



Sri Devaraj Urs Academy of Higher Education & Research
Comprising Sri Devaraj Urs Medical College
(A Deemed to be University)
Research and Development Cell

Central Ethics Committee Re-registered under CDSCO -Registration No. ECR/425/Inst/KA/2013/RR-20 dated 28.4.2020

No. SDUAHER/ KLR/ ADMN/ R & D Cell/277/ 2024=25

18.06.2024

Minutes of the Central Ethical Committee meeting held on 10th June 2024 at 11.00 AM
Venue: Academic Council Hall, SDUAHER

The following members were present for the meeting:

1.	Prof. Dr. S.R Prasad Former Professor & Head, Dept. of Microbiology, SDUMC	Chairman
2.	Dr. Bhuvana K Professor, Dept. of Pharmacology, SDUMC	Basic Medical Scientist
3.	Dr. Vaishnavi B.V Assistant Professor, Dept. of Dermatology, SDUMC	Clinician
4.	Mr. N.G. Vasudev Moorthy Advocate, Kolar	Legal expert
5.	Shri. Swami Dattapadanandaji Chinmaya Mission Institution, Kolar	Social Scientist
6.	Mrs. Veena S Karanjikatte, Kolar	Lay person
7.	Dr. Azeem Mohiyuddin S.M Professor & HoD, Dept. of Otolaryngology, SDUMC	CEC Member
8.	Dr. Arvind Natarajan Professor & HoD, Dept. of Microbiology, SDUMC	CEC Member
9.	Dr. Prabhavathi K Professor & HoD, Dept. of Biochemistry, SDUMC	Basic Medical Scientist
10.	Dr. Madhavi Reddy M Professor, Dept. of Clinical Nutrition & Dietetics, SDUAHER	CEC Member
11.	Dr. Venkateswarlu Raavi Assistant Professor, Dept. of Cell Biology & Molecular Genetics, SDUAHER	CEC Member
12.	Ms. Apoorva H.M Assistant Professor, Dept. of Speech Pathology & Audiology, SDUAHER	CEC Member
13.	Dr. Pradeep Mitra V Assistant Professor, Dept. of Pathology, SDUMC	R & D cell, core committee member
14.	Ms. Saniksha Assistant Professor, Dept. of Physiotherapy, SDUAHER	R & D cell, core committee member
15.	Dr. Shilpa M D Associate Professor, Dept. of Pathology, SDUMC	R & D cell, core committee member
16.	Dr. Shashidhar K Associate Professor, Dept. of Anatomy, SDUMC	R & D cell, core committee member
17.	Dr. Kalyani R Director, Research and Development Cell, SDUAHER Professor of Pathology, SDUMC	Member Secretary, CEC

Members of the scientific committee:

1.	Dr. Shivkumar C S (Special invitee) Assistant Professor and I/c HOD Dept. of Clinical Nutrition and Dietetics, SDUAHER	Member Secretary, Scientific committee, FAH & BS
2.	Dr. Vishwas A (Special invitee) Assistant Professor, Dept. of Community Medicine, SDUMC	Member Secretary, Student research committee, SDUMC

Member who could not attend the meeting:

1.	Dr. Ashwini K Shetty Professor, Dept. of Physiology, SDUMC	CEC Member
2.	Dr. Satishbabu P Post doctoral Research Fellow, Dept. of Cell Biology & Molecular Genetics, SDUAHER	R & D cell, core committee member



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3.	Dr. Sujatha M P (Special invitee) Professor, Dept. of Anesthesiology, SDUMC	Member Secretary, Scientific committee, SDUMC
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➤ **Welcome:**

- Dr. Kalyani R, the member secretary of CEC welcomed the chairperson, external members, internal members and the principal investigators of the to be funded projects for the meeting.

