

Minutes of the IRB committee on: 16th August, 2022

Due to the prevailing Covid -19 pandemic situation, the IRB meeting was scheduled on an online platform (Google Meet) on **16th August, 2022**. The IRB Members and the Principal investigators were given the Google link before hand and were requested to join at 10:00 on **16th August, 2022**. The IRB Chairman welcomed Dr. Melvin, Associate Professor, SRM Medical College Hospital and Research Centre.

The previous minutes of the IRB Meeting was approved in this meeting.

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. G. Sulochana	MBBS, MD-Pathology	Basic Medical Scientist
Dr Athulya G Asokan	MD (General Medicine)	Member
Dr Tressia Alias Princy Paulose	PhD Chemistry	Member
Dr. Stephen James	M Tech	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: 12 out of 15.

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

I: INITIALREVIEW

IRB Study Reference No: 01/2022

Protocol Title: A pilot study of the use and perceived utility of ECDT to assess clinical dental teaching within an Indian Dental college setting.

Principal Investigator: Dr. Subbalekshmi

Primary reviewer of IRB: Comments from IRB Member

Dr. Athulya

1. How are you going to fulfil the second and third objective?
2. Will you be giving separate questionnaire for each subject?

Dr. Nebu

1. What is the duration of the study?
2. What is the sample size?
3. Did you follow a sample size formula to calculate sample size?
4. It would be better to do a multicentric study to avoid bias.

Motion:

Comments:

IRB Study Reference No: 02/2022

Protocol Title: Comparative study on the effect of citicoline versus calcium in osteoporosis.

Principal Investigator: Dr. P S John

Primary reviewer of IRB: Comments from IRB Member

Dr. Athulya

1. What is the difference between group I and group II?
2. Where are you planning to do DEXA scan?
3. Any exclusion criteria for patients?
4. Do you expect any adverse effects in patients?
5. Will you be have a separate adverse effect reporting?

Dr. Melvin

1. Are you using bisphosphonate for treatment?
2. As group II patients are only receiving citicholine, are you denying them from proper treatment?

Motion:

Comments:

IRB Study Reference No: 03/2022

Protocol Title: A comparative study on the effect of citicoline versus calcium in non-union of fractures.

Principal Investigator: Dr. P S John

Primary reviewer of IRB: Comments from IRB Member

Dr. Melvin

1. Is this a heterogeneous group of study?
2. How will you manage the analysis?
3. Can you restrict your study to one particular area of fracture
4. What is your sample size?
5. If your not receiving your sample size, it would be better if you make it a multicentric study

Dr. Athulya

1. Can you define non- union of fracture mentioned in your inclusion criteria
2. It would be better if you can analyse the reasons of non-union of fractures

Motion:

Comments:

IRB Study Reference No: 04/2022

Protocol Title: A comparative study on acceleration of fracture healing in osteoporotic fractures with citicoline versus calcium.

Principal Investigator: Dr. P S John

Primary reviewer of IRB: Comments from IRB Member

Dr. Melvin

1. Record the safety of the subject and submit the report to IRB
2. Suggesting a multicentric study for getting a good sample size

Motion:

Comments:

IRB Study Reference No: 05/2022

Protocol Title: Deep Learning Approach for the Diagnosis of Pediatric Heart Disease using Wireless Phonocardiogram

Principal Investigator: Dr. Saji Philip

Primary reviewer of IRB: Comments from IRB Member

Dr. Melvin

1. Where is the study been done?
2. Can you get the information from data base
3. What is the sample size?
4. Will the selected sample size be sufficient for deep learning?
5. Is there any work published in India?
6. Have you made a device for this study?
7. Who is doing validation of the study?

Dr. Athulya

1. Will you confirm the study with echocardiography?
2. Will all patients undergo echocardiography?
3. How are you going to divide the sample?

Motion:

Comments:

IRB Study Reference No: 06/2022

Protocol Title: A study on Clinical Profile of ESUS and Cardioembolic study upon South Indian patients

Principal Investigator: Dr. Nikhil

Primary reviewer of IRB: Comments from IRB Member

Dr. Melvin

1. How investigator going to analyse the health related quality of life ?

Motion:

Comments:

IRB Study Reference No: 07/2022

Protocol Title: The Role of community in tackling antibiotic resistance in India: A Cross-sectional study

Principal Investigator: Dr. Philip Mathew

Primary reviewer of IRB: Comments from IRB Member

Dr. Melvin

1. Where is the centre of the study?
2. Once you get approval, submit the investigators list and centre of study.
3. Who is the coordinator for this study?

