



VELS



INSTITUTE OF SCIENCE, TECHNOLOGY & ADVANCED STUDIES (VISTAS)

(Deemed to be University Estd. u/s 3 of the UGC Act, 1956)

PALLAVARAM - CHENNAI

ACCREDITED BY **NAAC** WITH '**A**' GRADE

INSTITUTION WITH **UGC 12B** STATUS

*Marching Beyond **30** Years Successfully*

CRITERION 7 - INSTITUTIONAL VALUES AND BEST PRACTICES

7.1. INSTITUTIONAL VALUES AND SOCIAL RESPONSIBILITIES

7.1.10. THE INSTITUTION HAS A PRESCRIBED CODE OF CONDUCT FOR STUDENTS, TEACHERS, ADMINISTRATORS AND OTHER STAFF AND CONDUCTS PERIODIC PROGRAMMES IN THIS REGARD.

Criterion Number	7
Metric	7.1.10
Details	Supporting Documents for Institutional ethics committee
Pages	1 to 20

Campus : Velan Nagar, P.V. Vaithiyalingam Road, Pallavaram, Chennai - 600 117. INDIA.

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ECR/1644/VELS/Indt/TN/2017/Re-Registration-2021

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

The Chairman**VISTAS-SPS-IEC****School of Pharmaceutical Sciences, VISTAS,****Velan Nagar, P V Vaithyalingam Road Pallavaram,****Chennai, Kanchipuram, Tamil Nadu – 600117, India.**

20 JAN 2023

Subject: Ethics Committee Registration No. **ECR/288/Indt/TN/2018/RR-21**, amendment to the composition of the Ethics Committee—regarding.**Sir/Madam,**

Please refer to your application dated 07.01.2023 submitted to this Directorate vide no. P-2972148 dated 12.01.2023 for change in composition of the Re-Registered Ethics Committee.

Based on the documents submitted by you, the composition of your Ethics Committee bearing Registration number **ECR/288/Indt/TN/2018/RR-21** dated **01.06.2021** valid until **31.05.2026** 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. Melvin George	MBBS, MD (Pharmacology)	Chairperson
2.	Dr. A. Vijayalakshmi	M.Pharm (Pharmacognosy), PhD	Member Secretary
3.	Dr. Naresh Kumar Krishnamurthy	MBBS, MS (Ortho)	Clinician
4.	Dr. Deepa Gurunathan	MDS, PhD	Clinician
5.	Dr. A. Maduram	MBBS, MD (Pharmacology)	Medical Scientist
6.	Mrs. Selin Semila Rani	MA (English)	Lay Person
7.	Dr. Dilshad Shaik	LLM, PhD	Legal Expert
8.	Dr. V. Karthikeyan	LLM	Legal Expert
9.	Mr. Bijukumar K Gopinathan	BBA, Hons. Doctorate in Social Work	Social Scientist
10.	Dr. Paul Ravikumar B	MTh, DD.	Social Scientist
11.	Dr. C. Ronald Darwin	M.Pharm (Pharmacology), PhD	Scientific Member

ECR/1644/VELS/Indt/TN/2017/Re-Registration-2021

12.	Dr. A. Kathiresan	M.Sc (Microbiology), PhD	Scientific Member
13.	Dr. B. Prem Kumar	M.Pharm (Pharmacology), PhD	Scientific Member
14.	Dr. R.J. Hemalatha	ME (Biomedical), PhD	Scientific Member

Yours faithfully



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



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

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 01-Jun-2021

To

The Chairman
VISTAS-SPS-IEC
School Of Pharmaceutical Sciences, VISTAS
Velan Nagar, P V Vaithyalingam Road Pallavaram
Pallavaram Kanchipuram Tamil Nadu - 600117 India

Subject: Ethics Committee Re-Registration No. ECR/288/Indt/TN/2018/RR-21 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/RENEW/IND/2021/11516 dated 12-Apr-2021 submitted to this Directorate for the Re-Registration of Ethics Committee.

Please find enclosed registration of your Independent Ethics Committee in Form CT-02 vide Registration No. ECR/288/Indt/TN/2018/RR-21. The said registration is subject to the conditions as mentioned below:-

Yours faithfully

VENUGOPAL
GIRDHARILA
L SOMANI

Digitally signed by VENUGOPAL
GIRDHARILA SOMANI
DN: c=IN, o=MINISTRY OF HOME
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(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

Conditions of Registration

1. The registration is valid from 01-Jun-2021 to 31-May-2026, unless suspended or cancelled by the Central Licencing Authority.
2. This certificate is issued to you on the basis of declaration/submission made by you.
3. Composition of the said Ethics Committee is as per the Annexure.
4. No clinical trial or bioavailability or bioequivalence protocol and related documents shall be reviewed by an Ethics Committee in meeting unless at least five of its members as detailed below are present in the meeting, namely:-
 - (i) medical scientist (preferably a pharmacologist);
 - (ii) clinician;
 - (iii) legal expert;
 - (iv) social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person;
 - (v) lay person.