➤ **Address by the chairperson:**

- The chairperson, Dr. S R Prasad informed the members about the following aspects:
 - The research proposals and their progress should be maintained at the R & D cell for a minimum of 3 years after the completion of the project and Ph.D proposals as long as Ph.D scholars are there in the institute.
 - The HOD's name should be clearly mentioned in the research proposal's cover letter/checklist/application, wherever applicable.
 - The CEC reviewers should also mention their names
 - As per the principle of professional competence (ICMR guidelines for Biomedical and Health Research), the CEC should ensure that the reviewer is competent in reviewing the given research proposal.
 - The soft copies of the funded research proposals should be sent to the chairperson and the committee members 10 days prior to the meeting.

➤ **Action taken report of the previous CEC meeting held on 9th May 2024:**

- Dr. Kalyani R briefed on the projects reviewed in the last meeting and the number of projects approved/ waiting for approval as below:

S. No	Research project proposals	No of projects submitted	No of projects approved	Remaining
1.	SDUMC Faculty projects - Funded	03	01	02
	SDUMC Faculty projects – Non Funded	08	01	07
2.	SDUMC PG dissertation projects	-	53 (old)	0
3.	SDUMC PG projects	06	04	02
4.	SDUMC UG projects	03	02	01
5.	F AH & BS projects – Funded	04 (2 faculty; 2 Ph.D)	02 (Ph.D)	02
6.	F AH & BS projects – non-funded	03 (2 faculty; 1 PG)	01	02
	Total	27	11 + 53	16

- A total of 27 new project proposals were received in the last meeting out of which 11 proposals were approved as there were no ethical issues.
- It was informed that a total of 64 projects (11 + 53 PG dissertations) were approved in the previous meeting.
- It was further informed that the remaining 16 projects were sent back to the respective scientific committees for minor revisions.



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➤ Research proposals received by CEC in May 2024:

- Dr. Kalyani R briefed regarding the projects submitted in May 2024 as below:

S. No	Research project proposals	No of the projects submitted		
		New (May 2024)	Revised (April 2024)	Revised (March 2024)
1.	SDUMC Faculty projects - Funded	05	02	-
2.	SDUMC Faculty projects – Non-Funded	07	05	01
3.	SDUMC PG projects	24	02	-
4.	SDUMC UG projects	01	00	-
5.	F AH & BS projects - Faculty	05	04	05
6.	F AH & BS projects - UG	08	00	-
Total		50	13	06

- Dr Kalyani R informed that 50 new proposals were received in May 2024 from SDUMC (faculty, PG and UG) and FAH & BS (Faculty and UG) along with 13 revised proposals of April month and 6 revised proposals of March month.
- Dr. Kalyani R informed that the 50 proposals will be discussed in today's meeting and asked Ms. H M Apoorva to brief on the status of the revised proposals received.
- Ms. H M Apoorva informed that the revised proposals were again sent to the same CEC reviewer who suggested the corrections earlier. It was further informed that the respective reviewers have approved the revisions for 11 out of 13 projects of April month and all 6 projects of March month. The chairperson and the CEC members decided to send the 2 revised proposals of faculty, SDUMC for re-submission as the PIs did not incorporate the corrections suggested.
- After reviewing the modified proposals and the corrections made, the chairperson and the CEC members agreed to approve 11 revised proposals of April month and 6 revised proposals of March month.

➤ Agenda 1: To issue the ethical clearance for the start of study for faculty projects from SDUMC (Funded -5; Non-funded - 7)

- Ms. Apoorva H M briefed that there were 5 faculty projects from SDUMC requesting for funding as mentioned in the below table.
- Ms. Apoorva H M requested the PIs of the funded project to give a brief presentation with the permission of the chairperson.
- The PIs presented their proposal before the committee, the CEC committee gave the following suggestions which need to be addressed before considering for the approval by the CEC.:

S. No.	Title	Investigators	Suggestions from CEC
1	"Comparison of the outcome of cataract surgery using different pupil expanders in eyes with small pupil"	Dr. Chaitra M C Dr. Harshitha C Dr. Manjula T R Dr. Athira	<ul style="list-style-type: none">• Dr. S R Prasad asked the committee to get the proposal reviewed by a competent ophthalmologist• Dr Bhuvana suggested to get safety studies for new devices• Dr. Kalyani asked the PI to discuss with CTC (clinical trial centre)



