No. 25/441/2009– AWD
Government of India
Ministry of Fisheries, Animal Husbandry and Dairying
Department of Animal Husbandry and Dairying
O/o Committee for the purpose of Control and Supervision of Experiments on Animals
*****

Krishi Bhawan, New Delhi – 110001
Date: 02/02/2021

To,

Dr Santosh Pillai, Chairman IAEC
Pushpagiri Medical College Sciences & Research Centre
Tiruvalla - 689 101 Kerala
Email: drsantosh74@gmail.com
Mobile: 9447596426

Subject: Renewal of Registration and Reconstitution of Institutional Animals Ethics Committee (IAEC) -regarding

Sir,

The registration of Animal House Facility of your establishment with CPCSEA has been renewed **for a period of five years from the date of issue of this letter.**

2. The registration number of Animal House Facility of your establishment is **602/PO/Re/S/02/CPCSEA for Research for Education purpose on small animals**. Henceforth, this registration number may kindly be quoted in all your future correspondence.

3. The CPCSEA has accepted the following members recommended by the establishment.

Name of the IAEC Members	**Designation in IAEC**
1) Dr Santosh Pillai	Biological Scientist cum Chairperson
2) Dr Bhagyalekshmi N	Scientist In-charge of Animal House Facility cum Member Secretary
3) Dr Prashanth Rathinam	Scientist from different biological discipline
4) Dr Pooja Raghunath	Scientist from different biological discipline
5) Dr P. N Sasidharan	Veterinarian

4. CPCSEA hereby nominates the following members to the Institutional Animals Ethics Committee (IAEC) of your establishment:

Details of Nominee(s)	Nominated as
1) Dr. Sachin J. Shenoy Biomedical Technology Wing, Sree Chitra Tirunal Institute of Medical Science, Poojapura, Thiruvananthapuram 695012, Kerala Contact No :9447432656 Email :sacshen@sctimst.ac.in	Main Nominee
2) Dr. Nishant Kumar Gupta Sr. Research Associate, Arjuna Natural Extracts ltd., PB No 126, Bank Rd, Periyar Nagar, Aluva, Kerala – 683101 Contact No :9400348605 Email :nishant@arjunanatural.com	Link Nominee

Contd..

3) Dr.Prakash K.G Department of Anatomy, Academic Block, Azeezia Institute of Medical Science & Research Meeyyannor Post, Kollam, Kerala- 691537 Contact No :9645216564 Email :drprakashkg@gmail.com	Scientist from outside the Institute
4) Dr. Sibi P.I. Dept of Pharmaceutical Sciences, M.G. University, RIMSR, Puthuppally Rubber Board, Kottayam, Kerala – 686009 Contact No :9446883809 Email :sibitho@gmail.com	Socially Aware Nominee

(Please note that any change in IAEC members can be made only with prior approval of CPCSEA.)

5. The IAEC is valid for a period of five years and is coterminous with renewed period of registration. IAEC is required to be reconstituted at the time of renewal of registration as per CPCSEA guidelines.

6. You are requested to convene the meeting of the re-constituted IAEC within a period of 30 days and upload the same on the website of the CPCSEA.

7. It is stated that only above approved IAEC members shall sign, with date, on the attendance sheet of the IAEC meetings, and decisions will be taken only in meetings where quorum is complete. The quorum for holding IAEC meeting is six (6), and Main Nominee, Scientist from outside the Institute and Socially aware Nominee must be present in such meetings. Link Nominee can attend in case main nominee conveys his unavailability in writing to the chairman IAEC. However, the Link Nominee must be invited once a year to update him/ her about the activities of the IAEC. Any decision taken in the meetings of IAEC without quorum shall be considered invalid.

8. It is also to inform you that before commencing any research on large animals you are required to send research protocols with due recommendation of IAEC to CPCSEA for further approval (procedure for submission of Research Protocols is available on the website of CPCSEA).

Yours sincerely,

(Dr. S. K. Dutta)
Member Secretary (CPCSEA)

Copy for necessary action to: Nominees of CPCSEA.

The Main Nominee is requested to ensure that the IAEC meetings are held regularly as stipulated in the SOP of CPCSEA and submit the Annual Inspection Reports of the Animal House Facility regularly on the Website of CPCSEA.

Dr. Aby Mathew T. MDS
Principal
Pushpagiri College of Dental Sciences

PUSHPAGIRI COLLEGE OF DENTAL SCIENCES · PUSHPAGIRI MEDICITY · TIRUVALLA

INSTITUTIONAL REVIEW BOARD
PUSHPAGIRI INSTITUTE OF MEDICAL SCIENCES & RESEARCH CENTRE

No: IRB/03/2023 27th October, 2023

MINUTES OF THE MEETING

The IRB meeting was held on 27th October, 2023 from 09:00 am at **the Conference Hall, Pushpagiri Research Centre.** All the members of the ethics committee attended the meeting. Dr. Hari Kumar welcomed everyone for the meeting. Previous minutes of the meeting was approved

ATTENDANCE: the table below lists all members of the ethics committee, their role, and attendance