Motion:

Comments:

IRB Study Reference No: 08/2022

Protocol Title: Assessment of the multi-sectoral impact of the National Action Plans on Antimicrobial Resistance in Bangladesh and Vietnam: A qualitative study

Principal Investigator: Dr. Philip Mathew

Primary reviewer of IRB: Comments from IRB Member

Dr. Melvin

1. Who are the people participating in the study?
2. Will this IRB approval be enough to conduct study in Bangladesh and Vietnam
3. Is there any MOU signed with these institutions?
4. It is better to have agreement signed among the investigator level and submit to Ethics committee of Pushpagiri

Motion:

Comments:

IRB Study Reference No: 09/2022

Protocol Title: Enablers and barriers for state action plans for antimicrobial resistance in India:
A multicentric study

Principal Investigator: Dr. Philip Mathew
Primary reviewer of IRB: Comments from IRB Member

Dr. Melvin

1. It is better to have agreement signed among the investigator level and submit to Ethics committee of Pushpagiri

Motion:
Comments:

IRB Study Reference No: 10/2022

Protocol Title: EEG monitoring Findings in critically Ill adults with impaired consciousness and their correlation with clinical and functional outcome

Principal Investigator: Dr. Miny Susan Abraham
Primary reviewer of IRB: Comments from IRB Member

Dr. Melvin

1. Are you taking data from records?
2. Is this a retrospective study?
3. Will you have sufficient data to record?

Dr Athulya

1. Are you going to follow-up all patients after 1 month?
2. If you lose patients, how will you adjust the sample size?
3. Kindly modify your objective – pattern instead of prevalence
4. Modify your third objective

Motion:

Comments:

IRB Study Reference No: 11/2022

Protocol Title: Longitudinal effects of non-restorative caries control treatment on Oral Health related quality of life, salivary microbial levels and immunoglobulin levels in children with Autism Spectrum Disorder

Principal Investigator: Dr. Sherin Sara George
Primary reviewer of IRB: Comments from IRB Member

No Comments

Motion:
Comments:

IRB Study Reference No: 12/2022

Protocol Title:

Low heme iron intake as a predictor of iron deficiency in adolescent girls

Principal Investigator: Dr. Asha K K
Primary reviewer of IRB: Comments from IRB Member

Dr. Melvin

1. You should get a document from CIFT (parent institution) regarding the reference of above study of Pushpagiri institutional ethics committee (IEC).
2. ICMR letter giving permission of IEC to review the above study

Motion:
Comments:

IRB Study Reference No: 13/2022

Protocol Title: Use of OLFM4 as prognostic marker in Type 2 diabetes and its role in S.aureus survival in neutrophils

Principal Investigator: Dr. Haritha V H

Primary reviewer of IRB: Comments from IRB Member

Dr. Melvin

1. Does your study include blood sample collection?

Motion:

Comments:

IRB Study Reference No: 14/2022

Protocol Title: Perception of Indian medical and dental practitioners regarding the 2022 outbreak of monkey pox disease

Principal Investigator: Dr. Nebu George Thomas

Primary reviewer of IRB: Comments from IRB Member

No Comments

Motion:

Comments:

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



**INSTITUTIONAL REVIEW BOARD
PUSHPAGIRI INSTITUTE OF MEDICAL SCIENCES & RESEARCH CENTRE**

No: IRB/01/2023

21st January, 2023

Minutes of the IRB committee

1. Due to the prevailing Covid -19 pandemic, the IRB meeting was scheduled online (Google Meet) on **12th January, 2023**. The IRB Members and the Principal investigators were given the meet link before hand and were requested to join at 09 am on **12th January, 2023**. The IRB Chairman welcomed Dr. Melvin Associate Professor from SRM Medical College Hospital and Research Centre.
2. The previous minutes of the IRB Meeting was approved in this meeting.

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 Tressia Alias Princy Paulose	PhD Chemistry	Member
Dr. Stephen James	M Tech	Member
Dr. Melvin	Associate Professor from SRM Medical College Hospital and Research Centre.	External Subject Expert

Members Absent with apologies: NIL

Non-Voting Member: NIL

Members alternating: NIL

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

Total count: 12 out of 12.