5. The Ethics Committee shall have a minimum of seven and maximum of fifteen members from medical, non-medical, scientific and non-scientific areas with at least,
 - (i) one lay person;
 - (ii) one woman member;n
 - (iii) one legal expert;
 - (iv) one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.
6. One member of the Ethics Committee who is not affiliated with the institute or organization shall be the Chairperson, and shall be appointed by such institute or organization and one member who is affiliated with the institute or organization shall be appointed as Member Secretary of the Ethics Committee by such Institute or organization.
7. The Ethics Committee shall consist of at least fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted.
8. The committee shall include at least one member whose primary area of interest or specialisation is non-scientific and at least one member who is independent of the institution.
9. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.
10. Members should be conversant with the provisions of New Drug and Clinical Trials Rules, 2019, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.
11. The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialization, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.
12. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.
13. The Ethics Committee may associate such experts who are not its members, in its deliberations but such experts shall not have voting rights, if any
14. No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the Clinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no conflict of interest.
15. While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson. The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.
16. Any change in the membership or the constitution of the registered Ethics Committee shall be intimated inwriting to the Central Licencing Authority within thirty working days.
17. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7: provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be: provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site.
18. Where a Bioavailability or Bioequivalence study centre does not have its own Ethics Committee,bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the protocol from the Ethics Committee registered under rule 8:Provided that the approving Ethics Committee shall in such case be responsible for the study at the centre:Provided further that both the approving Ethics Committee and the centre, shall be located within the same city or within a radius of 50 kms of the

bioavailability or bioequivalence study centre.

19. The Ethics Committee shall review and accord approval to a Clinical trial, Bioavailability and Bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause (B) of Table 1 of the Third Schedule of New Drugs and Clinical Trials Rules, 2019 and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules, Good Clinical Practices Guidelines and other applicable regulations.

20. Ethics committee should review such number of protocols of Clinical trials, Bioavailability and Bioequivalence study protocols which should commensurate to the infrastructure and facilities available with them.

21. Ethics committee shall indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licencing Authority.

22. Ethics committee shall make, at appropriate intervals, an on-going review of the trials for which they have reviewed the protocol. Such a review may be based on the periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites.

23. Status report of the functioning of the Ethics committee should be submitted to the CDSCO headquarters and concerned zonal office on quarterly basis.

24. Where any serious adverse event occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee shall analyse the relevant documents pertaining to such event and forward its report to the Central Licencing Authority and comply with the provisions of Chapter VI, New Drugs and Clinical Trials Rules, 2019.

25. The Ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts wherever required, for deciding relatedness and quantum of compensation, as per condition no (24) mentioned above.

26. Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the Ethics committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licencing Authority.

27. Ethics committee shall comply with the requirements or conditions in addition to the requirements specified under the Drugs & Cosmetics Act, 1940 and New Drugs and Clinical Trials Rues, 2019, as may be specified by the Central Licencing Authority with the approval of the Central Government, to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.

28. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial.

29. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial.

30. Ethics committee should have dedicated office with required infrastructure and supporting staff.

31. Funding mechanism for the Ethics Committee to support their operations should be designed and approved to ensure that the committee and their members have no financial incentive to approve or reject particular study.

32. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.

33. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained.

34. The Ethics Committee shall allow any officer authorized by the Central Licencing Authority to enter, with

or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects.

35. Where Central Licencing Authority is of the opinion that Ethics Committee fails to comply with any provision of the Drugs and Cosmetics Act, 1940 and New Drugs & Clinical Trials Rules, 2019, it may issue show cause notice to such Ethics Committee specifying therein such non-compliances and the period within which reply shall be furnished by such Ethics Committee. After consideration of the facts and reply given by the Ethics Committee, the Central Licencing Authority may take one or more actions specified under provision of Rule 14, Chapter III of New Drugs and Clinical Trials Rules, 2019.