Dr Harikumar B Nair	Ayurvedic Physician & Researcher	Chairperson
Dr Nebu George Thomas	Professor, Pushpagiri College Of Dental Sciences	Member Secretary
Dr Nibu Verghese	PhD (Plant Biotechnology)	Scientific Member
Dr Vikram Gowda	Vice-principal, Medical college	Medical Scientist
Dr Liya Roslin Joseph	Assistant Professor of Pharmacology	Medical Scientist
Fr. Sibin Mathew	Bachelor in Theology	Member
Dr T M Chary	PhD	Scientific Member
Mr Lijo George	B.Com	Lay Person
Adv. Minu Mathews	Advocate	Legal Expert
Dr. T P Thankappan	MBBS (MD-Dermatology and Venereology)	Clinician
Dr Athulya G Asokan	MD (General Medicine)	External Member
Dr. Rosin George	MD Community Medicine	Scientific Member
Dr. Melvin	Associate Professor from SRM Medical College Hospital and Research Centre.	External Subject Expert

Members Absent with apologies: 3

Non-Voting Member: NIL

Members alternating: NIL

Guests (Include Affiliation): Dr. Melvin, Associate Professor, SRM Medical College Hospital and Research Centre.

Total count: 10 out of 13.

Quorum: The quorum was present. > 50% members with 5 specified category as per ICMR Guidelines/Schedule Y. The chair person called the meeting to order, after confirming the Quorum was present

Attendance Notes:

 Members in attendance who recused themselves: None

 Conflict of Interest of IRB Members: None

Regulations followed for IRB Motion: Schedule Y, ICMR 13 principles

SL NO	TITLE OF THE PROPOSAL	NAME OF PI	STARTING TIME
	General Discussion: Previous Meeting Minutes Approval Welcoming of Dr. **Melvin George,** Professor Department of Clinical Pharmacology, SRM Medical College Hospital & Research Centre		09.00 am
01/2023	Knowledge and awareness of dental implants as a treatment choice for prosthetic rehabilitation among an adult population –A Cross-sectional study **Motion** **Comments** Dr. Chary What is the intention of the study? Dr. Harikumar In the inclusion criteria, why do you include patients with missing teeth rather than including the general population? *The PI will start the study only after the receipt of approval letter by the Committee.	**Dr. Sunu Alice Cherian**	09: 30am
02/2023	Proportion of Temporomandibular disorders among the Central Kerala population: A cross- sectional study **Motion** **Comments** Dr. Athulya 1. What is the sample population? 2. What is the sample size 3. Better to modify the title 4. Add Malayalam version of the questionnaire Dr. Vikram Gowda 1. Modify the title as we include only dental OP patients	**Dr. Robin Alex Cherian**	09.45 am

	2. Better to check validation of questionnaire after clinical examination Dr Chary 1. What is the purpose of the study? 2. Modify the objective by adding what is done for patients after getting diagnosed – include treatment and outcome Dr. Harikumar 1. Translate the questionnaire into local language Dr. Rosin 1. The questionnaire and clinical examination can be compared and questionnaire can be checked for validity Dr. Liya 1. Better to use a paper based questionnaire survey rather than Google forms Dr. Melvin **1.** There is no mention in the protocol how the investigators plan to ensure that the population of Central Kerala is represented? **2.** What will be the sampling strategy adopted? **3.** The authors should define which all districts come under Central Kerala in the protocol and highlight how from each of these regions a representative sample will be drawn. *The PI will start the study only after the receipt of approval letter by the Committee.		
03/2023	Clinical And Epidemiological Profile Of Liver Dysfunction In Dengue Fever – An Observational Single Centre Study **Motion**	**Dr. Maria Davis**	10:00 am

	Comments Dr. Athulya 1. What is the inclusion and exclusion criteria? 2. Elaborate more on exclusion criteria 3. Is it mandatory to have CBC checked on every visit? 4. Are you looking for primary or secondary dengue patients? 5. Are you checking for PTT and APTT 6. Check urine analysis if you are checking for clinical profile 7. What is the sample size? 8. What is the duration of the study? Dr. Liya 1. What is the objective of the study? 2. Specify the objectives 3. Better to change the title of the study Dr. Chary 1. Are you planning to establish diagnostic criteria? Dr. Vikram Gowda 1. It's better not to collect name, address for informed consent Dr. Rosin 1. What is the study design? 2. What is the outcome of the study? *The PI will start the study only after the receipt of approval letter by the Committee.		
04/2023	Association of serum Calcium concentration and blood glucose levels in Type 2 Diabetic Patients attending a Tertiary care hospital in South Kerala.	**Dr. Leya Elizabeth**	10:15am

