature		**Principal Investigator's Contact Number**	
Protocol Title			
Reported by		**Contact Number**	

Description of Deviation/ Violation:

Action(s) Taken		**Date** (MMM/DD/YYYY)	

Nature of the Protocol Deviation/ Violation:	
☐ Principal Investigator Deviation from the protocol ☐ Participant Non Compliance ☐ Others: _	☐ Major ☐ Minor

TO THE PRIMARY REVIEWER : *PUT A (√) MARK ON THE APPROPRIATE TICK BOX. PRINT NAME, SIGN AND DATE THIS FORM.*

IRB DECISION	☐ Continue study and monitor compliance ☐ Request for further information ☐ For site visit ☐ Amend Protocol	☐ Amend Informed Consent Form ☐ Suspend the study ☐ Terminate approval of current study

Primary Reviewer's Name	Signature	Date (MMM/DD/YYYY)

Date of IRB meeting the report was presented (MMM/DD/YYYY)	

REQUEST/ QUERY RECORD (Form 3.6)

TO THE IRB SECRETARIAT: *ENCODE THE NECESSARY INFORMATION. PUT A (✓) MARK ON THE APPROPRIATE TICK BOX.*

Type of Request
☐ Fax ☐ Mailed Letter ☐ E-mail ☐ Walk-in ☐ Others:_ _

Participant's Name	
Contact Address	
Phone Number	
Title of the Participating Study	
Starting Date of Participation	
What is/are requested	
Request forwarded to	
Action Taken	
Outcome	
Date of IRB meeting the report was presented (MMM/DD/YYYY)	

IRB Chair	Signature	Date (MMM/DD/YYYY)

INSTITUTIONAL REVIEW BOARD

TO THE IRB SECRETARIAT: *ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED.*

IRB Protocol Number		**Sponsor's Protocol Number**	
Sponsor		**Co-investigator(s) (if any)**	

Principal Investigator	**Contact Number**	**Department (for residents/ fellows only)**

Protocol Title	

Total number of expected subjects:		**Total number of subjects enrolled:**	

TO BE FILLED OUT BY THE MMC IRB REPRESENTATIVE

TO THE IRB MEMBER/ REPRESENTATIVE: *PUT A (√) MARK ON THE APPROPRIATE TICK BOX.SPECIFY THE REQUIRED INFORMATION IN THE SPACE PROVIDED. PRINT NAME, SIGNATURE AND DATE IN THE SPACE PROVIDED. PLEASE DO NOT USE PENCIL IN ACCOMPLISHING THIS FORM.*

Are the site facilities appropriate?	☐ **No**	☐ **Yes**
Comment (s):		

Are the informed consents recent?	☐ **No**	☐ **Yes**
Comment (s):		

Any adverse events found?	☐ **No**	☐ **Yes**
Comment (s):		

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

Are all case record forms up to date?	☐ No	☐ Yes
Comment (s):		

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

How well are participants protected?	☐ No	☐ Yes
Comment (s):		

Any outstanding tasks or results of visit?	☐ No	☐ Yes
Comment (s):		

Date of Visit (MMM/DD/YYYY)		Duration of Visit (hours)		Time started		Time Ended	

Name of IRB Member/ Representative/ Companion	

Date of IRB meeting the report was presented (MMM/DD/YYYY)	

IRB Decision
☐ Continue study and post approval monitoring ☐ Amend the protocol ☐ Amend the Informed Consent form ☐ Stop recruitment ☐ Terminate the study ☐ Blacklist Principal Investigator/ Sponsor ☐ Recommend other corrective measures (specify): _ ☐ Others (specify): _

Completed by: (signature over printed name)		**Date** (MMM/DD/YYYY)	

Name of IRB Chair	**Signature**	**Date** (MMM/DD/YYYY)

EARLY STUDY TERMINATION (Form 3.8)

TO THE PRINCIPAL INVESTIGATOR: *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PRINT, DATE AND SIGN THIS FORM BEFORE SUBMISSION.*

Date of Submission (MMM/DD/YYYY)		**IRB Protocol Number**	
Sponsor		**Sponsor's Protocol Number**	
Principal Investigator		**Co-investigator(s)** (if any)	
Principal Investigator's Signature		**Principal Investigator's Contact Number**	
Protocol Title			
Date of Last Progress Report (MMM/DD/YYYY)		**Starting Date of Recruitment** (MMM/DD/YYYY)	
Termination Date (MMM/DD/YYYY)		**Date of Last Recruitment** (MMM/DD/YYYY)	
Target Number of Participants		**Actual Number Enrolled**	

Reason for Termination:

Actions of the Investigator on the Management of Participants still enrolled in the study after termination	☐ Informed the participants of the termination ☐ Study Drug was made available to the participants after the termination ☐ Follow up the participants who are still active in the study	☐ Others:

TO BE FILLED OUT BY IRB

TO THE PRIMARY REVIEWER: *PUT A (√) MARK ON THE APPROPRIATE TICK BOX. PRINT YOUR NAME, SIGN AND DATE THIS FORM.*

IRB Decision
☐ Approval with no further action ☐ Request additional information ☐ Request meeting with the principal investigator ☐ Others:

Primary Reviewer's Name	**Signature**	**Date** (MMM/DD/YYYY)

Date of IRB meeting the report was presented (MMM/DD/YYYY)	

EXPIRED STUDY REPORT (Form 3.9)

TO THE PRINCIPAL INVESTIGATOR: *CLEARLY TYPE ALL PORTIONS OF THIS FORM. SPECIFY YOUR ANSWER IN THE SPACE PROVIDED. PRINT, SIGN AND DATE THIS FORM.*

Date of Submission (MMM/DD/YYYY)		**IRB Protocol Number**	
Sponsor		**Sponsor's Protocol Number**	
Principal Investigator		**Co-investigator(s)** (if any)	
Protocol Title			
Date of Initial Approval of Protocol (MMM/DD/YYYY)			
Were any subjects enrolled after the expiration date?	☐ No ☐ Yes		
Were any research activities (study visits, chart reviews, data analysis using subject identifiable data, etc.) conducted after the expiration date?	☐ No ☐ Yes	**If YES, provide a description of these activities:**	

Provide an explanation why a timely Continuing Review Application (Form 3.3A) was not submitted prior to the expiration date:

Provide a corrective action plan describing how this can be prevented from occurring in the future:

Principal Investigator's Name	Signature	Date (MMM/DD/YYYY)

REQUEST FOR CLOSURE OF EXPIRED PROTOCOL (Form 3.10)

IRB approval expires automatically when continuing review of a study protocol does not occur prior to the end of the approval period specified by the IRB. Enrollment of new subjects/study related activities cannot occur after the expiration of IRB approval. In order for the IRB to determine whether they can approve your request for closure the following information is required.

TO THE PRINCIPAL INVESTIGATOR: *CLEARLY TYPE ALL PORTIONS OF THIS FORM. SPECIFY YOUR ANSWER IN THE SPACE PROVIDED. PRINT, SIGN AND DATE THIS FORM.*

Date of Submission (MMM/DD/YYYY)		**IRB Protocol Number**	
Sponsor		**Sponsor's Protocol Number**	
Principal Investigator		**Co-investigator(s)** (if any)	
Protocol Title			
Date of Initial Approval of Protocol (MMM/DD/YYYY)			
Have you been previously suspended on this or any other study?	☐ **No** ☐ **Yes**		
Were any subjects enrolled or did any research activities (study visits, chart reviews, data analysis using identifiable data, etc.) occur after the expiration date?	☐ **No** ☐ **Yes**	**If YES, provide a description of these activities:**	

Provide an explanation why a timely Request for Closure was not submitted prior to the expiration date:

Provide a corrective action plan describing how this can be prevented from occurring in the future:

Principal Investigator's Name	**Signature**	**Date** (MMM/DD/YYYY)

REQUIREMENT CHECKLIST – CONTINUING REVIEW (Form 3.11)

TO THE PRINCIPAL INVESTIGATOR: *OBTAIN AN ELECTRONIC COPY OF THIS FORM AND ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PRINT, DATE AND SIGN THIS FORM BEFORE SUBMISSION.*

Date of Submission (MMM/DD/YYYY)		**IRB Protocol Number**	
Sponsor		**Sponsor's Protocol Number**	
Principal Investigator		**Co-investigator(s)** (if any)	
Principal Investigator's Signature		**Principal Investigator's Contact Number**	
Protocol Title			
Date of Initial Approval of Protocol (MMM/DD/YYYY)			

TO THE IRB SECRETARIAT: CHECK FOR COMPLETENESS UPON SUBMISSION. INDICATE WITH (√) MARK ON THE TICK BOXES, IF APPLICABLE.

Put a check mark (√)	NO. OF COPIES		DOCUMENT SUBMITTED
	Expedited	Full Board	
			Accomplished forms:
☐	5	15	-Continuing Review Application (Form 3.3A)
☐	5	15	-Progress Report Evaluation Form, if applicable (Form 3.3B)
☐	5	15	-Final Report Form (Form 3.4)
☐	5	15	-In case the investigators wish to amend the approved protocols at the time of continuing review, submit requirements for review of amendments (Form 2.4) including any proposed modifications to the informed consent document or protocol (Form 3.2)
☐	5	15	-Expired Study Report Form (Form 3.9) for expired approval.
☐	5	15	Letter of intent with itemized documents submitted.
☐	5	15	Letter from the adviser and chairman of the Research Committee of the Department attesting that the study protocol has been **reviewed and approved** (for In-house Medical Interns, Residents and Fellows only).
☐	5	15	Copy of the latest version of the IRB-Approved protocol, informed consent forms and other documents (for progress report and expired study report) or final paper (for final report only).
☐	5	5	Current Investigator's Brochure for FDA-regulated research, if available, including modification.
☐	5	15	Any significant information related to subject risk, such as the reports of the DSMB or DMC monitoring the research, if available.
☐	1	1	All approved amendments/ revisions since the last renewal (for submission of progress/ annual report only)
☐	1	1	All previously submitted Progress Reports (for submission of progress/ annual report only)
☐	1	1	CD or DVD copy of Report, protocol and other documents attached e.g. Informed Consent, Case Report Form and Investigator's Brochure, etc.

**Note: Handwritten forms will not be accepted.*