



LUNG CENTER OF THE PHILIPPINES

INSTITUTIONAL ETHICS REVIEW BOARD

Quezon Avenue Extension, Quezon City, Philippines 1100

4th Flr. Room 4013 Tel Nos. 9246101 local 568

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MEETING, MINUTES & AGENDA

<Date>

<Venue>

ATTENDANCE	
<i>PRESENT</i>	<i>ABSENT</i>
Member 1	Member 1
Member 2	Member 2
Member 3	
Member 4	
Member 5	
Member 6	
Member 7	
Secretariat Staff	
1	
2	

1. CALL TO ORDER

<Title, First Name, Surname>, **LCP-IERB Chair**, called this regular meeting to order at <time> **AM**.

2. DETERMINATION OF QUORUM

A quorum was declared with the presence of ___ members, inclusive of the presence of ___ Medical, ___ Non-Medical members, ___ Non-Affiliated with ___ male members.

3. DISCLOSURE OF CONFLICT OF INTEREST

<Title, Surname of LCPIERB Chair>, called for disclosure of Conflict of Interest (COI) in the Study Protocols scheduled for deliberation in the meeting. The following member/s inhibited from participation in the panel deliberations during the full board meeting for the following reasons:

<Title, Name, Surname> as **Principal Investigator** for the study entitled, "TITLE" (STUDY PROTOCOL NUMBER)

4. READING AND APPROVAL OF THE MINUTES OF THE LAST MEETING

<Title, Surname of IERB Chair> presided over the discussion of the minutes of the meeting held last <dd/mm/yyyy> (Date of last meeting). The minutes were corrected during the discussion and approved as amended.

5. APPROVAL OF THE AGENDA

6. BUSINESS ARISING FROM THE MINUTES OF THE LAST MEETING

1. Corrections in the Minutes
2. Matters requiring LCPIERB action

7. STUDY PROTOCOL REVIEW

6.1. FULL REVIEW

6.1.1. Study Protocols for Initial Review

LCPIERB Code	
Sponsor Code	
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Sponsor	
Quorum status	
Conflict of interest	
Assessment of scientific soundness	<ol style="list-style-type: none"> 1. Objectives/Expected output 2. Literature review 3. Research design 4. Sampling design, sample size 5. Inclusion criteria, exclusion criteria, withdrawal criteria 6. Specimen collection and processing 7. Statistical and data analysis plan 8. PI qualifications 9. Suitability and choice of site

Assessment of ethical issues	<ol style="list-style-type: none"> 1. Conflict of Interest: 2. Privacy and confidentiality including data protection plan 3. Vulnerability 4. Risks 5. Benefits 6. Informed consent process and recruitment: 7. Informed Consent Form (ICF) (including translation)
Conclusion and Recommendations	
Action taken	Decision (Approve <date of continuing review>, Major Modification, which require full board deliberation, Minor Modification, which can be expedited at the level of the Chair, Disapprove)
Approval expiration date (if applicable)	
Frequency of continuing review (in case of approval)	

6.1.2. Resubmissions or Study Protocols for Modification

LCPIERB Code	
Sponsor Code	
Study Protocol Resubmission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Quorum status	
Conflict of Interest	
Assessment of PI response to initial review	
Conclusion and Recommendations	
Action taken	Decision (Approve <date of continuing review>, Major Modification, which require full board deliberation, Minor Modification, which can be expedited at the level of the Chair, Disapprove)
Approval expiration date (if applicable)	
Frequency of continuing review (in case of approval)	

6.1.3. Study Protocols for Clarificatory Interview

LCPIERB Code	
Sponsor Code	
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Quorum status	
Conflict of Interest:	
Assessment of PI responses to Panel queries	
Conclusion and Recommendations	
Action taken	Decision (Decisions are based on the assessment of the PI's response to the queries.)

6.1.4. Withdrawal of Study Protocol Applications

LCPIERB Code	
Sponsor Code	
Withdrawal Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Quorum status	
Conflict of Interest:	
Assessment of reasons for Study Protocol withdrawal	
Conclusion and Recommendations	
Action taken	Decision (Approve, Request information, Recommend further action)

6.1.5. Study Protocol Amendment Applications

LCPIERB Code	
Sponsor Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Amendment Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Quorum status	
Conflict of Interest:	
Assessment of amendment requested	
Conclusion and Recommendations	
Action taken	Decision (Approve, Minor modification to the study protocol amendment, citing reasons for action, subject to expedited review at the level of the Chair, Major modification to the study protocol amendment, stating reasons for action, subject to full board review, Disapprove)

6.1.6. Continuing Review Applications

LCPIERB Code	
Sponsor Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Quorum status	
Conflict of Interest:	
Assessment of progress report	
Conclusion and Recommendations	
Action taken	Decision (Approve, Request information, Recommend further action, Disapprove)

6.1.7. Final Reports

LCPIERB Code	
Sponsor Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Quorum status	
Conflict of Interest:	
Assessment of final report	
Conclusion and Recommendations	
Action taken	Decision Points (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decisions will be made)