	Motion **Comments** Dr. Athulya 1. Why do you want patients with 5 years of diabetes? 2. Better to include newly diagnosed cases 3. Many confounding factors will be present after 5years of diabetes Dr. Liya 1. Certain drugs can affect the Calcium level and hence its better to get newly diagnosed patients 2. Are you checking Vit D levels along with calcium? Dr. Chary 1. Where are you planning to assess the Calcium level? 2. How can you correlate Calcium level with diabetes? Dr Vikram Gowda 1. Suggestion to do an animal study in 2 groups and establish the calcium level with insulin secretion Dr. Melvin George 1. The investigators may attempt to increase the complexity of the study- for eg. determination of insulin resistance, VitD/PTH levels and if its confounding influence can be reduced. 2. Studies have shown hypercalcemia can increase DM risk. But will this sample size be sufficient to identify that? Answers 1) We will be correcting the inclusion criteria as suggested by the committee members to Newly diagnosed Diabetes patients		

	2)YesONLY newly diagnosed diabetes patients will be included in the studies 3) Keeping confounding factors in mind newly diagnosed diabetes patients will be included in the study 4) Since certain drugs will affect calcium levels ,newly diagnosed patients will be taken for the study and NOT those with more than 5 years of history of Diabetes 5) Yes 6) It will be conducted in Biochemistry lab of Pushpagiri Research Centre 7) We will correlate it with blood sugar levels and see if there is any association as calcium is said to play a role in the intracellular regulation for release of insulin and uptake of glucose as mentioned the in the rationale and introduction of the proposal submitted with the references 8) yes we are thinking of conducting this study in animals if funding is available . *The PI will start the study only after the receipt of approval letter by the Committee.		
05/2023	A prospective cross-sectional study – Diaphragm dysfunction on ultrasonography as a noninvasive technique for detecting intraabdominal hypertension in clinically suspected patients -a pilot study Dr. Athulya 1. What is definition of clinically suspected intra-abdominal pressure? 2. How is intra-abdominal pressure intravesicular pressure? 3. Better to put intravesicular pressure in title 4. How is intravesicular pressure correlated to intra-abdominal pressure? 5. How are you going to measure intra-abdominal pressure? 6. Intra-abdominal pressure is a vague term	**Dr. Manju Mathew**	10.30 am

	7. Look for complications of patients with increased pressure Dr. Vikram 1. Try to first establish the intra-abdominal pressure first in series of patients 2. Intravesicular pressure is a surrogate marker for intra-abdominal pressure 3. Who is going do the USG for your patients? 4. Get consent from first degree relative Dr. Liya 1. What is the objective of the study? Dr. Chary 1. Is doing USG a routine for all patients? Dr Rosin 1. What is the outcome of the study? 2. Are you going to find a cut off for diaphragm dysfunction? *The PI will start the study only after the receipt of approval letter by the Committee.		
06/2023	Comparison of teaching methodology during ultrasonography training session for MBBS students during elective posting in critical care unit– a retrospective study Dr. Athulya 1. One group you train with video and hands on and then cross over 2. The study should be a prospective study 3. Method of teaching should be defined clearly Dr. Liya 1. Make a checklist before initiating the study. Dr. Vikram	**Dr. Manju Mathew**	10.45 am

	1. Define you study properly 2. Define you outcomes of the study and evaluate it 3. This study has to restructured and submitted Dr. Chary 1. Grouping should be carefully done Dr. Melvin **1.** No sample size calculation is mentioned. **2.** no statistical analysis plan is present. The study is advised to be submitted in next IRB meeting by making necessary corrections. *The PI will start the study only after the receipt of approval letter by the Committee.		
07/ 2023	Clinical profile of acute kidney injury in diabetic Ketoacidosis – An observational single centre study **Motion** **Comments** Dr. Athulya 1. What is the average monthly admission of DK? 2. Is it difficult to get 97 patients within 6 months 3. What is the novelty of the study? 4. What characteristics of DK are you looking for? 5. Define the determinants of DK are you looking for before the start of the study? 6. Are you going to follow up these patients? Better to do so 7. Are you going to do USG for these patients Dr. Liya 1. The term prevalence has to be changed 2. It is a longitudinal study	**Dr. Anna Mary Thomas**	11.00 am

	3. What is the prevalence of kidney injury in literature? Dr. Chary 1. What is the recurrence of DK patients? *The PI will start the study only after the receipt of approval letter by the Committee.		
08/2023	A comparative study to evaluate the oxidative stress markers in athletes and non-athletes Motion Comments Dr. Vikram 1. High attitude has to be defined properly 2. Define your population clearly 3. Who are the athletes and non-athletes in this study 4. On basis did you identify the 25 samples? Dr. Athulya 1. Define all category of athletes. 2. What is the sample size? 3. Include informed consent in your study Dr. Chary 1. Define altitude - how above the sea level 2. What is the oxygen pressure there? 3. Better to include SOD 4. How are you going to assess NRF 2? 5. Will 25 sample be enough Dr. Liya 1. How do select the population?	**Dr. Suboj Babykutty**	11.15 am

	2. What is the study setting 3. How are you going to collect blood sample? 4. Include the sample size formula 5. Is both males and females included in the study? Dr. Rosin 1. Method of selecting your sample? 2. What is your sampling method? *The PI will start the study only after the receipt of approval letter by the Committee.		
09/2023	**P**revalance And Risk Factors For Postpartum Depression**.** Dr. Vikram 1. How did you get the sample size? 2. Study will be more strong if you have psychiatric person in the study 3. Avoid name while data collection Dr. Athulya 1. How frequently will you check for score? Minu 1. Get informed consent Dr. Liya 1. This is a sensitive study so better to add a psychiatrist in this study. 2. Title has to be modified as it is a hospital based study Dr. Rosin	**Dr. Vineetha Wills**	11.30 am

