IRB: 01/2022 **12th January, 2022**

Minutes of the IRB committee

1. Due to the prevailing Covid -19 pandemic situation, the IRB meeting was scheduled on an online platform (Google Meet) on **11th January, 2022**. The IRB Members and the Principal investigators were given the zoom link before head and were requested to join at 12pm on **11th January, 2022**. 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

S.No.	Name	Primary Scientific or Non-scientific Specialty	Role in IEC
1	Dr Harikumar B Nair	Primary	Chairperson
2	Dr Nebu George Thomas	Primary	Member Secretary
3	Rev Dr. Mathew Mazhavancheril	Primary	Member
4	Dr Vikram Gowda	Primary	Member
5	Dr Liya Roslin Joseph	Primary	Member
6	Dr Philip Mathew	Primary	Member
7	Dr Krishnan Namboodiri	Primary	Member
8	Dr Athulya G Asokan	Primary	Member
9	Dr Tressia Alias Princy Paulose	Primary	Member
10.	Dr. Melvin	Primary	Guest

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: 10 out of 10.

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: Prevalence of oral manifestations post COVID-19 among the adult population of the state of Kerala, India.

Principal Investigator: Dr. Nebu George Thomas

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

Dr Melvin

1. How can you tell the oral manifestations are related to Covid -19 infection
2. Is this a multicentric study??

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

IRB Study Reference No: 02/2022

Protocol Title: Assessment of Survival Rate, Success rate and patient satisfaction of Dental Implants

Principal Investigator: Dr. Prameetha George Ittycheria

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

Dr. Nebu

1. What is the age criteria for your study?
2. What all hard tissue findings are you going to assess?
3. Which radiographic modality are u selecting?
4. Is cbct better than rvg?
5. Suggestion: It is always better to select a particular age group
6. Are you assessing prosthetic component in your study

Dr chary

How did you calculate sample size?

Dr. Athulya

1. How are you going to assess survival rate of implant?
2. Is there a pre-definition for survival rate
3. How will you overcome placement bias

Dr. Melvin

1. It would be better if you can give a cut off time period for longitudinal assessment of implant
2. This is not a prospective study, it is a retrospective cohort study

Dr. Liya

1. Suggestion to add point regarding survival rate

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

IRB Study Reference No: 03/2022

Protocol Title: Comparison of Peyton's four-step approach with conventional bedside technique in teaching clinical examination skills to MBBS students – An interventional study

Principal Investigator: Dr. Sajit Varghese

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

Dr. Chary

1. Which skills are you going to evaluate?

Dr. Minu Mathew

1. Are you getting help from GMC – Kottayam, if so at which stage are you going to get their help?

Reply Comments

1) The 3 skills sets which I will be evaluating are : Examination of Tone, Examination of Deep tendon reflexes, Examination of signs of free fluid in abdomen.
(Please see the details of these in the attachments I have already sent - the draft proposal and annexures for OSCE).
2) I am pursuing the ACME (Advanced Course in Medical Education) under the NMC NODAL CENTER FOR FACULTY DEVELOPMENT, at GMC KOTTAYAM. This research is a part of this course and has to be conducted by me at my institution itself (Pushpagiri MCH) within a year. I am not getting any financial or any other help from GMC Kottayam or elsewhere, at any stage.

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

IRB Study Reference No: 04/2022

Protocol Title: Effectiveness of Direct Observation of Procedural Skills (DOPS) as formative assessment in surgical hand scrub among interns in Orthopaedics – an interventional study

Principal Investigator: Dr. Kiran R

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments: Nil

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

IRB Study Reference No: 05/2022

Protocol Title: Atypical clinical presentation and late diagnosis: A retrospective study of complicated and uncomplicated appendicitis in pediatric age groups

Principal Investigator: Dr. John Joseph

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

Dr. Melvin

1. Is there similar studies or data in literature in last 10 years?

Reply Comments

1) Zenon Pogorelic et al. Acute appendicitis in children younger than five years of age:Diagnostic challenge of pediatric surgeons. Surg Infect (Larchmt) (2020)
2) Hamdi Hameed Almaramhy. Acute appendicitis in young children less than 5 years. Italian Journal of Pediatrics (2017)
3) S. Bansal et al. Appendicitis in children less than 5 years old: influence of age and presentation and outcome. The American Journal of Surgery (2012)

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

IRB Study Reference No: 06/2022

Protocol Title: Limberg's Flap Procedure for sacrococcygeal pilonidal sinus in a tertiary care centre – a retrospective study

Principal Investigator: Dr. Manoj Gopal V

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

Dr. Melvin

1. On what basis can you say this procedure is effective
2. Do you have a control group?
3. Since it's a research, it is always better to have a control group to check effectiveness
4. If no control is included , then it is a limitation of the study
5. Is this the only procedure that has been carried out for pilonidal disease in the dept.? Are there other patients with pilonidal sinus who have gone through an alternative procedure who can act as a control group?
6. Can the authors consider doing an analysis of factors that can increase the risk of complications in patients who have gone through the Limberg's flap procedure?

