

No. 445/2020

Certificate of Ethical Approval

Name	of	Ethics	Committee:	Research	Ethics	Committee	No.4
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Faculty of Medicine, Chiang Mai University

Address of Ethics Committee: 110 Intavaroros Rd., Amphoe Muang, Chiang Mai, Thailand

50200

Principal Investigator: Muangloei Rungoutok, M.D.

Department of Obstetrics and Gynecology, Faculty of Medicine, Chiang Mai University.

Protocol title: A Sixteen Period Oncology and Fertility Outcome after Fertility Sparing

Treatment of Malignant Ovarian Germ Cell Tumor.

STUDY CODE: OBG-2563-07736

Research ID: 7736

Sponsor: -

Documents approved	Document reference		
Research protocol	Version date 21 December 2020		
Case report form - Case report form	Version 1 date 9 November 2020		
Supplementary documents reviewed Principal Investigator Curriculum vitae - Muangloei Rungoutok,M.D. Co-Investigator Curriculum vitae -Assoc.Prof.Prapaporn Suprasert,M.D.	Version date 9 November 2020 Version date 9 November 2020		

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[1	/] By expedited review			
[]	By full committee review	Committee No	meeting no.	Date

Date of Approval: December 2020 Expiration Date: December 2021

Progress report required every 1 year



This Ethics Committee is organized and operates according to GCPs and relevant international ethical guidelines, the applicable laws and regulations.

Signed

(Emeritus Professor Panja Kulapongs, M.D.)

Chairman of REC, Faculty of Medicine, CMU

POSTAPPROVAL REQUIREMENT:

- Investigator must renew approval by submission of progress report for REC continuing review about one month prior to the expiration date if the research is to be continued.
- Prior Research Ethics Committee approval is required before implementing any changes in the consent documents or protocol unless (a) these changes are necessary for the safely of subjects, (b) minor changes such as logistical or administrative aspects of the trial (e.g., change of monitor(s), telephone number(s)).
- Any event or new information that adversely affect the safety of the subject or conduct of the trial must be reported to the REC promptly.
- Any protocol deviation/violation/noncompliance must be reported to the REC.
- All adverse drug reactions (ADRs) that are both serious and unexpected must be reported to the REC promptly as stated in Faculty of Medicine Notice..