	1. Will you assess a patient who scored more than 13 in the second visit in the third visit also? 2. What is the significance of this score in second test period? Dr. Melvin 1. The protocol should minion what are the specific factors that the investigators are considering to increase the risk of postpartum depression. *The PI will start the study only after the receipt of approval letter by the Committee.		
10/2023	Attitude and practice regarding the use of over the counter medicines after the emergence of covid-19 pandemic among general population. Motion Comments Dr. Vikram Gowda 1. Suggestion to reduce the sample size 2. Change study setting to community areas *The PI will start the study only after the receipt of approval letter by the Committee.	**Ms. Suby Ipe**	11:45am
11/2023	"Mycogenic Synthesis and Antimicrobial Evaluation of Zinc Oxide Nanoparticles against Clinical Isolates of Klebsiella species from a Tertiary Care Hospital in Kerala, India". Motion Comments Dr. Vikram 1. How are collecting the sample?	**Sijo A**	12:00pm

	2. What are your sample? 3. Do you collect personal details of the patients? 4. What will you do with the samples? Dr. Chary 1. What nanoparticle are you preparing? 2. What is the function of the nanoparticle? 3. What is the advantage of using nanoparticles? Dr. Liya 1. Where will be preparation of nanoparticles be carried out? *The PI will start the study only after the receipt of approval letter by the Committee.		
12/2023	Prevalence Of Metabolic Syndrome Among Adults In Two Suburban Medical Facilities In Southern Kerala. Motion Comments Dr Vikram 1. Title is not clearance 2. Who is your population? 3. Patients who visit hospital have systemic problems 4. So random population should be selected Dr. Athulya 1. How will you diagnose patients with metabolic disorders? 2. Where will you analyse the sample? Dr. Chary 1. What is the function of angiotensin? 2. People you have selected what life style they belong to?	**Savitha Jose**	12:15pm

	Dr. Liya 1. Is it a funded study? 2. Get a proper consent before collecting blood samples 3. How will you store the sample? Dr. Rosin 1. How will you decide the no of samples in each centre? 2. Why don't you select a single centre? *The PI will start the study only after the receipt of approval letter by the Committee.		
13/2023	Factors associated with overweight and obesity in under-five children – a hospital-based study Dr. Vikram 1. What is the sample size? 2. Modifying the title would be better. 3. Its better we get an assent. *The PI will start the study only after the receipt of approval letter by the Committee.	**Dr. Jacob**	12:30pm
14/2023	Preventive oral health behaviors, health status, and dental treatment needs of children with special health care needs. Motion Comments: No Comments *The PI will start the study only after the receipt of approval letter by the Committee.	**Dr. Nebu**	12:45pm

INSTITUTIONAL REVIEW BOARD
PUSHPAGIRI INSTITUTE OF MEDICAL SCIENCES & RESEARCH CENTRE

No: IRB/01/2024 23rd April, 2024

MINUTES OF THE MEETING

The IRB meeting was held on 23rd April, 2024**@ 09:00 am at Research Centre Hall.** All members attended the meeting. Dr. Harikumar welcomed the gathering and the external subject expert Dr. Arun M Xavier from Amrita School of Dentistry. Previous minutes of the IRB meeting was read and approved.

Attendance: The table below lists all members of the ethics committee, their role, and attendance.

Dr Harikumar B Nair	Ayurvedic Physician & Researcher	Chairperson
Dr Nebu George Thomas	Professor, Pushpagiri College Of Dental Sciences	Member Secretary
Dr Vikram Gowda	Vice-principal, Medical college	Medical Scientist
Dr Liya Roslin Joseph	Assistant Professor of Pharmacology	Medical Scientist
Fr. Sibin Mathew	Bachelor in Theology	Member
Dr T M Chary	PhD	Scientific Member
Mr Lijo George	B.Com	Lay Person
Adv. Minu Mathews	Advocate	Legal Expert
Dr Athulya G Asokan	MD (General Medicine)	External Member
Dr. Stephen James	M Tech	Member
Dr. Rosin George Varghese	Assistant Professor, Department of Community Medicine	Internal Member
Dr. Arun M Xavier	Amrita College of Dentistry	External Subject Expert

Members Absent with apologies: NIL

Non-Voting Member: NIL

Members alternating: NIL

Guests (Include Affiliation): Dr. Arun M Xavier, Associate Professor, Amrita School of Dentistry

Total count: 11 out of 11

Quorum: The quorum was present. > 50% members with 5 specified category as per ICMR Guidelines/Schedule Y. The chair person called the meeting to order, after confirming the Quorum was present

Attendance Notes:

 Members in attendance who recused themselves: None

 Conflict of Interest of IRB Members: None

Regulations followed for IRB Motion: Schedule Y, ICMR 13 principles

SL NO	TITLE OF THE PROPOSAL	NAME OF PI	STARTING TIME
• General Discussion: Previous Meeting Minutes Approval Welcoming of Dr. **Arun M Xavier, Amrita School of Dentistry**			09.00 am
1.	The assessment of oral health status among older adults residing in old age homes and its association with behavioural, psychosocial and nutritional factors – A multi centric cross-sectional study. **IRB Comments** **Dr. Nibu Verghese** 1. Why have u selected north Kerala and government institutions 2. How many old age homes are available 3. How will you obtain permission to conduct the study 4. What is the difference between the oral health status of people living in old age homes and the general population 5. What is the research problem 6. If govt doesn't allow, take 50% from govt and private old age homes **Dr. Chary** 1. Will there be more organized data in government old age homes? 2. Mention the number of old age homes 3. Why don't you ask the home in charge regarding nutritional assessment rather than inmates **Dr. Nebu** 1. Is your questionnaire validated 2. Mention the study setting	**Dr. Abdul Saheer P**	**09:15am**

	3. What is the sample size 4. What is the benefit for the vulnerable population? **Dr. Athulya** 1. How are you going to assess behavioural factors 2. Which tool will you be using to assess each factor? 3. Modify your second objective 4. How is social support related to oral health?? **Dr. Liya** 1. You need to specify which tool will be used to assess each factors 2. MNA tool is very vague 3. Is this a follow-up study? 4. Why have you particularly selected old age homes? 5. Modify the title 6. How will you exclude medically compromised patients better specify which components will be excluded. **Dr. Rosin** 1. If you approach district level, you will have easy access to 2. How have you calculated the sample size? 3. The sample size is too high 4. Better to mention the number of old age homes. 5. Out of total how many homes will be selected **Dr. Arun** 1. Choosing govt institutions won't be sufficient 2. Ideal to include ppl from private old age homes 3. Do you anticipate any difference in the quality of life of ppl living in old age homes and general population 4. Mention the names of the institution		

	5. Whether the institutions will represent the districts 6. Do you think the study population will get exhausted with the half an hr questionnaire 7. Is the questionnaire suitable for Indian population 8. Better to go for validation process		
2	Development and validation of a tool to analyse the social determinants of oral health outcomes among adults in rural and urban areas of South Kerala – A mixed methods approach. IRB Comments **Dr. Athulya** 1. Is the sample size calculated **Dr. Liya** 1. How is the panel selected? Detailed report needed 2. What is the designation of the panel selected 3. Will you assess criterion validity 4. How will you select the population? **Dr. Vikram** 1. What social factors are considered 2. How is questionnaire validated **Dr. Chary** 1. You will need to present the study again after pilot study (phase I study) 2. Which districts are you selecting? 3. How will you select the subjects? 4. What is your exclusion criteria? **Dr. Arun**	**Dr. Saira Siraj E**	**09.30 am**

	1. What are the oral diseases expected in this age group? 2. Who is the person going to help you to categories the 3. Who would community members comprise of? 4. Sample of 40 does it represent the male and female population 5. Better submit for funding		
3	Adjunctive Low-Level Light Therapy for Periodontitis and Oral Mucositis in Cancer Patients IRB comments **Dr. Athulya** 1. What are other indications of this light 2. Are there any prior studies done? 3. Will patients will trained to use it? 4. How will you manage the side effects? 5. When will the outcome measured? 6. What will do if patient has continues chemo treatment 7. Will you continue the treatment after the mucositis subside? 8. There may be many confounders if you check outcome after 1 year. 9. 3rd objective may not be needed **Dr. Liya** 1. What is the cost of the instrument? 2. Written consent form need to be added **Dr. Vikram** 1. Safety of the instruments to be assessed 2. What are the side effects of continuous use? 3. How will you make sure that patients uses it correctly 4. Do not include ongoing treatment patients, so selection bias will happen	**Dr. Betsy Joseph**	**09.45 am**

	5. Decide the compensation rate 6. Enquire the diet pattern during this study **Dr Chary** 1. What is the action of treatment? **Dr. Arun** 1. Asking the patient to rinse with the effervescent tablet and placing the instrument in mouth might be difficult for patient to perceive 2. Sterilization of instrument is questionable 3. What if VAS score goes high will you stop the treatment? 4. Modify the inclusion criteria 5. Are you doing a patch test for every patient before introducing the dye? 6. What are the potential risk to patients? 7. Choosing patients should be careful.		
4	To study the prevalence, risk factors, associations, clinical characteristics, lab parameters, radiological features, treatment approach, outcomes, complications in IIH patients. IRB Comments **Dr. Athulya** 1. How will you assess the prevalence of the study 2. What are novel risk factors going to be assessed 3. Which drugs are you going to assess 4. How will you categorize the clinical characteristics 5. What ophthalmic assessments will you do 6. What novel imaging findings will you do 7. How will you follow up the patients 8. How will you define the treatment outcome? 9. Minimize the objectives	**Dr. Reji Thomas**	**10.00 am**