Copy to:- Concerned zonal office of CDSCO





File No. EC/21/000130
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 01-Jun-2021

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Dr. M THAMILARASAN	BA-Sociology (MA - Sociology)	Social Scientist
2	Mr. S ASHOK KUMAR	LLB (Master of Laws (LL.M.))	Legal Expert
3	Dr. R GEETHA	MBBS (MD-Pharmacology)	Medical Scientist
4	Mr. M SEKAR BABU	M.Pharm (Not Applicable)	Scientific Member
5	Ms. R UMA MAHESWARI	12th (Not Applicable)	Lay Person
6	Dr. T.N UMA MAHESWARI	BDS (Ph.D)	Clinician
7	Dr. M VIJEY AANANDHI	M.Pharm (Ph.D)	Member Secretary
8	Dr. V MOHAN RAM	MBBS (Ph.D)	Clinician
9	Dr. S SATHESH KUMAR	M.Pharm (Ph.D)	Scientific Member
10	Dr. D PRAVEEN	Pharm.D (Ph.D)	Scientific Member
11	Dr. R SANGEETHA	BSc (Ph.D)	Scientific Member
12	Dr. J ANBU	M.Pharm (Ph.D)	Chair Person
13	Mr. J DAVID GNANA PRAKASAM	Bachelor in Theology (BD)	Social Scientist

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
DN: cn=VENUGOPAL GIRDHARILAL SOMANI, o=CDSCO, ou=Directorate General of Health Services, email=VENUGOPAL.GIRDHARILAL.SOMANI@cdco.gov.in, c=IN
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(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority


REGISTRAR
VELS INSTITUTE OF SCIENCE, TECHNOLOGY
& ADVANCED STUDIES (VISTAS)
Velan Nagar, P.V. Vaithiyalingam Road,
Pallavaram, Chennai - 600 117.



VISTAS SPS IEC

Registration number ECR/288/Indt/TN/2018/RR-21

Minutes of Meeting

Institutional Ethical Committee (IEC) meeting held on 06.04.2023 (Thursday) in CARD Conference Hall, Vels Institute of Science Technology and Advanced Studies, Pallavaram, Chennai-600117, Tamilnadu at 9.00 AM onwards.

Members Present

1. Dr. Melvin George - Chairperson
2. Dr. A. Vijayalakshmi - Member Secretary
3. Dr. A. Maduram - Medical Scientist
4. Dr. Naresh kumar Krishnamurthy - Clinician
5. Dr. Dilshad Shaik - Legal Expert – External
6. Dr. V. Karthikeyan - Legal Expert – Internal
7. Dr. B. Prem Kumar - Scientific Member-External
8. Dr. C. Ronald Darwin - Scientific Member-Internal
9. Dr.A. Kathiresan - Scientific Member-Internal
10. Dr. R. J. Hemalatha - Scientific Member-Internal
11. Mr. Bijukumar K Gopinathan - Social Scientist
12. Dr. Paul Ravikumar B - Social Scientist
13. Mrs. Selin Semila Rani – Lay Person

Following protocols were presented before IEC members with recommendation against each member.

S.No	Name of the Principal Investigator	Title	Remarks
1	Mr. M. Immanuel Jebastine Research Scholar	Tolerability and efficacy of Lacosamide and Levetiracetam monotherapy in patients diagnosed with epilepsy for the first time and concomitant psychiatric conditions	Approved
2	Ms. Jayasree. S Research Scholar	A study to find out the effectiveness of Barre & Conventional Core Training Programs along with Meridian Exercises	Approved

		on Women's Health with Primary Dysmenorrhea - A RCT study	
3	Ms. S. Chelsea Jennifer Monica, II Yr M.Pharm (Practice) Student	A prospective study in types of hypersensitivity reaction occurring in tertiary care hospital	Approved
4	Mr. Suriya R II Yr M.Pharm (Practice) Student	A prospective study on complications of proton pump inhibitors utilization among patients in tertiary care hospital	Approved
5	Mr. Sathish G II Yr M.Pharm (Practice), Student	A prospective study on adverse drug reaction of antibiotic in a tertiary care hospital in Chennai	Approved
6	Mr. A.Riyaz khan II Yr M.Pharm (Practice), Student	Effectiveness of alpha lipoic acid in type 2 diabetes mellitus patients with cardiac autonomic neuropathy	Approved
7	Ms. Priyanka Kumari II Yr M.Pharm (Practice) Student	A prospective observational clinical study of medication error in different wards with multiple prescription in tertiary care hospital	Approved
8	Ms. J. Punitha II Yr M.Pharm (Practice) Student	A Prospective study on Prevalence of Antibiotic Resistance in Tertiary care hospital	Approved
9	Mr. Gowthaman.V II Yr M.Pharm (Practice) Student	Assessment of adverse drug reaction in cancer patients in tertiary care hospital	Approved
10	Mr. Praveen Kumar E II Yr M.Pharm (Practice) Student	Assessment of microbial profile and antimicrobial susceptibility pattern of pathogens isolated from lower respiratory tract infectious patients	Approved
11	Ms. Priyanka M, II Yr M.Sc (Microbiology) Student	A Study on the predominant vaginal bacterial flora of women with fertility problems	Approved
12	Ms. A. Fhamitha Saara , Mr. K.Gopal, Mr. S.Karthick, Ms. A.Nitharshana Ashi, VI Yr Pharm.D	A comparison of the efficacy of Glimpiride plus Metformin versus Teneligliptin plus Metformin therapy in	Approved

