MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

AGENDA OF THE MEETING

NOTICE OF MEETING

TO: Makati Medical Center Institutional Review Board Members

<IRB Member>	<IRB Member>
<IRB Member>	<IRB Member>
<IRB Member>	<IRB Member>
<IRB Member>	<IRB Member>
<IRB Member>	<IRB Member>

DATE OF MEETING:
TIME OF MEETING:
VENUE OF MEETING:

1. **CALL TO ORDER**
2. **DETERMINATION OF QUORUM**
3. **DISCLOSURE OF CONFLICT OF INTEREST (COI)**
4. **APPROVAL OF THE AGENDA OF THE MEETING**
5. **APPROVAL OF THE MINUTES FROM THE PREVIOUS MEETING**
6. **BUSINESS ARISING FROM THE PREVIOUS MINUTES**
7. **SUMMARY OF APPROVALS**
    - **7.1 Approvals of Full Board**
    - **7.2 Approvals of Expedited/SPARES**
    - **7.3 Approved Amendments**

8. **POST APPROVAL MONITORING**
    - **8.1 Protocol Amendments**
    - **8.2. Continuing Review**
    - **8.2.1. Safety Reports**
    - **8.2.2. Protocol Deviation**
    - **8.2.3. Site Visit Reports – NONE**
    - **8.2.4. Progress Report**
    - **8.2.5. Updates/ Notifications**
    - **8.3. Final Report - NONE**
    - **8.4. Early Study Termination - NONE**
    - **8.5. Queries or Complaints - NONE**
    - **8.6. Communications - NONE**
9. **PROTOCOL REVIEW**
    - **9.1. Initial Review**
    - **9.2. Review of Resubmitted Protocols**
10. **OTHER MATTERS**

Prepared by:

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

<IRB Admin Staff>
Administrative Staff

Approved by:

<IRB Chairman>
Chair, MMC IRB

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

Date: DD/MMM/YYYY (Tuesday)		
Venue:		
Members Present:	**Members Absent**:	**Independent Consultants:**
<IRB Member>		<Independent Consultant>
<IRB Member>		
<IRB Member>		
<IRB Member>		
<IRB Member>		
<IRB Member>		
<IRB Member>	**IRB Staff:**	**Others Present:**
<IRB Member>	<IRB Staff>	<Principal Investigator>
<IRB Member>	<IRB Staff>	
	<IRB Staff>	

1. **CALL TO ORDER**

   <IRB Chair>, called this meeting to order at pm. The Invocation was led by __.

2. **DETERMINATION OF QUORUM**

   A quorum was declared with the presence of () permanent members and, inclusive of the presence of () institutional medical members and () non-institutional non-medical members, as confirmed by the Secretariat.

3. **DISCLOSURE OF CONFLICT OF INTEREST (COI)**

   There was no disclosure of any conflict of interest.

4. **APPROVAL OF THE AGENDA OF THE MEETING**

   moved to approve the agenda of the meeting seconded by

5. **APPROVAL OF THE MINUTES OF PREVIOUS MEETING**

   moved for the approval of the modified minutes of the meeting seconded by

6. **BUSINESS ARISING FROM THE MINUTES**
7. **APPROVED PROTOCOLS**

   7.1. Full Board Review (Review of the last resubmission was expedited)

IRB Protocol No	
Protocol Title	
Principal Investigator	
Sponsor	

Primary Reviewers	
Turnaround Time	
Initial Submission	
Approval Date	
Frequency of Continuing Review	

7.2. Expedited/ SPARES

7.2.1.

IRB Protocol No	
Protocol Title	
Principal Investigator	
Sponsor	
Primary Reviewers	
Turnaround Time	
Initial Submission	
Approval Date	
Frequency of Continuing Review	

7.3. Approved Amendments

IRB Protocol No	
Protocol Title	
Principal Investigator	
Sponsor/CRO	
Primary Reviewers	
Initial Approval Date	

Submission Date of Amendment	
List of Amended Documents	

8. POST APPROVAL MONITORING

8.1. Protocol Amendments

IRB Protocol No		
Protocol Title		
Principal Investigator		
Sponsor/CRO		
Primary Reviewers		
Initial Approval Date		
Submission Date of Amendment		
List of Amendments		
Decision via email		
Decision Points	☐ **Approval** ☐ **Minor Modification**	☐ **Major Modification** ☐ **Disapproval** ☐ **Pending Decision**
Board's Decision	*/ of the amendment was recommended.*	