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

Study Number	TITLE OF THE PROPOSAL	NAME OF PI
01/ 2023	<p>Prevalence of temporomandibular disorders and its association with text neck syndrome due to Smartphone use among undergraduate dental students in kerala – a cross sectional study.</p> <p>Motion: Comments:</p> <p>Will you be able to get enough samples in group II (Second image) shown in your presentation? If not changing the group would be better to maintain an adequate sample size.</p> <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	Dr. Aby Mathew T
02/2023	<p>Knowledge and Attitude about Obstructive Sleep Apnoea among dental students in Kerala, India</p> <p>Motion: Comments:</p> <p>No Comments</p> <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	Dr. Ivin Elsa John

<p>03/2023</p>	<p>Breaking bad news: Communication skill of dentists</p> <p>Motion: Comments:</p> <p>As your PI is from abroad, is he supporting your study or are you including dentists from there also? Will you be providing the questionnaire online?</p> <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	<p>Dr. Sunu Alice Cherian</p>
<p>04/2023</p>	<p>Comparative study on the effect of citicoline Supplementation in the treatment of AVN (avascular necrosis) of femoral head.</p> <p>Motion: Comments:</p> <p>Will you get the adequate sample size? Can you consider a multicentric study?</p> <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	<p>Dr. P S John</p>
<p>05/2023</p>	<p>Comparative study on the effect of citicoline versus Calcium in aseptic loosening of total hip arthroplasty.</p> <p>Motion: Comments: Nil</p>	<p>Dr. P S John</p>

	<p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	
06/2023	<p>Identification of multimorbidity clusters and statistical modelling of associated risk factors among older adults of Kerala</p> <p>Motion: Comments:</p> <ol style="list-style-type: none"> 1. What is the sample size of your study? <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	<p>Dr. Nisha Kurian</p>
07/2023	<p>Anatomical study on Retrohepatic segment of Inferior vena cava and variation in the pattern of hepatic vein ostia in South Kerala population</p> <p>Motion: Comments:</p> <ol style="list-style-type: none"> 1. Are these not prescribed earlier 2. What is the implication of this study <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	<p>Dr. Stelin Agnes Michael</p>
08/2023	<p>Gross anatomical study of variations of Human liver in South Kerala population</p> <p>Motion: Comments:</p> <p>Nil</p> <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	<p>Dr. Stelin Agnes Michael</p>

<p>09/2023</p>	<p>Opinions and Experiences about patients online access to their full health records – A mixed method study among the stake holders in Kerala</p> <p>Motion: Comments:</p> <p>Nil</p> <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	<p>Dr. Gaddam Vijaya Lakshmi</p>
<p>10/2023</p>	<p>Cost effectiveness analysis of Unfractionated Heparin and Low molecular weight heparin: Enoxaparin among patients with acute myocardial infarction in a tertiary care hospital</p> <p>Motion: Comments: Nil</p> <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	<p>Dr. Liya Roslin Joseph</p>
<p>11/2023</p>	<p>Comparison of pregnancy outcome and medical complications in elderly primigravida with that of younger primigravida.</p> <p>Motion: Comments:</p> <ol style="list-style-type: none"> 1. Is this an observational study 2. What is the novelty of the study 3. How are you going to follow-up the patients upto delivery 	<p>Dr. Fathimma Ali</p>

	<p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	
12/2023	<p>Evaluation of bacteriophages as biotherapeutic agents for chronic wound infections</p> <p>Motion: Comments:</p> <ol style="list-style-type: none"> 1. What is the hypotheis of the study? 2. What is the novelty in this study? 3. Will you be getting approval from the animal ethics committee? <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	<p>Dr. Yogesh Bharat Dalvi</p>
13/2023	<p>Study of microbiomes of implanted urinary catheter and development of Catheter biopolymer with reduced biofilm formation</p> <p>Motion: Comments:</p> <ol style="list-style-type: none"> 1. What is the source of funding? 2. Based on past experiences what is the percentage of catheter biofilm? 3. Will you be considering only samples with catheter biofilm? <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	<p>Dr. Reena Thomas</p>
14/2023	<p>Personality profile of patients with alcohol use disorder attending deaddiction clinic of a tertiary care centre in southern India</p> <p>Motion:</p>	<p>Dr. Vijayalal Vijayan</p>