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2	"Clinical evaluation of an extended depth of focus intraocular lens in cataract surgery"	Dr. Apoorva N Dr. Rashmi G Dr. Alisha Elizabeth Alex	<ul style="list-style-type: none"> • Dr. S R Prasad asked to look into the essentiality of the project • Dr. S R Prasad asked the committee to get the proposal reviewed by a competent ophthalmologist • Dr. Kalyani R asked to raise a proper research question and re-submit
3	"A study to compare effectiveness of Preoperative use of Bromfenac and Nepafenac Eye Drops in Maintaining Mydriasis during small incision cataract surgery in comparison with duration of surgery"	Dr. Asam Naveena Dr. Inchara N Dr. J. Megha Varnika DR.G. Bhavishya	<ul style="list-style-type: none"> • Dr. S R Prasad asked the committee to look into the essentiality of the project • Dr. Bhuvana asked to include information on who is concealing the drugs to be administered • Dr. Bhuvana informed that already a similar study conducted in 2011. On that note, Dr S R Prasad asked to justify the novelty of the research question • Dr. Kalyani asked to make appropriate corrections and re-submit
4	"Comparison of Posterior capsular opacification in patients implanted with aspheric monofocal square-edged and biconvex non-square-edged intraocular lenses in manual small-incision cataract surgery"	Dr. Athira K Dr. Usha B R Dr. Shwetha S Vernekar Dr. Yeddula Venkata Rohith Reddy Dr. Nakka Rachana	<ul style="list-style-type: none"> • Dr. S R Prasad asked the committee to look into the essentiality of the project • Dr Bhuvana suggested that the study evaluates opacification after implantation of two types of lenses namely aspheric monofocal square edged and biconvex non-square edged. The opacification is established with monofocal lens and using this type of lens in one arm is not justifiable ethically. So, she suggested to conduct single arm study using only biconvex lens. • Dr. Kalyani R asked the PI to change the title and methods accordingly and re-submit to scientific committee
5	"Comparison of effect of combination therapy with intravitreal injection of Ranibizumab and Photocoagulation versus Pan Retinal Photocoagulation in Severe Non-Proliferative Diabetic retinopathy and proliferative Diabetic Retinopathy with or without Macular edema"	Dr. Narendra B S Dr. Inchara N Dr. Sangeetha T Dr. Posina Sri Satviki	<ul style="list-style-type: none"> • Dr. S R Prasad asked the PI not to use abbreviations • Dr. Bhuvana suggested to add an objective on drug safety • Dr. Prasad questioned having one eye as control and the other as test eye. It was suggested to consider control eye and test eye from two different patients • Dr. S R Prasad mentioned that the essentiality of the proposal is justified. • Dr. Kalyani asked to make appropriate corrections and re-submit for approval

- Ms. H M Apoorva also presented the list of 7 non-funded research proposals to the committee as below:



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S. No.	Title of the project	Principal Investigator	CEC reviewer
1	"Staphylococcus aureus bacteremia and its antibiogram in a tertiary care hospital in Kolar"	Ms. Repati Gowri	Dr. Venkateswarlu Raavi
2	"Comparative analysis of the antibiogram of Klebsiella pneumoniae isolated from clinical samples in different clinical areas in a multispecialty Hospital, in South India"	Dr. Namitha B N	Dr. Venkateswarlu Raavi
3	"Effect of mediation as an Adjuvant Therapy in Chronic Kidney Disease (CKD)-A Pilot study"	Dr. Shobhana Nayak Rao1	Ms. H M Apoorva
4	"Assessment of Burden of Disease and Health-Related Quality of Life in Chronic Kidney Disease Patients on Maintenance Hemodialysis"	Dr. Shobhana Nayak Rao (Corresponding Author)	Dr. Madhavi Reddy M
5	A comparative study of morphometric and histological changes of placenta and umbilical cord in preeclampsia and normotensive pregnant women with and without periodontitis	Dr. Poulomi Banik	Dr. Madhavi Reddy M
6	A Double-blinded RCT Study of Topical 2 % Tofacitinib Versus Clobetasol Propionate 0.05% in the Treatment of Localised Alopecia Areta- A Pilot Study	Dr. Rajashekar T S	Ms. H,M. Apoorva.
7	"Eyeing Victory with 5 FU: Ocular surface squamous neoplasia- A Case report"	Dr. Chaitra M C	Ms. H M Apoorva