	Student	patients with type 2 diabetes mellitus	
13	Mr. Abdul Aziz. A, Ms. Abhinaya. N, Mr. Abinash. M, Ms. Aishwarya. B, VI Yr Pharm. D Student	Assessment of combined pharmacotherapies and behavioral interventions for alcohol withdrawal syndrome- An open observational study	Approved
14	Ms. A. Sowndaryavalli, Mr. R. Subash chandrabose, Ms. J. Sujana, VI Yr Pharm.D Student	A prospective study on prevalence, risk factors and recommendations on post operative activities of hernia	Approved
15	Mr. G.Sanjay, Mr. K. Selva Kumar, Mr. H.Shaikh Jassim, Ms. A. Shivani, VI Yr Pharm. D Student.	To compare the outcome of patients with urinary tract infection based on the clinical and microbiological profile in tertiary care hospitals	Approved
16	Ms R. Uma Maheswari Mr. C.P. Yogavigneshwaran, Mr. G.B Biju, VI Yr Pharm. D Student	An Interpretation of Polypharmacy and Prescription Pattern in Geriatric patients: A Prospective Observational Study	Approved
17	Mr. B.T. Udhaya Moorthi, Mr. S. Mukesh, Mr. S.Vignesh, Mr. V. Sivashankar, V Yr Pharm.D Student	Prospective study of non-steroidal anti-inflammatory drug induced adverse drug reaction in a tertiary care hospital	Approved
18	Ms. Pranayini D, Ms. Prissila Merlin S, Ms. Rakshana S Ms. Sandhya A M, V Yr Pharm. D Student	Therapeutic and operational factors influencing the antibiotic treatment duration for cellulitis- a prospective study	Approved
19	Mr. Manigandan.J, Ms. Meena Varshini. P Mr. Mohamed Akram A.N, Mr. Mohan Babu B, V Yr Pharm.D, Student	A clinical comparative observational study on irrational use of proton pump inhibitors & H2 receptor antagonists in the in patients	Approved
20	Mr. Aakash. R, Mr. Aswin Prathap.S, Mr. Deepak raj. S,	A prospective study on antimicrobial resistance pattern at a secondary care	Approved

	Ms. Dharshne. P.T, V Yr Pharm.D Student	hospital in Chennai	
21	Ms. P.L Ashika, Mr. Dhanasekar R, Ms. Drishya Nagaraj, Mr. Elumalai V, V Yr Pharm. D Student	Safety and effectiveness of Cefoperazone Sulbactam vs Piperacillin Tazobactam in CKD patients - A Prospective study	Approved
22	Mr. Shashank. K, Ms. Shanmugapriya. S.K, Ms. Subashini.S, Ms. Sujitha.G.S, V Yr Pharm. D Student	Impact of Clinical Pharmacist's Intervention in the Management of Type 2 Diabetes Mellitus: A Comparative Study	Approved
23	Ms. Farheena Thasneem.F, Ms. Gopikanath.S, Ms. Haripriya.B, Ms. Janavi.M, V Yr Pharm. D Student	Evaluating the incidence of Pre-diabetes in PCOS women with depressive symptoms: A Cross Sectional Study	Approved
24	Mr. P. Puviyarasu, Mr. C.K.Samuel, Ms. P.J.Nithila, V Yr Pharm. D Student.	A Prospective Observational study on the Evaluation of Acute Post-surgical Pain Management in Secondary care hospital.	Approved
25	Mr. Tilson Mathew.S, Mr. Yoganathan.K, Mr. Yuvan Hadhithya.H Pharm.D V year Ms. Akila K.I II Yr Pharm.D (PB) student	Effect of SGLT-2 inhibitor and Metformin in patients with Metabolic Syndrome	Approved
26	Mr. Karthikeyan. S Mr. Kumaran.B Ms. Jessica Vanathi. M Ms. Jazeera Jamil.R, V Yr Pharm. D Student	A prospective observational study on drug utilization evaluation of antihypertensive drugs	Approved
27	Ms. Riya. A, Mr. Sathish Kunar. D, Mr. Sayed Farhan. F, Mr.Keshav. S, IV Yr B.Pharm Student,	Over Sight of Anemia Logistics in Patient with Congestive Heart Failure	Approved
28	Ms. Punitha Jennifer Mr. Ragavendra T Rao Mr.Priyanshu dilipsingh IV Yr B.Pharm Student	A Questionnaire study to assess the levels of stress in pharmacy students and to identify factors that contribute to stress related illness	Approved