	<p>Comments:</p> <ol style="list-style-type: none"> 1. How many types of personality disorders are you expecting to get? 2. Will the sample size be enough to do group analysis 3. Are you trying to state that people with personality disorders are more prone to alcohol dependence or vice versa. <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	
15/2023	<p>Assessment of pattern of eating behaviour and its association with Non Alcoholic Fatty Liver Disease.</p> <p>Motion: Comments:</p> <ol style="list-style-type: none"> 1. What is your objective of the study? 2. How will you screen your control patients? 3. When will you interview your patients? 4. Are you including only new cases of fatty liver? <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	<p>Dr. Punya Chandran.</p>
16/2023	<p>Maternal and fetal outcome in pregnant women with threatened Miscarriage</p> <p>Motion: Comments:</p> <ol style="list-style-type: none"> 1. As there are many published studies done in Kerala, what is the novelty of this study? 	<p>Dr. Riya Mary Saju</p>

	<p>2. What is the justification for carrying out this study?</p> <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	
17/2023	<p>Correlation between risk factors of cardiovascular diseases and carotid intima media thickness (CIMT) in chronic kidney disease patients admitted in tertiary care centre in Kerala.</p> <p>Motion: Comments:</p> <p>1. What is the novelty in this study?</p> <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	Dr. Chandana Ram
18/2023	<p>Variations in origin and branching pattern of Coeliac Trunk and Superior Mesenteric Artery among patients undergoing abdominal imaging in a Tertiary Care Centre in South Kerala</p> <p>Motion: Comments:</p> <p>1. Is this a retrospective study? 2. Will you be able to trace the course of the artery in the specimen? 3. Do you need special tools for this?</p>	Dr. Gaddam Vijaya Lakshmi

	*The PI will start the study only after the receipt of approval letter by the Committee.	
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**INSTITUTIONAL REVIEW BOARD
PUSHPAGIRI INSTITUTE OF MEDICAL SCIENCES & RESEARCH CENTRE**

No: IRB/02/2023

6th May, 2023

Minutes of the IRB committee

1. Due to the prevailing Covid -19 pandemic, the IRB meeting was scheduled online (Google Meet) on **25th April, 2023**. The IRB Members and the Principal investigators were given the meet link before hand and were requested to join at 09 am on **25th April, 2023**. The IRB Chairman welcomed Dr. Arun M Xavier, Amrita School of Dentistry.
2. The previous minutes of the IRB Meeting was approved in this meeting.

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 Tressia Alias Princy Paulose	PhD Chemistry	Member
Dr. Stephen James	M Tech	Member
Dr. Rosin George Varghese	Assistant Professor, Department of Community Medicine	Internal Member
Dr. Arun M Xavier	Amrita School 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: 13 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
<ul style="list-style-type: none"> General Discussion: Previous Meeting Minutes Approval Welcoming of Dr. Arun M Xavier, Amrita School of Dentistry 		
<p>01/2023</p>	<p>Role of Natriuretic Peptides and Inflammatory Markers levels in Hypercholesterolemia: A Case Control Study</p> <p>Motion: Comments:</p> <p>Dr. Liya</p> <ol style="list-style-type: none"> 1.Explain how you will select case and control in your study? 2. How to overcome bias in selecting patients 3. Does age have any role in your study? 4. Are you going age and gender matching? <p>Dr. Rosin</p> <ol style="list-style-type: none"> 5. What are the inclusion criteria for selecting the patients? 6. Sample size calculation recalculate as per the objective stated. 7. suggestion - Study setting centre can include general medicine area <p>Dr. Athulya</p> <ol style="list-style-type: none"> 8.Better to include newly diagnosed patients with dyslipidemia than those on treatment. 9. Study duration seems quite short for patient recruitment 10. Is it a case control study??A prospective observational study would be a better term. 11. Funding of the study and budget not clear <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	<p>Dr. Soumya R S</p>
<p>02/2023</p>	<p>Role of vitamin D in sleep quality of medical undergraduate students.</p> <p>Motion: Comments:</p>	<p>Dr. Amrutha Mary Zacharia</p>

Dr. Nebu

1. Students are considered as vulnerable population- there are chances of Bias in the study if you select students from you own institution
2. Better to do study in another institution