- Ms. H M Apoorva read the suggestions given by the respective CEC reviewer for each research proposal mentioned in the above table.
- The chairperson advised to get the CEC review by a competent subject expert (Ex: proposal No. 1 and 2 by a microbiologist; 3 and 4 by a physician and 6 by a Dermatologist).
- Dr. Kalyani R stated that the proposals have already been reviewed by the scientific committee, and the CEC reviewers have only checked for ethical concerns. The chairperson highlighted the importance of considering the subject specialty of the CEC reviewer when commenting on ethical aspects as well, in accordance with the principle of competence.
- Dr. Kalyani R acknowledged and informed that the necessary measures will be taken henceforth.
- The chairperson and the members agreed to provide approval for the 7th proposal which was a case report.

➤ **Agenda 2: To issue ethical clearance for the start of study for post-graduate student project proposals of SDUMC**



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- Dr. Vaishnavi BV mentioned that there were 10 new proposals, 9 proposals for publication and 5 proposals for change of guide/title making it a total of 24 submissions for postgraduate students of SDUMC.
- Dr. Vaishnavi BV presented the concerns raised by each CEC reviewer for the below mentioned 10 proposals.
- Dr. Bhuvana asked Dr Vaishnavi to mention the CTRI registration wherever is required.
- The Chairperson suggested that the respective Principal Investigators be notified to integrate corrections/suggestions before granting ethical clearance.
- The details of the 10 new proposals are as follows

S. No.	Title of the project (new proposals)	Principal Investigator	CEC reviewer
1	"Questionnaire-Based Study on Post Anaesthesia Visits in a Tertiary Hospital"	Dr. Katta Dinesh Chandra Reddy	Dr. Bhuvana. K
2	"Evaluation of Risk Factors Associated with Post-operative Uveitis after Cataract Surgery"	Dr. Nakkana Rachana	Dr. Bhuvana. K
3	"Maternal and fetal neonatal outcome of Dengue virus infection during pregnancy at RLJH.	Dr. Mulakala Samyukthanjali ,	Dr. Prabhavathi. K
4	"Uterine Scar Dehiscence in previous cesarean section and their fetomaternal outcome at tertiary care center"	Dr. Kandregula Meghana Sai	Dr. Prabhavathi. K
5	"Cryotherapy with intralesional steroids Versus intralesional pentoxifylline in the treatment of Recalcitrant Alopecia Areata: A Randomized Control Trial"	Dr. Anajana G	Dr. Ashwini K Shetty
6	"Topical 0.5% Bakuchiol VS Facial Exercises in improving the signs of facial ageing: A Randomised Control Trial"	Dr. Hariharasubramaniam	Dr. Ashwini K Shetty
7	"Study of chronic kidney disease-mineral bone disease in hemodialysis patients "	Dr. Athish K K	Mrs. Apoorva. H.M
8	"Association of serum magnesium level with and without retinopathy in type-2 Diabetes mellitus"	Dr. Reddy Hari Priya Vani Vineela	Mrs. Apoorva. H.M
9	Assessment of Local Anesthetic Proficiency among Non-Anesthesiology Resident Doctors Procedures in South India	Dr. Akhil Kumar	Dr. Venkateswarlu Raavi
10	"A Revisit to endolymphatic duct identification using middle cranial fossa dural plate -A Novel Method "	Dr. Gautham	Dr. Venkateswarlu Raavi

- Dr. Vaishnavi BV informed the members that there were 9 proposals requesting ethical clearance for publication as shown in the table below.