29	Ms. Pavithra.S Ms. Pavithra. R Ms. Priscilla.A IV Yr B.Pharm Student	Quality of Life assessment in patients with peptic ulcer during treatment	Approved
30	Mr. Naveen ajai. B Mr. Nirmal kumar J, Mr. Nithish kumar. E, Ms.Nivethitha. G, IV B.Pharm Student	A Prospective study on Efficacy of Clomipramine in the Treatment of patient with Obsessive compulsive disorder	Approved
31	Mr. Narendran. K Research Scholar	Assessment of Effects of New Changes in Drugs and Cosmetics Act and Rules - A Way Forward for Regulatory System Strengthening as per Global Benchmarking Tools	Approved

A. Vijayalakshmi
(Dr. A. Vijayalakshmi)

Member Secretary, IEC

Copy to

1. All Institutional Ethics Committee Members
2. Vice Chancellor-VISTAS
3. Dean, SPS



VISTAS SPS IEC

Registration number ECR/288/Indt/TN/2018/RR-21

Minutes of Meeting

Institutional Ethical Committee (IEC) meeting held on 17.05.2023 (Thursday) in CARD Conference Hall, Vels Institute of Science Technology and Advanced Studies, Pallavaram, Chennai-600117, Tamilnadu at 9.00 AM onwards.

Members Present

1. Dr. Melvin George - Chairperson
2. Dr. A. Vijayalakshmi - Member Secretary
3. Dr. A. Maduram - Medical Scientist
4. Dr. Naresh kumar Krishnamurthy - Clinician
5. Dr. Dilshad Shaik - Legal Expert – External
6. Dr. V. Karthikeyan - Legal Expert – Internal
7. Dr. C. Ronald Darwin - Scientific Member-Internal
8. Dr.A. Kathiresan - Scientific Member-Internal
9. Dr. R. J. Hemalatha - Scientific Member-Internal
10. Mrs. Selin Semila Rani – Lay Person

Following protocols were presented before IEC members with recommendation against each member.

S.No	Name of the Principal Investigator	Title	Remarks
1	Mr. Chandan. C M.Sc. Student (Yoga)	Effect of Trataka Practice on Visual acuity among college students	Approved
2	Mr. Darshangowda. MS M.Sc. Student (Yoga)	Effect of Asana on body composition level among obesity men.	Approved
3	Ms. Devi. K M.Sc. Student (Yoga)	Effect of Selected Asanas and Pranayama on Lipid Profile among Hypertension Women	Approved
4	Mr. Dinesh Kumar.S M.Sc. Student (Yoga)	Impact of Suryanamaskar and Asanas on Flexibility Levels among School Children	Approved
5	Mr. Gandharva Natesh M.Sc. Yoga	Effects of Yoga Nidra Practice on Blood Glucose Level among Middle-Aged Men with Type 2 Diabetes Mellitus	Approved