Dr. Liya

3. Since you are withdrawing blood, better to include this in the consent form
4. Students should not be charged for testing the blood
5. Consider the Confounders in your study and exclude them

Dr. Chary

6. Which form of Vitamin D are you analysing
7. Why not analysing 125 form of vitamin D
8. Title is confusing. Kindly reframe as correlation/ association

Dr. Rosin

9. What is the primary objective?
10. Include all data obtained which can be used for further analysis

Dr. Athulya

11. Kindly provide details on the funding of the study.
12. There can be many confounders for the study like using electronic devices close to bed time, meeting deadlines/ stress during exams, a sleeping environment that is noisy or not having the right temperature. Kindly modify the Performa so as to minimize confounders or modify the inclusion/exclusion criteria.

*The PI will start the study only after the receipt of approval letter by the Committee.

<p>03/2023</p>	<p>Antidepressant Prescription Patterns and Clinical Correlates within Psychiatry Treatment Settings in Asia: A Cross Sectional REAP Consortium Study (REAP-AD3)</p> <p>Motion: Comments:</p> <p>Dr. Rosin</p> <ol style="list-style-type: none"> 1. What will be the criteria for selecting the patients? 2. What is your sample size? 3. How many centres have you selected for this study? <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	<p>Dr. Roy Abraham Kallivayalil</p>
<p>04/2023</p>	<p>Central Venous Access Device Management in Critical Care Units – A Multicentric Implementation Project in Low Resource Setting</p> <p>Motion: Comments : Nil</p> <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	<p>Dr. Sunu Alice Cherian</p>
<p>05/2023</p>	<p>Penetration depth of irrigants into root dentine after Activation using manual dynamic activation, Navitip Fx, Sonic and Xp Endo finisher file – An in vitro study</p> <p>Motion: Comments:</p> <p>Dr. Arun</p> <ol style="list-style-type: none"> 1. Protocol is submitted in PDF format. Reformat it to the IRB protocol sample. 2. Suggestion to include comparative study in the title 3. Are you only including only manual methods? 	<p>Dr . Aswathi U</p>

	<ol style="list-style-type: none"> 4. What are the expected findings in your study? 5. What studies are considered in sample size calculation? 6. No citation was included in sample size calculation slide 7. Its better to change Group O to control group 8. Who will take and upload the images? 9. What is the quantity of methylene blue used in your study? 10. Who will assess the median penetration? 11. What are the expected outcome? <p>Dr Rosin</p> <ol style="list-style-type: none"> 1. What was the sample size that came out after calculating with the formula? <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	
<p>06/2023</p>	<p>Comparative evaluation of caries removal with smart bur and ceramic bur -an in vitro CBCT volumetric study</p> <p>Motion: Comments:</p> <p>Dr. Arun</p> <ol style="list-style-type: none"> 1. In the summary of the protocol cite references 2. Cite your key article in the protocol 3. Sample size calculation need clarity 4. How are you going to standardise the teeth used for the study 5. What are your inclusion and exclusion criteria? 6. Mention how are you going to standardise the decay? Its always better to follow a criteria 7. How will you measure the volume of caries removal? 8. Include this in the protocol is separate software is used. 9. Include the flow chart in the protocol. 	<p>Dr. T A Arif</p>

	<p>10. What is the difference between 2 types of burs? 11. The study outcome mentioned is not clear. 12. What is the dye used for detection of caries? What quantity and time will dye be used?</p> <p>Dr. Rosin</p> <p>1. How will you divide the sample size and how will you select which bur to be used in which tooth?</p> <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	
<p>07/2023</p>	<p>Comparative Evaluation Of The Influence Of Temperature On The Cyclic Fatigue Of Reciproc Blue And Waveone Gold, Reciprocating Files – An Invitro Study</p> <p>Motion: Comments:</p> <p>Dr. Arun</p> <ol style="list-style-type: none"> 1. In research problem and summary cite references. 2. What is the difference between cyclic fatigue and cyclic fatigue resistance? 3. Why did you chose temperature at 35 and 39 degree Celsius? 4. How will you maintain the temperature? 5. Does instrument has thermometer attached? 6. In sample size calculation, cite references 7. Why is sample size high? 8. What was the results of the key article? 9. Are you checking both groups at sample temperature? 10. What is machine oil used in this study? 11. Where are you doing the analysis? 12. Who charted the budget for your study? 	<p>Dr. Ajanya K</p>