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- Dr. Kalyani R mentioned that these proposals received ethical clearance for start of study before the re-notification CEC. She added that at present, once the start of the study is obtained, the same certificate holds good for conference presentation and publication and that the PIs submit for conference presentation/ publication only if there is a change in author number or order.
- The chairperson Dr. S R Prasad asked Dr. Kalyani R to check for the same and do the needful for the approval of the same.

S. No.	Title of the project (for publication)	Principal Investigator	CEC reviewer
1	Ocular Sequelae following snake bite envenomation	Dr. Susmitha Joshy	Dr. Vaishnavi B V
2	Nephrogenic ascites: A case Series with review of literature	Dr. Shobhana Nayak Rao	Dr. Vaishnavi B V
3	Unmasking Negative Pressure Pulmonary Edema Following Hanging	Dr. Athish K.K	Dr. Madhavi Reddy. R
4	Unusual cause of persistent painless hematuria	Dr. Shobhana Nayak Rao	Dr. Madhavi Reddy. R
5	Peripartum Cardiomyopathy and its Obstetric outcome	Dr. Lakshmi Nalla	Dr. Arvind Natarajan
6	Histologically aggressive breast cancer in a young woman	Dr. M. Sushma	Dr. Arvind Natarajan
7	A case report on retinal toxicity from ectoparasiticide exposure or coincidental?	Dr. Devi Sinduja S	Dr. Bhuvana. K
8	Granulosa Cell Tumor-Right Adnexal Mass: A rare Case	Dr. Radhika SR	Dr. Ashwini K Shetty
9	Triple to double trouble a rare case report of fetal reduction of triplets to twin pregnancy	Dr. Radhika SR	Dr. Prabhavathi. K

- Dr. Vaishnavi BV informed the members that there were 5 proposals requesting ethical clearance for change of guide/ title as shown in the table below.
- The chairperson Dr. S R Prasad asked Dr. Kalyani R to check and do the needful for the approval of the same.

S. No.	Title of the project (change of guide/title)	Principal Investigator
1	Immunohistochemical expression of MDM2 in Invasive Ductal carcinoma of breast and its association with histopathological parameters and hormonal status	Dr. Damarasingu V
2	Programmed death ligand -1 and MUTL Homolog-1 expression in colorectal cancer and its association with clinicopathological parameters	Dr. A Queen
3	The association between body mass index and abnormal Uterine bleeding in perimenopausal women - An analytical study	Dr. Madhurya Nagesh
4	A comparative study on the effect of topical mitomycin-C and Normal Saline on Granulation Tissue in Tracheostomised patients	Dr. Sreelekshmy
5	Study of outcome of sepsis in Culture – Positive Neonates – A Retrospective	Dr. Gurrarn Kamalakar

➤ **Agenda 3: To issue ethical clearance for undergraduate research projects of SDUMC**



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- Dr. Shilpa M D presented one project proposal submitted by UG student of SDUMC as mentioned below:

S. No.	Title of the project	Principal Investigator	CEC reviewer
1	Knowledge, Perception and attitude of medical students and pharmacists towards generic medicines: A cross-sectional study.	Mr. Harsh Sharma UG Student	Ms. Apoorva H.M

- The Chairperson and the committee members agreed to approve the above-mentioned student research proposal.

➤ Agenda 4: To issue ethical clearance for the proposals received from faculty and students of FAH & BS (5 - faculty; 8 - UG)

- Dr. Shashidhar K mentioned that there were 5 proposals received from F AH & BS and 8 proposals from students of BPT as mentioned in the below table. He also mentioned that all 13 proposals were non-funded.