6	Ms. Geetha. S M.Sc. Student (Yoga)	Effect of Yoga Practices on Hemoglobin Levels among Women	Approved
7	Ms. Kavitha. S M.Sc. Student (Yoga)	Impact of Creative Yoga intervention on attention span and grip strength in higher functioning Autistic children	Approved
8	Ms. Mamatha M.Sc. Student (Yoga)	Effect of Yoga Mudras on Blood Pressure levels among Middle-Aged Men with Hypertension	Approved
9	Ms. Mamatha. K C M.Sc. Student (Yoga)	Effect of Ujjayi Pranayama on Thyroid Hormones levels among Women with Hypothyroidism	Approved
10	Ms. Mythreyee. B K M.Sc. Student (Yoga)	Effect of yogic practices on memory level among school children	Approved
11	Ms. Piriamalini Pandurengan M.Sc. Student (Yoga)	Effect of Yoga Nidra on Blood Pressure Level among people with Hypertension	Approved
12	Ms. Poonamalli Amulya M.Sc. Student (Yoga)	Impact of Silent Meditation and Pranayama on Stress Level among IT Professionals	Approved
13	Ms. Prathibha. T M.Sc. Student (Yoga)	Impact of Prana Pranava meditation on Blood Pressure level among Hypertension people	Approved
14	Ms. Rama. S M.Sc. Student (Yoga)	Effects of Mudra and Nadanusandhana Pranayama on Blood Pressure among Hypertension in Men	Approved
15	Mr. Ravanikar. HM M.Sc. Student (Yoga)	Effect of Pranayama Practice on selected physiological variable of sports persons	Approved
16	Ms. Rohini. K M.Sc. Student (Yoga)	Effects of Yoga Practices on TSH levels on women with Hypothyroidism	Approved
17	Ms. Sandhya. K M.Sc. Student (Yoga)	Effect of selected Yoga Practices on clinical variables among Geriatric patients with Chronic Low Back Pain	Approved
18	Ms. Shyamala. V M.Sc. Student (Yoga)	Impact of chanting 'OM' on Blood Pressure and Heart Rate levels among persons with Hypertension	Approved
19	Ms. Suganya. K M.Sc. Student (Yoga)	Efficacy of Yogic interventions on Hormone level among women with Polycystic Ovarian Syndrome	Approved
20	Ms. Sumithra. M M.Sc. Student (Yoga)	Effect of Yogic practices on Liver Enzyme levels among Obesity women	Approved
21	Ms. Surabhi. CK M.Sc. Student (Yoga)	Effect of selected Pranayama on Breath Holding Time and Vital Capacity among College Students	Approved
22	Ms. Suvarna Gaonkar M.Sc. Student (Yoga)	Effect of Yogic Practices on Muscular Endurance among School Children	Approved

23	Mr. Vasu. M M.Sc. Student (Yoga)	Effect of selected Asanas and Pranayama on flexibility and Cardiovascular endurance among Tennis Players	Approved
24	Ms. Shilpa M.Sc. Student (Yoga)	Effect of selected Yogic Practices on pain and flexibility level among Women with Mechanical Low Back Pain	Approved
25	Ms. Anuradha. M Research Scholar (Yoga)	Effect of Asana Pranayama and Yoga Nidra on Physiological and Biochemical Level of Type-2 Diabetic Working Male Participants	Approved
26	Ms. Gajalakshmi. A Research Scholar (Yoga)	Effect of selected Asanas and Pranayama on Clinical and Physiological Variables among Women with Neck Pain	Approved
27	Mr. Harindranath. TG Research Scholar (Yoga)	Effect of Pranayama Practices on Pulmonary Function in Subjects with Bronchial Asthma	Approved
28	Ms. Poornima. R Research Scholar (Yoga)	Impact of Yoga Practices on Psychophysiological and Metabolic Variables among Male Adults with Metabolic Syndrome	Approved
29	Mr. Rajeevan. P V Research Scholar (Yoga)	Impact of selected Yogic Practices on Physiological and Biochemical variables among Middle-Aged men with Hypertension in Kannur district, Kerala	Approved
30	Ms. Sapna. K Research Scholar (Yoga)	A Comparative Study on Selected Yogic Practices and Bharatanatyam Adavus on Anthropometric Parameters and Lipid Profile among Overweight Women in Calicut District	Approved
31	Ms. Sumitra Patil Kulkarni Research Scholar (Yoga)	Effect of Yogic Practices on Physical and Biochemical variables among Polycystic Ovarian syndrome Women's	Approved

A. Vijayalakshmi
(Dr. A. Vijayalakshmi)

Member Secretary-IEC

Copy to

1. All Institutional Ethics Committee Members
2. Vice Chancellor-VISTAS
3. Dean, SPS





INSTITUTE OF SCIENCE, TECHNOLOGY & ADVANCED STUDIES (VISTAS)
(Deemed to be University Estd. u/s 3 of the UGC Act, 1956)
PALLAVARAM - CHENNAI

VISTAS SPS IEC

Registration number ECR/288/Indt/TN/2018/RR-21

Minutes of Meeting

Institutional Ethical Committee (IEC) meeting held on 21.12.2023 (Thursday) in Pharmacy Conference Hall, Fleming Block, Vels Institute of Science Technology and Advanced Studies, Pallavaram, Chennai-600117, Tamil nadu from 9.00 AM onwards.