	<p>Dr. Rosin</p> <ol style="list-style-type: none"> 1. Are you using the same file system in you key article? 2. Its better to find out a study that used same material as you have planned. <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	
08/2023	<p>Comparative Analysis Of The Levels Of Tissue Inhibitors Of MMP In GCF Using Micro Osteoperforation Induced And Conventional Canine Retraction Technique</p> <p>Motion: Comments:</p> <p>Dr. Arun</p> <ol style="list-style-type: none"> 1. Why do we need to know the biological action in MOP? 2. How do you expect change in current treatment modality? 3. Cost of performing MOP 4. In sample size add the key article. 5. Will you be considering diet, oral hygiene while selecting the patients? How will you monitor this? 6. How will you monitor the entire study? 7. What are the exclusion criteria? <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	<p>Dr. Drishya Padmanabhan</p>
09/2023	<p>A Comparative Analysis Of The Levels Of Runx2 In Gcf Using Micro-Osteoperforation Induced And Conventional Canine Retraction Techniques</p> <p>Motion: Comments:</p>	<p>Dr. Manjusha Baker</p>

	<p>Dr. Arun</p> <ol style="list-style-type: none"> 1. From where will you purchase the ELISA kit? 2. How long will it take to reach you? <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	
10/2023	<p>In-Vitro Comparative Assessment Of Bone Regenerative Potential Of Fish Scale Derived Hydroxyapatite Loaded With Simvastatin And Fish Scale Derived Hydroxyapatite.</p> <p>Motion: Comments:</p> <p>Dr. Arun</p> <ol style="list-style-type: none"> 1. Suggestion to reframe the objectives 2. Are there similar studies done in your department? 3. What are the expected outcome? 4. Are you checking for the biofunctionality of the graft? <p>Dr. rosin</p> <ol style="list-style-type: none"> 1. What is the variable used for sample size calculation? 2. Are you considering systolic blood pressure as mentioned in your protocol? <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	Dr. Lekshmi M
11/2023	<p>Comparative Assessment Of Salivary Cystatin C Levels In Healthy And Severe Periodontitis Patients.</p> <p>Motion: Comments:</p>	Dr. Kavya S

	<p>Dr. Arun</p> <ol style="list-style-type: none"> 1. Why can't you have 2 groups – stage 3 and stage 4 2. Better to stick on to a particular group either 3 or 4 3. Is Cystatin already studied in literature? 4. Is there any novelty in this study? <p>Dr. Rosin</p> <p>Sample size has to be re calculated.</p> <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	
<p>12/2023</p>	<p>The Comparative Evaluation Of Biocompatibility In Synthetic And Fish Scale Derived Hydroxyapatite Coated Titanium Implant:-An Invitro Study.</p> <p>Motion: Comments:</p> <p>Dr. Arun</p> <ol style="list-style-type: none"> 1. Is there any study proving osseintegration in fish scales is better than synthetic hydroxyapatite? 2. Are you checking for Osteopontic expression? <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	<p>Dr Merin Basil</p>

<p>13/2023</p>	<p>Comparative Evaluation Of Flexural Strength And Surface Roughness Of Denture Base Resins Incorporated With Zirconium Oxide Nanoparticles And Thymoquinone - Antimicrobial Agents- An In-Vitro Study.</p> <p>Motion: Comments:</p> <p>Dr Arun</p> <ol style="list-style-type: none"> 1. What is the novelty in your study? 2. What are the study centres? 3. How will you consider the methodology by following any previous studies? <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	<p>Dr. Riya Sabu</p>
<p>14/2023</p>	<p>Comparative Evaluation Of Static Compressive Strength And Fractography Analysis Between Conventional Titanium Implants And Alumina Toughened Zirconia Implants: An In-Vitro Study</p> <p>Motion: Comments:</p> <ol style="list-style-type: none"> 1. What are the disadvantage of Zirconia? 2. Where are both tests being done? 3. Why do you consider both conventional and customised implants? 4. How are samples being considered? 5. Modify the methodology and reframe it 6. Table of analysis not in the protocol <p>Dr.Rosin</p> <ol style="list-style-type: none"> 1. What is the sample size 2. Recalculate the sample size <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	<p>Dr. Girish Harikumar</p>

