中華崇仁總醫院暨醫學中心
CHINESE GENERAL HOSPITAL AND MEDICAL CENTER
EXCEPTIONAL CARE WITHIN REACH

Department of Medical Education and Research
RESEARCH ETHICS REVIEW BOARD (RERB)
Contact#: 8711-4141 local 418 and 481
Email Address: cghmc.irb@gmail.com

NOTIFICATION OF RERB DECISION

Date: 18 August 2025

VICTORIA ELENA B. CHAN, M.D.
DEPARTMENT OF SURGERY (FELLOW)

This is to inform you of the RERB decision related to your application for review of the following documents:

CGHMC RERB Protocol No.	CGHMC RERB 2025-F-36	Sponsor Protocol No.	None; investigator-initiated

Type of Submission
- ☑ **Initial review of Documents submitted**
- ☐ Resubmission
- ☐ Amendment
- ☐ Others

Principal Investigator/s	Dr. Victoria Elena B. Chan	Sponsor	None; investigator-initiated
Title	The Incidence, Clinicopathologic Characteristics, and Outcomes of Ductal Carcinoma In Situ: A Retrospective Study in a Tertiary Institution in Metro Manila, Philippines		
Protocol Version No.	V 1.0	Version Date	
ICF Version No.	N/A	Version Date	
Other Documents			

Type of review
- ☑ **Expedited**
- ☐ Full Board Meeting

RERB Decision
- ☐ Approved
- ☑ **Minor revisions required**
- ☐ Major revisions required
- ☐ More information needed
- ☐ Others

RERB Chair Person	Name	Signature	Date
	BERNICE ONG-DELA CRUZ, M.D.		

Actions required from PI:

1. If you're primary objective is just "To describe the clinic pathologic characteristics of patients diagnosed with DCIS", won't your study be a descriptive study and not an analytical study?
2. No Null and Alternative Hypothesis
3. Why exclude core needle biopsy with DCIS?
4. There is no dummy table for data collection (the one that you will be using in Excel for data analysis), please include. Is the Standardized Data Abstraction Form the same as the Data Collection Form? If not, please include it in your appendix.
5. How long will you be following up the patient? This should be standardized for all of your subjects as to prevent bias.
6. Ensure waiver letter is signed.
7. Don't use initials as identifier for the data collection form, as this can be used to identify the patient's data, thus defeating the purpose of data confidentiality/privacy.

Kindly resubmit revised protocol for review.

The Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB) functions in full compliance with national/local and international human research ethical guidelines including the principles of ICH Harmonized Tripartite Guidelines for Good Clinical Practice.

Received by:
Name and Signature: _____ Date Received: _____

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NOTIFICATION OF RERB DECISION

Date: 22 August 2025

MARY ANGELI GRACE TIENZO, M.D.
DEPARTMENT OF MEDICINE (RESIDENT)

This is to inform you of the RERB decision related to your application for review of the following documents:

CGHMC RERB Protocol No.	CGHMC RERB-2025-R-37	Sponsor Protocol No.	None; investigator-initiated

Type of Submission
- ☑ **Initial review of Documents submitted**
- ☐ Resubmission
- ☐ Amendment
- ☐ Others

Principal Investigator/s	Dr. Mary Angeli Grace Tienzo	Sponsor	None; investigator-initiated
Title	Monocyte Distribution Width (Mdw) As A Predictor Of Clinical Outcomes Among Urosepsis Patients In A Philippine Tertiary Private Hospital		
Protocol Version No.	V 1.0	Version Date	
ICF Version No.	N/A	Version Date	
Other Documents			

Type of review
- ☑ **Expedited**
- ☐ Full Board Meeting

RERB Decision
- ☐ Approved
- ☑ **Minor revisions required**
- ☐ Major revisions required
- ☐ More information needed
- ☐ Others

RERB Chair Person	Name	Signature	Date
	BERNICE ONG-DELA CRUZ, M.D.		

Actions required from PI:

8. May I ask why zero in urosepis? Higher MDW is associated with sepsis in general, how to differentiate what particular infection is it associated to.
9. Latest CBC results only have RDW included, where can we get the MDW?
10. Re inclusion and exclusion criteria, since you will use sepsis-3 criteria to assess, we have to make sure all the lab parameters are included, meaning there is bilirubin fio2/ PaO2 as well; exclusion criteria compels you to read the chart from start to end to make sure patient has no hematologic disease/ malignacy. What about previous antibiotic use? Will the CBC at ER be your basis? or it can also be patient who came in as direct admissions (CBC in the ward)
11. Regarding the dummy table: if you are to focus on urosepis, you should also include proteus mirabilis, s haemolyticus, etc. will patient who did not have blood/urine culture be excluded as well?

Kindly resubmit revised protocol for review.

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Name and Signature: _____ Date Received: _____

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NOTIFICATION OF RERB DECISION

Date: 22 August 2025

AILENE GUEVARRA, M.D.
DEPARTMENT OF MEDICINE (RESIDENT)

This is to inform you of the RERB decision related to your application for review of the following documents:

CGHMC RERB Protocol No.	CGHMC RERB 2025-R-44	Sponsor Protocol No.	None; investigator-initiated

Type of Submission
- ☑ **Initial review of Documents submitted**
- ☐ Resubmission
- ☐ Amendment
- ☐ Others

Principal Investigator/s	Dr. Ailene Guevarra	Sponsor	None; investigator-initiated
Title	Comparative Evaluation of Modified PASS and BISAP in Stratification of Prognosis in Acute Pancreatitis in a Tertiary Hospital: A Retrospective Cohort Study		
Protocol Version No.	V 1.0	Version Date	
ICF Version No.	N/A	Version Date	
Other Documents			

Type of review
- ☑ **Expedited**
- ☐ Full Board Meeting

RERB Decision
- ☐ Approved
- ☑ **Minor revisions required**
- ☐ Major revisions required
- ☐ More information needed
- ☐ Others

RERB Chair Person	Name	Signature	Date
	BERNICE ONG-DELA CRUZ, M.D.		

Actions required from PI:

1. There is no null and alternative hypothesis
2. Include the in-house mortality and complications developed during hospital stay in your dummy table (It is only seen in your data extraction form). These were included in your objectives and is an important basis for your endpoint in determining the severity of acute pancreatitis. Thus it is important to be presented clearly in your study. I would suggest to include also patient's stay in intensive care unit (ICU).
3. In the Data Extraction Form, remove date of admission and date of discharge, as these dates can be used to trace patient identity. Length of hospital stay will suffice.

Kindly resubmit revised protocol for review.

The Chinese General Hospital and Medical Center Research Ethics Review Board (CGHMC RERB) functions in full compliance with national/local and international human research ethical guidelines including the principles of ICH Harmonized Tripartite Guidelines for Good Clinical Practice.

Received by:
Name and Signature: _____ Date Received: _____