S. No.	Title of the project	Principal Investigator	CEC reviewer
1	Development, Validation and Pilot Testing of a standard Yoga Module for Chronic Kidney	Dr. Ashween Bilagi	Dr. Madhavi Reddy. M
2	Genetic Disorders associated with hemoglobinopathy, a possible underlying cause for anemia a pilot study.	Dr. Kiranmayee. P	Dr. Madhavi Reddy. M
3	Effectiveness of Reflex Integration Approach of ATNT in Child with Developmental Delay- A Case Study	Mr. Naveen Kumar I	Dr. Prabhavathi. K
4	Enhancing Upper Extremity Function Post Craniotomy Hemiplegic Patient: A Comprehensive Motor Relearning and Suspension Therapy Approach – A Case Study	Mr. Naveen Kumar I	Dr. Prabhavathi. K
5	Development of Interprofessional Ethics Module for Healthcare Students	Dr. Sarulatha H	Dr. Bhuvana. K
6	Relationship between Physical Activity and Spinal Curvatures using Kyphosis Index among Young Adults: A Cross-Sectional Study	Ms. Maria Paul (BPT)	Dr. Bhuvana. K
7	Correlation between core strength and change of direction of speed among amateur football players: A cross-sectional study	Mr. Abhishek L (BPT)	Dr. Vaishnavi
8	Investigating the agreement of health-related physical fitness assessment via telehealth with in-person assessment among adults: An observational study	Ms. Deepika R (BPT)	Dr. Vaishnavi
9	A Survey of Physiotherapy Student's Experiences and Attitudes Towards Treating Individuals with Mental Illness in India.	Ms. Prithvi J Chodankar (BPT)	Dr. Venkateswarlu Raavi
10	Physical Activity Prevalence among Patients Undergoing Primary Cancer Therapies	Ms. Sama Afsar (BPT)	Dr. Venkateswarlu Raavi
11	Evaluating Knowledge and Adherence to	Ms. Chaithra R	Dr. Ashwini K



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	Osteoarthritis Clinical Practice Guidelines among Indian Physiotherapists: A Cross-Sectional Study	(BPT)	Shetty
12	Peak Rate Pressure Product in Healthy individuals: An Observational Study	Ms. Priyanka K S (BPT)	Ms. Apoorva. HM
13	Resting Heart Rate in Health Individuals. An Observational Study	Ms. Lavanya Shree G (BPT)	Dr. Venkateswaralu Raavi

- Dr. Shashidhar K presented the concerns raised by each CEC reviewer of the above-mentioned proposals.
- The Chairperson and the members opined that Ethical approval may be issued to those proposals that qualify for clearance.

➤ General instructions to various scientific committees:

Dr. Kalyani R provided some general instructions to the member secretaries of the scientific committee as below:

- a) CEC format to be adhered to - Application format and Checklist formats will be mailed to all departments again.
- b) Projects from PGs and faculty of SDUMC to be segregated and sent to CEC (separate list for PG projects and faculty projects).
- c) CEC is not liaising with the departments directly. Submissions and revisions should happen through their respective scientific committees only.
- d) All the research proposals to reach CEC only between 25th -28th of every month. (If late, will be considered for the next month)
- e) ICMR STS for intramural funds – SOP need to be drafted by Dr. Viswas A and get it approved by the Registrar, SDUAHER.
- f) Funded project documents need to be maintained in CEC office; Non funded projects need to be maintained at the respective scientific committees.

➤ Vote of thanks by the Member Secretary

- Dr. Kalyani R delivered the vote of thanks by thanking the Chairperson of the committee Dr. S R Prasad and all the external members for their gracious presence and valuable inputs.
- She also thanked all the internal members for the time and effort taken in reviewing the research proposals and for their active participation during the meeting.
- Further, Dr. Kalyani R thanked the supporting staff Ms. Suma and Mr. Chalapathi for all their contribution to the conduct of this meeting.

Prepared by:

Ms. HM Apoorva

CEC member

Member

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Verified by:

Dr. Venkateswarlu

Raavi

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Member

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Reviewed by:

Dr. Kalyani R

Member Secretary.

Prof. Dr. Kalyani. R.

Member Secretary

Central Ethics Committee

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Approved by:

Dr. S R Prasad

Chairperson

Prof. Dr. S. R. Prasad

Chairman

Central Ethics Committee

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