8.2. Continuing Review

8.2.1. Safety Report

IRB Protocol No	
Protocol Title	

Principal Investigator		
Sponsor/CRO		
Primary Reviewers		
SAE Subcommittee Members		
Initial Approval Date		
Submission Date of Report		
SAE Report		
Decision Points	☐ **Request an amendment to the protocol or the consent form** ☐ **Request further information** ☐ **Suspend or terminate the study**	☐ **Take note and continue monitoring** ☐ **Others**
Board's Decision		

8.2.2. Protocol Deviation

IRB Protocol No	
Protocol Title	
Principal Investigator	
Sponsor/CRO	
Primary Reviewers	

Initial Approval Date		
Submission Date of Report		
Deviation Reported		
Decision Points	☐ **Amend Protocol** ☐ **Amend Informed Consent Form** ☐ **Suspend the study**	☐ **Terminate approval of current study** ☐ **For site Visit** ☐ **Continue Study and Monitor Compliance** ☐ **Request for further information**
Decision via email		
Board's Decision	*/ Further information regarding the protocol deviation was requested.*	

8.2.3. Site Visit Reports

IRB Protocol No	
Date of Visit	
Protocol Title	
Principal Investigator	
Sponsor/CRO	
Primary Reviewers	
Initial Approval Date	
Name of IRB Member/Representatives and Companion	

Duration of Visit		
Decision Points	☐ **Amend Protocol** ☐ **Amend Informed Consent Form** ☐ **Suspend the study**	☐ **Terminate approval of current study** ☐ **For site Visit** ☐ **Continue Study and Monitor Compliance** ☐ **Request for further information**
Decision via email		
Board's Decision	*/ Further information regarding the site visit was requested.*	

8.2.4. Progress Report

IRB Protocol No	
Protocol Title	
Principal Investigator	
Sponsor/CRO	
Primary Reviewers	
Initial Approval Date	
Submission Date of Report	
Reason of Renewal	
Summary of Results	

Decision Points	☐ **Uphold approval with no further action** ☐ **Approval pending:** —— **Recommend additional information** —— **Recommend modification**	☐ **Recommend suspension of:** —— **Enrollment of new subjects** —— **Research procedures in currently enrolled subjects** —— **The entire study** ☐ **Termination of approval** ☐ **Others**
Board's Decision		

8.2.5. Updates/Notification

IRB Protocol No		
Protocol Title		
Principal Investigator		
Sponsor/CRO		
Primary Reviewers		
Initial Approval Date		
Submission Date of Notification		
Notification		
Decision via email		
Decision Points	☐ **Acknowledged** ☐ **Request for information**	☐ **Recommend further action** ☐ **Others**

8.3. Final Report

IRB Protocol No	
Protocol Title	

Principal Investigator		
Sponsor/CRO		
Primary Reviewers		
Initial Approval Date		
Submission Date of Final Report		
Summary of Results		
Decision via email		
Decision Points	☐ **Acknowledged** ☐ **Request for information**	☐ **Recommend further action** ☐ **Others**

8.4. Early Study Termination

IRB Protocol No		
Protocol Title		
Principal Investigator		
Sponsor/CRO		
Primary Reviewers		
Initial Approval Date		
Termination Date		
Reason for Termination		
Decision via email		
Decision Points	☐ **Approval with no further action** ☐ **Request additional information**	☐ **Request meeting with the principal investigator** ☐ **Others**