	10. Treatment protocol should be included in proforma 11. How many patients do you get in a month 12. Modify the research question **Dr. Liya** 1. Is is a multi centric study 2. You need to correct it to proportion 3. Need to modify the objective 4. What is the study design 5. How long is the follow up **Dr. Chary** 1. Streamline the title **Adv Minu** 1. Informed consent to be added **Dr. Rosin** 1. What is your sample population? 2. What age group? 3. Add a control group in your study 4. Who will decide which method to follow? 5. Is there a follow up for patients? **Dr. Harikumar** 1. Is lumbar puncture a routine procedure for this study		
5	Safety and tolerance to Maranta arundinacea (arrowroot) added to formula feeds in ICU patients -a pilot study		

	IRB Comments **Dr. Liya** 1. Title is not clear and needs modification 2. Safety and tolerance can be added as secondary objective 3. Define you study design 4. How will you obtain the arrowroot powder **Dr. Rosin** 1. Modify the title – change the pilot study and add RCT in the study title 2. Add powder in the title **Dr. Athulya** 1. Modify the aims of the study 2. How long will you be giving the treatment 3. Modify you inclusion criteria and check for GI Side effects 4. Check and define the quantity of the feed 5. Check for the confounders 6. When will you assess the bacteremia? 7. Remove bacteremia and include only nosocomial infection 8. Methodology needs to be specified 9. GI tolerably of arrowroot powder with formula when compared with formula feeds **Dr. Nebu** 1. Need CTRI registration **Dr. Chary** 1. How is preparing arrowroot preparation 2. Are you using a standard powder 3. You cannot emphasize on protein content in Arrowrot	**Dr. Manju Mathew**	**10.15 am**

	4. You need a clear composition of the powder preparation 5. You need to reduce the calorie from the formula and the add arrowroot 6. How will you estimate that bacteria count is reduced **Dr. Harikumar** 1. Standardization of product is needed 2. CTRI registration is needed 3. Central standards of arrowroot if available please use the same		
6	Ultrasound training during elective posting of medical undergraduates in the critical care unit of a tertiary teaching hospital for integrated clinical and sonographic cardiorespiratory assessment: a prospective study **IRB Comments** **Dr. Athulya** 1. How many assessment for the students? 2. Will there be written assessment for students? 3. Define your objectives 4. Remove from -for integrated clinical – assessment 5. Are you checking feseablity of this study 6. How will you check time of image acquisition **Dr.Liya** 1. Will the same material used for all assessments? 2. Modify the title 3. Comparison of effectiveness of 2 different training techniques 4. Time taken for image acquisition also as primary objective 5. Check feedback as secondary objective	**Dr. Manju Mathew**	**10.30 am**

	Dr. Rosin 1. Add a comparison in title 2. It's an educational interventional study		
7	An audit of the time from ordering for the bilirubin level to reporting to measure the proportion of delayed reporting: A prospective study IRB Comments **Dr. Vikram** 1. Objective must be changed 2. What is sub clinical jaundice 3. Outcome of the patient based on particular delay time will be more meaningful 4. Add some more components to the study. **Dr. Liya** 1. Objective should be measurable 2. This study will not have relevance **Dr. Rosin** 1. First objective - To estimate 2. Second objective – to Determine **Dr. Athulya** 1. Is it an institutional problem? 2. What intervention will you do if there is a delay? Resubmit the proposal and present in the next IRB meeting	**Dr. Bincy Varghese**	**10.45 am**

8	The Role Of Prolotherapy And Platelet Rich Plasma In Chronic Osteoarthritis Knee - A Pilot Study **IRB Comments** **Dr. Vikram** 1. Is it an approved treatment modality for using both treatments at the same time? 2. Is there any literature supporting the above statement 3. Resubmit the proposal **Dr. Nebu** 1. Need CTRI registration **Dr. Athulya** 1. You need to anticipate the side effect 2. Check for similar studies in the literature. **Dr. Chary** 1. Resubmit the proposal	**Dr. Jimi Jose**	**11.00 am**
9	An Audit of admission to seizure control-Intervention time- A retrospective study **IRB Comments** **Dr. Vikram** 1. Is it an approved treatment modality for using both treatments at the same time? 2. Is there any literature supporting the above statement 3. Resubmit the proposal **Dr. Nebu** 4. Need CTRI registration	**Dr. Jewel Maria George**	**11.15 am**

	Dr. Athulya 5. Check for similar studies in the literature. 6. You need to anticipate the side effect **Dr. Chary** 7. Resubmit the proposal		
10	Comparative Evaluation Of Ctivation Techniques On Edta & Citric Acid Irrigants In Expression Of Growth Factors From Dentin: An Invitro Study **IRB Comments** **Dr. Vikram** 1. Change evaluate to estimate in objectives 2. Change it to varying concentrations **Dr Arun** 1. What is the novelity of the study. Kindly elaborate. 2. How will directly commute the loss of volume of canal to growth hormones after agitation? 3. How will you estimate the volume of the canal? 4. Why do you do manual agitation? 5. Suggestion – replace one parameters with something else novel **Dr. Chary** 1. What is your control group? 2. What is the mechanism of EDTA? 3. Is calcium an inhibing factor for growth factors? 4. Is it a multicentric study?	Dr. Megha S	11.30 am