Members Present

1. Dr. Melvin George - Chairperson
2. Dr. A. Vijayalakshmi - Member Secretary
3. Dr. A. Maduram - Medical Scientist
4. Dr. V. Karthikeyan - Legal Expert – Internal
5. Dr. B. Prem Kumar - Scientific Member-External
6. Dr. C. Ronald Darwin - Scientific Member-Internal
7. Dr. A. Kathiresan - Scientific Member-Internal
8. Dr. R. J. Hemalatha - Scientific Member-Internal
9. Dr. Paul Ravikumar B - Social Scientist
10. Mrs. Selin Semila Rani – Lay Person

Following protocols were presented before IEC members with recommendation against each member.

S.No	Name of the Principal Investigator	Title	Remarks
1.	Mr.Aravind.S Research Scholar	Effectiveness of aerobic training on heart rate recovery among preterm and term born young adults	Approved
2.	Mr.Logesh. E Research Scholar	Effect of specific mckenzie exercise on improving craniovertebral angle, neck disability and GERD impact scale among forward head posture patients with gastroesophageal reflux disease	Approved
3.	Ms.Manjula. S Research Scholar	Effects of neuroplasticity based brain-fit mind exercises on neuro cognition among college students with attentional deficits	Approved

4.	Ms.Sharmila. S Research Scholar	Effects of virtual reality training on muscle mass and balance parameters among elderly sarcopenic individuals with fall risk	Approved
5.	Ms.Siva Anandhi. R Research Scholar	Effects of shoulder eccentric strengthening exercise versus dynamic taping on scapular position, hand grip and quality of life among sub-acromial impingement syndrome	Approved
6.	Ms.Sumathi. M Research Scholar	Effect of plyometrics and high intensity resistance training on muscle activity and knee function among badminton players with post ACL reconstruction	Approved
7.	Ms.Vishnu Priya. T.M Research Scholar	Effectiveness of immersive virtual reality training on hand motor function among hemiparetics	Approved
8.	Ms.Deepa. R Research Scholar	Comparative study of pre and post donation samples of single donor platelet donors	Approved
9.	Ms.Sandhiya.M Research Scholar	Detection of abdomen disorder through iris by using deep learning techniques	Approved
10.	Dr.Jacintha Sharon Daniel Research Scholar	Post partum depression: prevalence, identification of parents at risk & intervention utilized for its management	Approved
11.	Mr.Sundar Sri. M.K Research Scholar	A prospective study on early predisposition to Osteomalacia in Indian adults on anti-convulsant therapy	Approved
12.	Mr.Adhiraj. B Ms.Akshaya. G Ms.Aparna.V (Pharm. D)	A Prospective study on Progress of Tacrolimus dosing using therapeutic drug monitoring	
13.	Mr.Aravind. M Ms.Dharshini. A.D Ms.Gnana Sundari. K (Pharm. D)	A prospective observational study based on the factors involved in escalation to de-escalation of anti microbial therapy among critically ill patients	Approved
14.	Mr.Immanuvel .T S.Jacintha Abisha angel Mr.Jagadesh. S (Pharm. D)	A prospective study on switch over from IV to oral antibiotic therapy among hospitalized patients in secondary care hospital Chennai	Approved
15.	Ms.Karunya Shree.G.V Ms.Krithika.V Ms.Lavanya.G (Pharm.D)	Assessing the effectiveness of virtual reality exposure in mitigating anxiety among pre and post operative patients undergoing surgery: A prospective study	Approved