8.5. Queries or Complaints

Date Received	
Protocol Title	
Request	
Action Taken	
Outcome	

8.6. Communications

9. PROTOCOL REVIEW

9.1. Initial Review

9.1.1. –

IRB Protocol No		
Research Protocol Submission Date		
Research Protocol Title		
Principal Investigator		
Sponsor/CRO		
Primary Reviewers		
Type of Initial Review		
Conflict of Interest		
Review	Protocol Assessment: Led by medical/scientific reviewer • () permanent members and, inclusive of the presence of () institutional medical members and () non-institutional non-medical members were present during the discussion of this protocol. **Technical/Scientific Review** a. **Ethical Review** **a.** **Informed Consent Assessment Points** **a.**	
Decision Points for the Protocol	☐ **Approved** ☐ **Minor Modifications** ☐ **Major Modifications**	☐ **Disapproved** ☐ **Pending Decision**
Decision Points for the Informed Consent Form	☐ **Approved** ☐ **Minor Modifications** ☐ **Major Modifications**	☐ **Disapproved** ☐ **Pending Decision**

Board's Decision	*/ decision of the protocol was recommended. The following issues needed to be addressed among others:* ***1.*** */ of the Informed Consent Form was recommended. Risk-benefit assessment was deemed acceptable. The following issues needed to be addressed among others:* ***1.***

9.2. Review of Resubmitted Protocols

IRB Protocol No		
Research Re-submission Protocol Submission Date		
Research Protocol Title		
Principal Investigator		
Sponsor/CRO		
Primary Reviewers		
Type of Initial Review		
Conflict of Interest		
Review	Protocol Assessment: Led by medical/scientific reviewer • () permanent members and, inclusive of the presence of () institutional medical members and () non-institutional non-medical members were present during the discussion of this protocol. **Technical/Scientific Review** b. **Ethical Review** **b.** **Informed Consent Assessment Points** **b.**	
Decision Points for the Protocol	☐ **Approved** ☐ **Minor Modifications** ☐ **Major Modifications**	☐ **Disapproved** ☐ **Pending Decision**

Decision Points for the Informed Consent Form	☐ **Approved** ☐ **Minor Modifications** ☐ **Major Modifications**	☐ **Disapproved** ☐ **Pending Decision**
Board's Decision	*/ decision of the protocol was recommended. The following issues needed to be addressed among others:* ***2.*** */ of the Informed Consent Form was recommended. Risk-benefit assessment was deemed acceptable. The following issues needed to be addressed among others:* ***2.***	

10. Other Matters

10.1. Financial Report

11. Adjournment

MAKATI MEDICAL CENTER

INSTITUTIONAL REVIEW BOARD

MAKATI MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD

CONFIDENTIALITY AGREEMENT FORM FOR NON-MEMBERS REQUESTING TO ACCESS MAKATI MEDICAL CENTER IRB DOCUMENTS (Form 4.3)

TO THE REQUESTOR: *ENCODE ALL INFORMATION REQUIRED IN THE SPACE PROVIDED. PRINT NAME, SIGN AND DATE THIS FORM.*

I, (Name Surname) as a non-member of the Makati Medical Center Institutional Review Board (MMC IRB), I understand that the documents I am given access to by the IRB are confidential. I shall use the information only for the purpose indicated in this form and shall not duplicate in any form, give or distribute these documents to any person(s) without permission from the Makati Medical Center Institutional Review Board. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

Requested document(s)

Reason for the Request

Number of copies requested		**Number of copies received**	

Name of the Recipient	**Signature**	**Date** (MMM/DD/YYYY)

Name of the Member-Secretary	**Signature**	**Date** (MMM/DD/YYYY)

MAKATI MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD
Document Tracker (Form 4.4A)

IRB Protocol No.:
Protocol Title:
Principal Investigator:

Document	Submitted by	Received by/Date	Member-Secretary		Chair	Reviewers		Return to IRB	
			Sent by	Received by/Date	Date Signed	Sent by	Received by/Date	Returned by	Received by/Date

* Adapted from TQSD (Ms. K.T. Cenri), dated 11 February 2013

MAKATI MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD
Document Tracker (Form 4.4B)

IRB Protocol No.:
Protocol Title:
Principal Investigator:

INCOMING			OUTGOING		
Document	Submitted by	Received by/Date	Document	Forwarded by	Received by/Date

*Adapted from TQSD (Ms. K.T. Cano), dated 11 February 2013

FM-MMC-RB-031-REV 00

MAKATI MEDICAL CENTER
INSTITUTIONAL REVIEW BOARD

PROTOCOL INDEX (Form 4.5)

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

IRB Protocol Number	

Protocol Title	

Document Title	Date Submitted (MMM/DD/YYYY)