



<b>NAME OF ETHICS COMMITTEE/IRB</b> Medical Research Ethics Committee, University Malaya Medical Centre	<b>MREC ID NO:</b> 2016111-4483
<b>ADDRESS :</b> LEMBAH PANTAI, 59100 KUALA LUMPUR, MALAYSIA	<b>NMRR.ID :</b> NMRR-17-311-34752
<b>PROTOCOL NO</b> (if applicable) :	
<b>TITLE:</b> Effect of opioid sparing protocol on the oxygen desaturation index among undiagnosed high risk-OSA patients undergoing surgery	
<b>PRINCIPAL INVESTIGATOR :</b> Dr Lai Hou Yee	<b>SPONSOR</b> -

The following item [✓] have been received and reviewed in connection with the above study to conducted by the above investigator.

[✓] Application to Conduct Research Project(form)	Ver.No :	Ver.Date : 02-02-2017
[✓] Study Protocol	Ver.No : 2	Ver.Date : 02-02-2017
[✓] Patient Information Sheet	Ver.No : 1	Ver.Date : 24-12-2016
[✓] Consent Form	Ver.No : 1	Ver.Date : 28-12-2016
[ ] Questionnaire	Ver.No :	Ver.Date :
Investigator's CV / GCP ( Dr Lai Hou Yee, CHAW SOOK HUI, LEE PUI KUAN, INA		
[✓] ISMIARTI BINTI SHARIFFUDDIN, WANG CHEW YIN, CHONG SHU JUEN, CHIN KIM HONG, Frances Chung, )	Ver.No :	Ver.Date :
[ ] Insurance certificate	Ver.No :	Ver.Date :
[✓] Other documents		
1) Effect of opioid sparing protocol on the oxygen desaturation index among undiagnosed high risk-OSA patients undergoing surgery	Ver.No : 1	Ver.Date : 24-12-2016

and the decision is [✓]

- [✓] Approved (Full Board)  
[ ] Approved (Expedited)  
[ ] Rejected(reasons specified below or in accompanying letter)

Comments:

Modified satisfactorily

*The Investigators are required to:*

- 1) follow instructions, guidelines and requirements of the Medical Research Ethics Committee.
- 2) report any protocol deviations/violations to Medical Research Ethics Committee.
- 3) provide annual and closure report to the Medical Research Ethics Committee.
- 4) comply with International Conference on Harmonization – Guidelines for Good Clinical Practice (ICH-GCP) and Declaration of Helsinki.
- 5) obtain a permission from the Director of UMMC to start research that involves recruitment of UMMC patient.
- 6) ensure that if the research is sponsored, the usage of consumable items and laboratory tests from UMMC services are not charged in the patient's hospital bills but are borne by research grant.
- 7) note that he/she can appeal to the Chairman of Medical Research Ethics Committee for studies that are rejected.
- 8) note that Medical Research Ethics Committee may audit the approved study.
- 9) ensure that the study does not take precedence over the safety of subjects.

Date of meeting : 18-01-2017