

University Level Ethics Committee
Standard Operating Procedures
University of Kerala

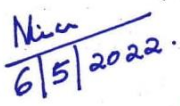
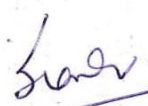
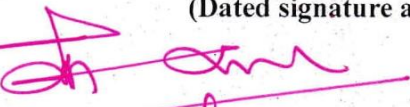
Application File Number: -EC/NEW/INST/2022/2586 (Department of Health Research, Ministry of Health & Family Welfare, Government of India)

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In Accordance with: NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS

Effective Date: January 2022 to December 2031

Distribution: Members of University Level Ethics Committee, University of Kerala

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University Level Ethics Committee

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University Level Ethics Committee

Chapter 1

Writing, Reviewing, Distributing and Amending Standard Operating Procedures for University Level Ethics Committee

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| PURPOSE: | <p>The purpose of this Standard Operating Procedure (SOP) is to define the process for writing, reviewing, distributing and amending SOPs of the University Level Ethics Committee (ULEC). The SOPs provide clear, unambiguous instructions so that the related activities of the committee are conducted in accordance with Indian regulations and relevant, national and international ethical guidelines.</p> <p>Detailed, written instructions, in a certain format, describe all activities and actions undertaken by an organization to achieve uniformity in the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify the organization and documentation of operation, whilst maintaining high standards of Good Clinical Practice and Good Community Interventions and to scrutinize the proposed projects of university departments and affiliated colleges, University of Kerala</p> |
| SCOPE | <p>This SOP covers the procedures of writing, reviewing, distributing and amending SOPs within the ULEC.</p> |
| RESPONSIBILITY | <p>It is the responsibility of the ULEC to appoint the SOP Team to prepare, draft or edit the SOP of the ULEC.</p> <p>Member Secretary/ SOP Team: Preparation of Draft SOP</p> <p>Chairperson: Reviews and approves the SOPs</p> |
| DETAILED INSTRUCTIONS | <p>The draft SOP will be discussed in ULEC meeting</p> <p>The approved SOPs will be implemented from the effective date.</p> <p>The approved SOPs will be distributed to the EC members, relevant staff members and principal investigators.</p> |

University Level Ethics Committee

Chapter 2

Constituting an Ethics Committee

The University Level Ethics Committee, University of Kerala is constituted by The Vice Chancellor

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| PURPOSE | <p>The University Level Ethics Committee is established in order to formalize and specify the Institution's commitment to promotion of high ethical standards in patient care, professional education, clinical research, and community interests.</p> <p>All Research involving human subjects shall be conducted in accordance with ethical principles, which includes,</p> <ul style="list-style-type: none">● Autonomy● Justice● Beneficence● Nonmaleficence● Fidelity● Privacy● Voluntarism● Informed Consent● Confidentiality● Risk minimization● Professional competence |
| SCOPE | <p>The SOP applies to the functioning of all activities under the University Level Ethics Committee. This includes the basic responsibilities of the ULEC, composition, appointment of the members and conduct of the meeting.</p> |
| RESPONSIBILITY | <p>To ensure the competent review and evaluation of all ethical aspects of research projects received to ensure compliance with the appropriate laws and safeguard welfare of study participants.</p> <p>Initiate ethics education and training programs to ensure that ULEC members are qualified to perform their specific roles and responsibilities.</p> |
| DETAILED INSTRUCTIONS | <p>The University Level Ethics Committee has applied for provisional registration with the National Ethics Committee Registry for Biomedical and</p> |

University Level Ethics Committee

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| | <p>Health Research (NECRBHR) with Application File Number: - EC/NEW/INST/2022/2586.</p> <p>All research proposals involving human participants will be reviewed by ULEC with a view to safeguarding the dignity, rights, safety and wellbeing of all participants, actual and potential. The ULEC may refer to its SOPs and Guidelines in order to review all ethical aspects of projects received by it in an objective manner.</p> <ul style="list-style-type: none">• ULEC will review the project proposals (basic research, clinical trials, socio- behavioural or operational studies), which are conducted at the Institute.• ULEC is to ensure a competent review of all ethical and scientific aspects of the project proposals received by it in an objective manner. |
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University Level Ethics Committee

The Composition of the University Level Ethics Committee

| No | Name | Position on ULEC | Designation and Ethics Affiliation | Qualification |
|----|----------------------------|---|---|-------------------------------|
| 1 | Dr. Srikantan S. | Chair Person Clinician (Dual Role) | Professor & Head, Clinical Medicine, Government Medical College, Kollam | MD in General Medicine |
| 2 | Dr Mini S. | Member Secretary Basic Medical Scientist (Dual Role) | Professor Department of Biochemistry, University of Kerala | Ph.D. |
| 3 | Dr. Prasad G. | Scientific Member | Professor and Head Department of Zoology, University of Kerala | Ph.D. in Marine Sciences |
| 4 | Dr. Jeena Badhar | Clinician | Resident Medical Officer University of Kerala | MBBS |
| 5 | Dr. Bushra Beegom R. K. | Social Scientist | Assistant Professor Department of Sociology, University of Kerala | Ph.D. |
| 6 | Dr. Lekshmi R. | Social Scientist | Associate Professor Department of Philosophy, University of Kerala | Ph.D. |
| 7 | Dr. Sindhu Thulaseedharan | Legal Expert | Associate Professor & Head Department of Law, University of Kerala | Ph.D. in Law |
| 8 | Mr. Sasidharan Nair K | Legal Expert | Vice-Chairman, Kerala Law Reforms Commission | LLB |
| 9 | Dr. Rajan J. | Member | Professor (Retd.) IMK, University of Kerala | Ph.D. in Financial Management |
| 10 | Mr. Harishchandran Nair K. | Lay Person | Self Employed | SSLC |
| 11 | Ms. Anjali S. L. | Other Supporting Staff | University Assistant University of Kerala | M.Com. |
| 12 | Ms. Sheeja P. | Other Supporting Staff | University Assistant University of Kerala | B.A. |
| 13 | Ms. Smitha J. S. | Other Supporting Staff | Section Officer University of Kerala | B.Sc. |