	Dr Rosin 1. Suggestion to reduce the objectives		
11	Combination of Vital Pulp Therapy (VPT) and Non-Surgical Endodontic Therapy (NSET) for management of permanent mandibular first molars with Symptomatic Irreversible pulpitis and Apical Periodontitis. **IRB Comments** **Dr. Vikram** 1. What is the outcome of the study? 2. What is the parameter measured? 3. 2nd point of objective as primary objective 4. 3rd and 4th point as secondary objective **Dr. Athulya** 1. What is the clinical outcome of the study? 2. How many exposures are you giving a patient? Suggestion to reduce the exposure 3. Is this a self funded study? **Dr. Arun** 1. Categories primary and secondary objectives 2. What is the symptom that you are looking for? 3. How will you categorize pain? 4. Be more specific while selecting sample 5. Why did you choose mandibular molars? 6. What is PIA score more than or equal to 3? 7. Is CBCT required for this study? Justify 8. Why is ASA type I used. Better use the term healthy patients 9. What is your line of treatment if hemostasis not obtained in 8 minutes 10. Why do you exclude patients taking antibiotics **Dr. Rosin** 1. CTRI registration is needed for the study	**Dr. Betty Shaji**	**11.45 am**

12	'Comparative Evaluation of the Efficacy of Various Methods in Locating the 2nd Mesiobuccal Canal in Maxillary First Molars: An In vitro Study' **IRB Comments** **Dr.Athulya** 1. How will you test the efficacy of the technique? 2. Can you equally divide the number of teeth under every technique 3. Add one more imaging modality and compare **Dr. Rosin** 1. Title has to be modified 2. Sample size has to be recalculated **Dr. Vikram** 1. It can be only a descriptive study 2. You should subject all teeth to all procedure and subject to MICRO CT **Dr. Arun** 1. Categorize the primary and secondary objectives 2. How will you check efficacy of a cross sectional view 3. How is the assessing the MICRO CT 4. What are the chances of having MB2 canal 5. Alteration of complete methodology needed 6. Efficacy cannot be calculated based on percentage 7. How will you calculate specificity and sensitivity of the test assessed?	**Dr. Meenu Sara**	**12:00pm**

13	Effect of zirconium oxide and silver nanoparticles on cell viability, tear strength and shore hardness of maxillofacial silicone elastomers: An in vitro study **IRB Comments** **Dr.Athulya** 1. How will you test the efficacy of the technique? 2. Can you equally divide the number of teeth under every technique 3. Add one more imaging modality and compare **Dr. Rosin** 1. Title has to be modified 2. Sample size has to be recalculated **Dr. Vikram** 1. It can be only a descriptive study 2. You should subject all teeth to all procedure and subject to MICRO CT **Dr. Arun** 1. Categorize the primary and secondary objectives 2. How will you check efficacy of a cross sectional view 3. How is the assessing the MICRO CT 4. What are the chances of having MB2 canal 5. Alteration of complete methodology needed 6. Efficacy cannot be calculated based on percentage 7. How will you calculate specificity and sensitivity of the test assessed?	**Dr. Sobin Kurian**	**12:15pm**
14	Comparative evaluation of the primary stability with different implant thread design using conventinal and osseodensification technique: A study on cadaver.	Dr. Firoz Khan	12:30pm

	IRB Comments **Dr. Arun** 1. Change the spelling mistake in title 2. Alter the title 3. Statastics will be complicated. 4. Lot of background information not required 5. Please change the tense to present tense 6. Variable – primary and secondary stability – check and correct 7. Are you taking 24 goat mandible? 8. Sample size need to be elaborated and more specified 9. Second part of protocol not submitted. Kindly resubmit protocol again 10. Add flowchart to the protocol **Dr. Chary** 1. Put less contents in each slide rather than making it over crowded		
15	To Compare The Impact Of Cast Endocrowns Over Other Auxillary Retentive Features As A Retentive, Alternative For Short Clinical Crowns: An Invitro-Study **IRB Comments** **Dr. Athulya** 1. Is this an in vitro study? **Dr. Arun** 1. Modify the title 2. Use of other auxillary features – modify 3. Work on protocol and second part not attended 4. Revise the methodology 5. Is modifivation done on tooth or crown 6. Protocol is vague. Correct and Resubmit	**Dr. Riya Ann Joseph**	**12:45pm**

	Dr. Vikram 1. what statistical analysis will be used ?		
	LUNCH BREAK		01:00pm
16	Comparative assessment of serum levels of C-reactive protein in Stage II and Stage IV periodontitis patients with type 2 diabetes reporting to a Tertiary health care centre in South Kerala. **IRB Comments** **Dr. Vikram** 1. Who will pay for lab work? **Dr. Athulya** 1. Why are you taking diabetic patients? 2. What is your exclusion criteria 3. It will be very difficult to find diabetic patients alone **Dr. Rosin** 1. Why are you excluding non smokers? Correct it **Dr. Arun** 1. Modify the title 2. What are you expecting in your results 3. Why have to exluded ppl under anti inflammatory medication– for past 6 months 4. What is the parameter checked for diabetes? 5. What are the grades of diabetes taken for this study? 6. Are you checking pre diabetic levels?	**Dr. Anjana Appukuttan**	**01:30pm**