6.1.8. Study Protocol Non-Compliance (Deviation or Violation) Reports

LCPIERB Code	
Sponsor Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Report Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Quorum status	
Conflict of Interest:	
Assessment of Non-Compliance Report 1:	
Conclusion and recommendations	
Action taken	Decision (Noted/No further action required, Request information, Recommend further action/Corrective action required)
Assessment of Non-Compliance Report 2:	

Conclusion and Recommendations	
Action taken	Decision (Noted/No further action required, Request information, Recommend further action/Corrective action required)

6.1.9. Early Study Termination Applications

LCPIERB Code	
Sponsor Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Quorum status	
Conflict of Interest:	
Assessment of risks from early termination	
Conclusion and Recommendations	
Action taken	Decision Points (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decisions will be made)

6.1.10. Queries, Notifications, and Complaints

LCPIERB Code	
Sponsor Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Quorum status	
Conflict of Interest:	
Assessment of query or complaint	

Conclusion and Recommendations	
Action taken	Decision Points (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decisions will be made)

6.1.11. SAE and SUSAR Reports

LCPIERB Code		
Sponsor Code		
Study Protocol Approval Date	<dd/mm/yyyy>	
Report Date	<dd/mm/yyyy>	
Study Protocol Title		
Principal Investigator		
Type of Review		
Primary Reviewers		
Technical Review		
Sponsor		
Quorum status		
Conflict of Interest:		
Assessment of SAEs reported		
SAE 1	Patient Code	<dd/mm/yyyy>
	Submission Date	<dd/mm/yyyy>
	Date of SAE	<dd/mm/yyyy>
	Date of randomization	
	Age/ Sex	
	Nature of SAE	
	Seriousness of SAE	
	Relation to Study/Drugs/ Device	
	Outcome	
Conclusion and Recommendations		
Action taken	Decision Points (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decisions will be made)	
SAE 2	Patient Code	<dd/mm/yyyy>
	Submission Date	<dd/mm/yyyy>
	Date of SAE	<dd/mm/yyyy>
	Date of randomization	
	Age/ Sex	
	Nature of SAE	
	Seriousness of SAE	

	Relation to Study/Drugs/ Device	
	Outcome	
Conclusion and Recommendations		
Action taken	Decision Points (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decisions will be made)	

6.1.12. Site Visit Reports

LCPIERB Code	
Sponsor Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Site Visit Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Quorum status	
Conflict of Interest:	
Assessment of Site Visit Report	
Conclusion and Recommendations	
Action taken	Decision Points (No further action required, Request information, Recommend further action/Corrective action)

6.2. REPORT OF PROTOCOL SUBMISSIONS FOR EXPEDITED REVIEW AND FULL BOARD PROTOCOLS WITH MODIFICATIONs EXPEDITED AT THE LEVEL OF THE CHAIR

6.2.1. Approved Protocols (New Protocols)

LCPIERB Code	
Sponsor Code	
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	

Primary Reviewers	
Technical Review	
Sponsor	
Study Protocol Approval Date	<dd/mm/yyyy>

6.2.2. Study Protocols for Initial Review

LCPIERB Code	
Sponsor Code	
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Action taken	Decision (Approve, Major Modification, which require full board deliberation, Minor Modification, which can be expedited at the level of the Chair, Disapprove)

6.2.3. Resubmissions (study protocols for minor modification)

LCPIERB Code	
Sponsor Code	
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Action taken	Decision (Approval, Minor modification, Major modification, Disapprove)

6.2.4. Study Protocol Amendments

LCPIERB Code	
Sponsor Code	
Study Protocol Approval Date	<dd/mm/yyyy>

Date of Amendment Submission	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Action taken	Decision (Approve, Minor modification to the study protocol amendment, citing reasons for action, subject to expedited review at the level of the Chair, Major modification to the study protocol amendment, stating reasons for action, subject to full board review, Disapprove)

6.2.5. Continuing Review Applications

LCPIERB Code	
Sponsor Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Date of Report	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Action taken	Decision Points (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decisions will be made)

6.2.6. Final Reports

LCPIERB Code	
Sponsor Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Date of Report	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	

Technical Review	
Sponsor	
Action taken	Decision Points (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decisions will be made)

6.2.7. Study Protocol Non-Compliance (Deviation or Violation) Reports

LCPIERB Code	
Sponsor Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Date of Report	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Action taken	Decision Points (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decisions will be made)

6.2.8. Early Study Termination Applications

LCPIERB Code	
Sponsor Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Action taken	Decision Points (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decisions will be made)

6.2.9. Queries, Notifications, and Complaints

LCPIERB Code	
Sponsor Code	
Study Protocol Approval Date	<dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Sponsor	
Action taken	Decision Points (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decisions will be made)

7. OTHER MATTERS

8. ADJOURNMENT

Prepared by	Approved by
Secretariat Staff <i>(Signature over Printed Name)</i>	Chairman, LCP-IERB <i>(Signature over Printed Name)</i>
Date:	Date: