

**Annexure – Thesis Protocol Approval (TPA)**

LHRC/MD/NBE/12/2022-7

December 21, 2022

The Executive Director  
National Board of Examinations in Medical Sciences  
Medical Enclave, Ansari Nagar, Mahatma Gandhi Marg  
(Ring Road), New Delhi – 110029.

**Subject : Thesis Protocol Approval Letter**

Sir,

This is for your kind information that the research proposal/Thesis protocol of the below given DNB candidate has been considered and reviewed by the Institutional Ethics Committee (IEC) in its meeting held on 28.04.2022.

S.No.	Name of DNB Candidate	Specialty	Session	Roll No.	Thesis Topic Title
1.	Dr Riya Tom	Anaesthesiology	January 2021 session	2166067681	"A prospective observational study on the efficacy and hemodynamic effects of 0.75% Ropivacaine with Fentanyl and 0.5% Bupivacaine with Fentanyl for spinal anaesthesia in Endourological procedures".

The IEC which reviewed the proposal is duly registered with the Department of Health Research (DHR), Ministry of Health & Family Welfare, Government of India. The authenticated copies of composition of the IEC is enclosed herewith. The IEC has approved conducting the study on above listed research proposal of DNB candidate for the purpose of writing her DNB thesis.

It is further certified that the proposed research protocol has not been/shall not be submitted elsewhere for any degree, fellowship or any other titles for recognition. The minutes of aforesaid meetings of IEC are available with the hospital and can be reproduced before NBEMS, if so required, at any point of time.

  
Dr H Ramesh  
Director, Medical Services



  
S-K Abdulla  
Managing Director

Encl : Composition of Institutional Ethics Committee (IEC)

**ECR/120/Lakeshore/Inst/KL/2013/Re-Registration-2019**

Government of India  
Directorate General of Health Services  
Central Drugs Standard Control Organization  
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,  
New Delhi - 110 002, India  
Dated:

To

11 MAR 2022

The Chairman  
Lakeshore Ethics Committee  
Lakeshore Hospital and Research Centre Limited  
XVII/612, NH 47 By Pass Nettoor P.O, Maradu  
Kochi, Ernakulam, Kerala - 682040 India

**Subject:** Ethics Committee Re-registration No. **ECR/115/Inst/Ker/2013/RR-19**, amendment to the composition of the Ethics Committee-regarding.

Sir/Madam,

Please refer to your application submitted to this Directorate for change in composition of the Re-registered Ethics Committee.

Based on the documents submitted by you, the composition of your Ethics Committee bearing Re-registration number **ECR/115/Inst/Ker/2013/RR-19** dated **04.09.2019** valid until **19.04.2024** is hereby amended as follows, with all conditions of the Registration Certificate initially granted to you, remaining the same including the condition that "the Ethics Committee shall review and accord approval to Clinical Trial and BA/BE Study protocol of new drugs and also conduct periodic review of the studies as per the New Drugs and Clinical Trial Rules, 2019".

Sr. No.	Name of member	Qualification	Role/Designation in Ethics Committee
1.	Dr. Sujit Vasudevan	MBBS, MD (General Medicine)	Chairman
2.	Dr. H Ramesh	MBBS, M.Ch (Surgery)	Member Secretary
3.	Dr. Vivek Mathew	MBBS, MD, DM (Endocrinology)	Clinician
4.	Dr. V P Gangadharan	MBBS, MD, DM (Oncology)	Clinician
5.	Dr. Abraham Koshy	MBBS, MD, DM (Gastroenterology)	Clinician
6.	Dr. Susan Mani	MBBS, MD (Pharmacology)	Medical Scientist
7.	Mr. Sunder Rajagopal	MBA	Lay Person
8.	Adv. Rekha Vasudevan	LLB	Legal Expert
9.	Fr. Antony Madavanakad	B.Ph, B.Th, Master of Science	Social Scientist

Yours faithfully

(Dr. V. G. Somani)  
Central Licensing Authority





## LAKESHORE RESEARCH & ADMINISTRATIVE COMMITTEE

Lakeshore Hospital & Research Centre Ltd

NH-47 By-pass, Maradu, Nettoor P.O., Kochi - 682040, Kerala, India. Te : 91-484-2701032/2701033  
Fax : 0484-2701996. E-mail : ethicscommittee@lakeshorehospital.org Web : www.lakeshorehospital.com

Mr. S.K Abdulla  
Chairman

Dr. Abraham Koshy  
Member

Dr. V.P. Gangadharan  
Member

Dr. H Ramesh  
Member

Dr. Mohan A. Mathew  
Member

Dr. Lazar J Chandy  
Member

I.HRC/LARC/04/16/22

April 19, 2022

Dr Mallie Abraham  
Principal Investigator  
Sr. Consultant, Dept. of Anaesthesia and Critical Care  
Lakeshore Hospital & Research Centre Ltd,  
Maradu, Nettoor P.O., Kochi - 682040.

Ref: Thesis Protocol of Dr Riya Tom, DNB Resident, Dept. of  
Anaesthesia and Critical Care, Lakeshore Hospital & Research  
Centre Ltd, Kochi.

**Thesis Title :** "A prospective observational study on the efficacy and  
hemodynamic effects of 0.75% Ropivacaine with Fentanyl and 0.5%  
Bupivacaine with Fentanyl for spinal anaesthesia in Endourological  
procedures".

### Sub : Research Committee Approval

Dear Dr. Mallie Abraham,

We have received the Thesis Protocol of Dr. Riya Tom, DNB Resident, Dept. of  
Anaesthesia and Critical Care submitted for Lakeshore Administrative and  
Research Committee's consideration and approval.

Thesis protocol submitted by Dr. Riya Tom, vide her letter dated 14.04.2022 has  
been reviewed and discussed during the Virtual meeting of Lakeshore Lakeshore  
Administrative and Research Committee held on 19.04.2022. After due  
consideration the Committee has decided to approve the conduct of the study  
under your guidance.

The Research Committee notes that this study is for the purpose of DNB  
Anaesthesia thesis only. Hence it does not have involvement of any external  
agency/sponsor and is purely an in-house study.

We approve the assessments as specified in the study and also the protocol.

Yours sincerely,

S K Abdulla  
Chairman,  
Lakeshore Administrative & Research Committee





## LAKESHORE ETHICS COMMITTEE

Lakeshore Hospital & Research Centre Ltd  
Maradu, Nettoor P.O., Kochi - 682040, Kerala, India. Tel : 91-484-2701032/2701033  
Fax : 0484-2701996. E-mail : [ethicscommittee@lakeshorehospital.org](mailto:ethicscommittee@lakeshorehospital.org)  
Web : [www.vpslakeshorehospital.com](http://www.vpslakeshorehospital.com)

LHRC/EC-2022-1/16

April 28, 2022

**Dr. Sujit Vasudevan**  
Chairman (Clinician)

**Dr. H Ramesh**  
Member Secretary

**Rev. Fr. Antony Madavanakadu**  
Member (Theologian)

**Adv. Rekha Vasudevan**  
Member (Legal Expert)

**Dr. Susan Mani**  
Member (Pharmacologist)

**Mr. Sunder Rajagopal**  
Member (Lay Person)

**Dr. Abraham Koshy**  
Member (Clinician)

**Dr. V.P. Gangadharan**  
Member (Clinician)

**Dr. Vivek Mathew**  
Member (Clinician)

**Dr Mallie Abraham**  
Principal Investigator  
Sr. Consultant, Dept. of Anaesthesia and Critical Care  
Lakeshore Hospital & Research Centre Ltd,  
Maradu, Nettoor P.O., Kochi - 682040.

**Ref: Thesis Protocol of Dr Riya Tom, DNB Resident, Dept. of Anaesthesia and Critical Care, Lakeshore Hospital & Research Centre Ltd, Kochi.**

**Thesis Title :** "A prospective observational study on the efficacy and hemodynamic effects of 0.75% Ropivacaine with Fentanyl and 0.5% Bupivacaine with Fentanyl for spinal anaesthesia in Endourological procedures".

**Sub : Ethics Committee Approval**

Dear Dr. Mallie Abraham,

We have received the Thesis Protocol of Dr. Riya Tom, DNB Resident, Dept. of Anaesthesia and Critical Care submitted for Ethics Committee's consideration and approval.

Thesis protocol submitted by Dr. Riya Tom, vide her letter dated 21.04.2022 has been reviewed and discussed during the Virtual meeting of Lakeshore Ethics Committee held on 28.04.2022. After due consideration the Committee has decided to approve the conduct of the study under your guidance.

Please inform us in case of any Serious Adverse Event is observed during the conduct of the study. You are required to submit thesis progress report once in six months and final thesis for Ethics Committee's review before submission to National Board. The Ethics Committee notes that this study is only for the purpose of DNB Anaesthesia thesis of Dr. Riya Tom. Hence it does not have involvement of any external agency/sponsor and is purely an in-house study.

We approve the assessments as specified in the study and also the protocol.

Yours sincerely,

**Dr. H. Ramesh**  
Member Secretary, Lakeshore Ethics Committee



*Note : As per the requirements of the ICMR 2017 the Ethics committee approval is furnished in*