15/2023	<p>Assessment Of Occlusal Derrangement Using T Scan In Patients Treated With Orif For Fracture Of Maxilla And Mandible –A Prospective Longitudinal Study</p> <p>Motion: Comments:</p> <p>Dr. Arun</p> <ol style="list-style-type: none"> 1. Can all variables be measured by T scan 2. Exclusion criteria non TMJ patients have to be added in protocol <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	Dr. Shyam
16/2023	<p>Comparative Evaluation Of Stability Of Single Titanium 4-Hole Miniplate, Two Titanium 4-Hole Miniplates And Single Titanium 4-Hole 3d Plate In Open Reduction And Internal Fixation Of Mandibular Angle Fractures: An In Vitro Study In Capra Aegagrus Malabaricus</p> <p>Motion: Comments:</p> <ol style="list-style-type: none"> 1. What is the difference between group 2 and 3? 2. Are you following the standard protocol in you study? 3. Why was the budget Rs 75,000/? 4. How easy is it to collect goat mandible? 5. References have to be cited. <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	Dr. Adithya Uday

	LUNCH BREAK	
17/2023	<p>Comparative evaluation of changes in vertical dimension of occlusion and gingival crevicular fluid biomarker TNFα following the placement of Stainless steel crowns by Hall technique and Conventional technique – A split mouth study</p> <p>Motion: Comments:</p> <p>Dr. Arun</p> <ol style="list-style-type: none"> 1. How was sample size calculated? 2. Cite the references of the article. 3. Add reference for each part of methodology 4. Make sure the patients you chose have good level of oral hygiene and have got all decayed tooth restored. <p>Dr. Rosin</p> <ol style="list-style-type: none"> 1. Sample size has to be recalculated <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	Dr. Namitha Jayan
18/2023	<p>Comparative Evaluation Of The Remineralizing Effects Of Nanohydroxyapatite And Sodium Fluoride Containing Tooth Paste On Artificially Induced Dental Caries Of Human Enamel – An Invitro Study</p> <p>Motion: Comments:</p> <p>Dr. Arun</p> <ol style="list-style-type: none"> 1. Add reference regarding sample size calculation 2. What is the primary and secondary outcome of this study? 3. How will you take sample size from block/ embedded throughout the study 	Dr. Jinimol

	<p>4. Is methodology designed as per the key article?</p> <p>5. How will you simulate oral environment?</p> <p>6. As the protocol submitted was different from what was presented today, you will have to resubmit the proposals with all corrections.</p> <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	
<p>19/2023</p>	<p>Identifying DNA Methylation Based Biomarker(S) In The Progression Of Oral Squamous Cell Carcinoma: A Cross Sectional Study.</p> <p>Motion:</p> <p>Comments:</p> <p>Dr. Arun</p> <ol style="list-style-type: none"> 1. Have you already selected the patients? 2. Will you use a standardised questionnaire before selecting the patients? 3. What are your inclusion criteria? 4. Should your patients have any lesions? 5. Till what stage of cancer will you select for your study? 6. How will you check for methylation profile? 7. What is the reason for choosing the markers? 8. What are the study outcomes? <p>Dr. Rosin</p> <ol style="list-style-type: none"> 1. Will you be looking for role of alcohol in your study? 2. Better to include control in you study while assessing habit 3. What are you planning to do with patients with habits? 4. Will you take samples from 3 sites always for biopsy? 	<p>Dr. Sharlene Sara Babu</p>

	<p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	
20/2023	<p>Cardiometabolic Risk And Periodontal Disease</p> <p>Motion: Comments:</p> <p>Dr. Arun</p> <p>Why did you choose MMP-8?</p> <ol style="list-style-type: none"> 2. What are the clinical parameters checked in general medicine? 3. What is the need of estimating MMP-8 from both blood and saliva? 4. Name the co-investigators in this study. 5. Are you expecting any outcome change as per specific geographic locations? 6. As there is huge variation range in terms of age, will there be variation in the results. Its better to categorise as per the age group. 7. Suggestion to remove the term convenient sampling. <p>Dr. Rosin</p> <ol style="list-style-type: none"> 1. How did you select the sample size? 2. What study design are you following? <p>*The PI will start the study only after the receipt of approval letter by the Committee.</p>	<p>Dr. Julie Toby</p>

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Principal
Pushpagiri College of Dental Sciences