17	Role Of Diffuse Reflectance Spectroscopy In Evaluation Of Periodontal Inflammation In Biofilm Induced Gingivitis And Periodontitis. **IRB Comments** **Dr. Athulya** 1. How will you obtain the second objective? 2. Are you determining the severity of periodontitis with clinical methods and then comparing? **Dr. Rosin** 1. What is clinical validity? 2. How will you measure it? **Dr. Arun** 1. What are steps taken to measure clinical validity?	**Dr. Rajasree**	**01:45 pm**
18	A comparative study on duration of recovery of infraorbital neurosensory deficits among patients who undergo open reduction and internal fixation (ORIF) of Zygomaticomaxillary complex(ZMC) fracture v/s conservative management. **IRB Comments** **Dr. Arun** 1. What is the conservative management for the zygomatic fracture 2. How can you say which method is better 3. Are you trying to compare the surgical and non-surgical method 4. What are the result outcome? 5. How many cases will you get per month 6. Are you taking retrospective sample? 7. What is your sample size?	**Dr. Ashley Roy**	**02:00 pm**

	8. Are you categorizing patients regarding the grade of fracture? **Dr Athulya** 1. What is your inclusion criteria? 2. Who is deciding which patients will go for conservative or surgical management? 3. Are you checking neurosensory deficient at time of admission 4. Inclusion criteria should include the classification of fracture 5. What is frequency of people having deficient **Dr. Vikram** 1. How will you compare the selected population? Only if sample population is of same condition, comparision can be done. 2. Recalculate the sample size again.		
19	A Comparative Study On Relapse Of Maxillary Orthognathic Surgery With Cad/Cam Assisted Method V/S Conventional Method. **IRB Comments** **Dr. Athulya** 1. How do you define relapse? **Dr. Arun** 1. Is it a surgical plan to take Ceph 2 days after surgery? 2. How common are orthnagntic surgeries in our institution? 3. Will you require retrospective data if you don't get sufficient sample? 4. Do you have records of all orthognathic surgeries done in your institution? 5. What is the difference between your study and with key article	**Dr. Ashwathi**	**02:15 pm**

20	The Evaluation Of The Biocompatibility Of 10 Popular Orthodontic Aligners Assessed Using Bisphenol–A Release Done In Human Salivary Substitutes And Estrogenic Beta Levels Done In Cell Culture. **IRB Comments** **Dr. Arun** 1. Modification of title needed – remove 10 popular and done in and add assessment 2. Why are 2 time points used? 3. Do you have 1 hr estimation of BPA? 4. After how long after make of aligner should you start the treatment? 5. What is the unit of estrogenic alpha and beta 6. Second part of protocol not entered. **Dr. Chary** 1. How BPA is released into saliva? **Dr. Athulya** 1. When will you check for BPA in artificial saliva	**Dr. Nooriya T K**	**02:30 pm**
21	The Evaluation Of The Biocompatibility Of 10 Popular Orthodontic Aligners Assessed Using Bisphenol–A Release Done In Human Salivary Substitutes And Estrogenic Alpha Levels Done In Cell Culture. **IRB Comments** **Dr. Arun** 7. Modification of title needed – remove 10 popular and done in and add assessment 8. Why are 2 time points used?	**Dr. Jareena Shareef**	**02:45pm**

	9. Do you have 1 hr estimation of BPA? 10. After how long after make of aligner should you start the treatment? 11. What is the unit of estrogenic alpha and beta 12. Second part of protocol not entered. **Dr. Chary** 2. How BPA is released into saliva? **Dr. Athulya** 2. When will you check for BPA in artificial saliva		
22	Evaluation of the oral hygiene status, caries prevalence, overjet and traumatic injuries to anterior teeth among visually impaired individuals in 4 districts of Kerala. **IRB Comments** **Dr. Vikram** 1.How will you evaluate oral hygiene index? 2. Get parents' consent mandatory 3. Informed consent should include parents signature 4. Get principals permission **Dr. Athulya** 1. How will you collect the sample? 2. Modify the title	**Dr. Aparna K**	**03:00pm**
23	Evaluation and comparison of the sedative efficiency of intranasal Dexmedetomidine, Midazolam, Ketamine and their effect on behavior in pediatric dental patients. **IRB Comments** **Dr. Vikram** 1. Remove safety from primary objective	**Dr. Hamna**	**03:15pm**

	2. Your secondary objective should be your primary objective 3. Why dexmedetomidine selected? **Dr Rosin** 1. How will you assess ease of treatment? **Dr. Arun** 1. Modify the research problem 2. There is mix up objectives. Modify it 3. Primary objective – behaviour management 4. Secondary objection - ease of completion of treatment 5. Do not add safety as objective 6. What type of sedation will you get from all 3 medication 7. Are you expecting change 8. how is sample size estimated 9. how will you eliminate selection bias. Modify with some kind of randomization		