16.	Ms.Mary Valentin.J Mr.Naveen.J Mr.Prashath.S (Pharm. D)	Effect of High intensity Statin on inflammatory bio markers as secondary therapy for patients with CAD	Approved
17.	Mr.Rakkesh Praveen. S Ms.Saipooja. G Mr.Shanmuga Chandru.S (Pharm. D)	A study on contact dermatitis patients among dermatitis population in Chennai hospital	Approved
18.	Ms.Shreesha. B Ms.Sreelakshmi. S Mr.Sriram. N (Pharm.D)	A prospective comparative study of two fixed combination drugs: Brinzolamide/Timolol and Brimonidine/Timolol in patients with open angle glaucoma	Approved
19.	Mr.Vignesh. S Ms.Vinisha. M Mr.Parigodson. G.K (Pharm.D)	A prospective comparative study on therapeutic efficacy of Telmisartan plus Amlodipine and Amlodipine plus Hydrochlorothiazide in patients with hypertension and diabetes mellitus	Approved
20.	Ms.Sherly Grace. J Mr.Sai Avinash. J Ms.Bhuvaneshwari. D (Pharm.D)	Comparative study of efficacy and adverse drug reaction monitoring of angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARB) in cardiovascular disease	Approved
21.	Mr.Deepak. H Ms.Gayathri. K Mr.Jagannath. C (Pharm.D)	Role of Sodium Glucose Cotransport 2 inhibitor improving cardiac and renal function in patients with diabetes mellitus	Approved
22.	Mr.Nandhaperumal. G Ms.Radhika. G Ms.Reethika. M (Pharm.D)	Assessment of antifungal use through antifungal stewardship interventions in a secondary care hospital	Approved
23.	Ms.Sandhya. N Mr.Surendhar. A Mr.Vasantha Kumar. S (Pharm.D)	Assessing the impact of Ceftazidime/Avibactam on antimicrobial resistance and clinical outcome	Approved
24.	Mr.Rishi Raj. K Mr.Zaid Zainal Hussain (Pharm.D)	Assessment of renal dosage adjustment for anti-hypertensive agents, oral hypoglycemic drugs, anti-hyperlipidemic drugs in chronic kidney disease patients (stage I, II, III): A prospective study	Approved
25.	Mr.Hari Prasath. D (M. Pharm)	A prospective study of measuring the cognitive function among geriatric patient using neurology drug (Donepezil) for Alzheimer disease at tertiary care hospital	Approved

26.	Mr.Balaji. K (M. Pharm)	Evaluating the adverse drug reactions, tolerability of Pregabalin in geriatrics	Approved
27.	Mr.Ajith. V (M. Pharm)	A study to compare the efficacy of Vildagliptin plus Metformin versus Glimepride plus Metformin in type 2 diabetes mellitus patients	Approved
28.	Mr.Ameen Amnullah. S (M. Pharm)	To evaluate the safety, tolerability and adverse reaction of antibiotics in elderly patients	Approved
29.	Mr.Pavan Kumar. D (M. Pharm)	Implement prospective medication safety initiatives in pediatric wards and assess their impact on reducing medication errors	Approved
30.	Mr.Harishwar. S (M. Pharm)	The effects of anti epileptic medications on lipid profile and thyroid function in epilepsy patients in tertiary care hospital	Approved
31.	Mr.Kiran Kumar. S (M. Pharm)	Effectiveness of clinical pharmacist interventions in a tertiary care hospital outpatient in general medicine department	Approved
32.	Mr.Linfred Suthix. J.S (M. Pharm)	A prospective to identify adverse reactions in medical therapy in the elderly patient	Approved
33.	Ms.Pooja. S (M. Pharm)	The effect of pharmacist involvement in senior citizens with chronic conditions suffering from rheumatoid arthritis	Approved
34.	Mr.Rajesh. S (M. Pharm)	A prospective study on Furosemide drug therapy induced electrolyte disturbance and its complication in hypertension patient	Approved
35.	Mr.Rohith. S. M (M. Pharm)	Knowledge, attitude and practice analysis towards polycystic ovarian syndrome (PCOS): A cross sectional study	Approved
36.	Mr.Vasanth. M (M. Pharm)	Evaluation of prescribing pattern of proton pump inhibitors among patients visiting tertiary care hospital: cross sectional study	Approved
37.	Mr.Vishva. S (M. Pharm)	Pharmacoeconomic evaluation of antidiabetic treatments	Approved

38.	Mr.Ruthrakotti. K (M. Pharm)	Testing a medicine information in hospital patients: a cross-sectional study	Approved
39.	Mr.Mukil Vannan. M (M. Pharm)	Statin in diabetes mellitus: Impact on lipids, glucose regulation, and cardiovascular risk reduction	Approved
40.	Ms.Dharshini Priya. P Ms.Lavanya. A Ms.Tamil Murasoli. B (B. Pharm)	Personalised medicinal approach for anticonvulsant drug selection in type 2 diabetic patient in secondary care hospital: An observational study	Approved
41.	Ms.Jothika. R Mr.John Peter. S Mr.Kaviarasu. S (B. Pharm)	Evaluation of self care behaviour among hypertensive patients: An observational study conducted in Chennai	Approved
42.	Mr.Haribaskar. S Mr.Jaiganesh. S Ms.Jane Susan Stacey. (B. Pharm)T	Clinical management of inpatient diabetic foot infections - an observational study	Approved
43.	Mr. Sarath Kumar. R Mr. Sakthi Bala. E Mr. Sakthivel. T (B. Pharm)	Knowledge, attitude and practice regarding high alert medication among health care professionals in secondary care hospital	Approved

A. Vijayalakshmi

Dr. A. Vijayalakshmi

(Member Secretary)

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