Reply Comments

1. On what basis can you say this procedure is effective?
The usual complications encountered after any procedure for sacrococcygeal pilonidal sinus disease include seroma formation, wound infection and recurrence. All three of these can be minimalized by using limberg's flap procedure as the treatment option.

2. Do you have a control group?
Since Limberg's flap procedure is emerging as the standard of acre for pilonidal sinus disease, all patients included in the study have undergone the same procedure. This however is a limitation of the study. But from data obtained from other research studies done at other centres, other treatment procedures such as Bascombe or Karydaki's procedure is associated with higher rates of complications. The study is proposed to be descriptive.

3. Can the authors consider doing an analysis of factors that can increase the risk of complications in patients who have gone through the Limberg flap procedure?
Since the complications studied in this research are minimal with Limberg's flap procedure, an accurate analysis of the risk factors for complications is difficult to pursue. However, we propose to give a few suggestions based on the outcomes of the study.

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

IRB Study Reference No: 07/2022

Protocol Title: Tacking of lax transversalis fascia and seroma in laproscopic direct inguinal hernia repair in a tertiary care centre in South Kerala-A retrospective study

Principal Investigator: Dr. Manoj Gopal V

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

Dr. Melvin

1. As all patients are going through same procedure how can you tell this packing caused seroma?
2. A control group is needed to compare
3. How can you say this procedure is beneficial unless you have a control group
4. Its better if you can revise your research methodology
5. Please justify on how conclusions can be made without a control group of patients who did not undergo the procedure.

Dr. Nebu

Resubmit the proposal

Reply Comments

1. As all patients are going through the same procedure how can you tell this packing caused seroma?

Seroma formation is one of most common complication in all large direct hernia repair.So my study how much this procedure can prevent formation of seroma

2. A control group is needed to compare :No need of any comparison as its a descriptive study .Previous researches are done on diffrent techniques was also with out any control group.1 .Li J, Zhang W. Closure of a direct inguinal hernia defect in laparoscopic repair with barbed suture: a simple method to prevent seroma formation? Surg Endosc. 2018 Feb;32(2):1082-1086. doi: 10.1007/s00464-017-5760-1. Epub 2017 Aug 4. PMID: 28779243.
3. How can you say this procedure is beneficial unless you have a control group:Seroma formation is common in post laproscopic direct hernia repair so my study is that how effective is this technique for prevention of these common seroma

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

IRB Study Reference No: 08/2022

Protocol Title: A Comparative study on the effect of therapeutic ultrasound supplemented with citicholine versus therapeutic ultrasound and placebo in non-union of fractures.

Principal Investigator: Dr. John P S
Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

Dr. Melvin

1. On what basis will patients receive citicholine and control drug
2. Suggestion is when you compare 2 groups it is always better to do Randomised Control trial
3. How are you going to evaluate the outcome of this study

Dr. Chary

1. It is better if you give one group Calcium and other group calcium and citicholine

Dr. Thankappan

1. When a new drug is used for an indication or a drug is used for new indication, is it mandatory to have CTRI registration?

1. On what basis will patients receive citicoline and control drug

I am panning a randomized comparative study with one group receiving therapeutic ultrasound along with citicholine and the other group receiving therapeutic ultrasound and calcium . Randdomisation is done by computer generated blocks.

2. Suggestion is when you compare 2 groups it is always better to do Randomized Control trial.

It is fully agreed sir. I am planning a randomized control study.

3. How are you going to evaluate the outcome of this study?

Radiological evaluation of healing of non-union by a radiologist who is blinded.

4. It is better if you give one group Calcium and other group calcium and citicholine

The research question here is whether citicholine can complement the fracture healing property of therapeutic ultrasound. It has been proved in most of the studies that calcium has no stimulatory role in fracture healing and most often the role of calcium is like a placebo. Hence citicholine and therapeutic ultrasound in one group is compared to therapeutic ultrasound and calcium as a placebo in the other group.

5. Are you going to use any drug as placebo? Yes sir. In one group calcium is given as a placebo.

6. Does this study require CTRI registration? Therapeutic ultrasound is a popular non-invasive modality of treatment for non- union, accepted all over the world. Citicholine and calcium are safe, supplements extensively used clinically. Hence I think there is no need for CTRI registration. However I would like to apply for CTRI registration for the purpose of publishing in good impact journals.

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

IRB Study Reference No: 09/2022

Protocol Title: Assessment of the sleep quality and daytime sleepiness among the undergraduate medical students and its relationship with their academic performance.

Principal Investigator: Dr. Punya Chandran

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

Dr. Melvin

1. Are you including students from outside college?
2. How will you obtain academic performance?
3. You need to plan how to move forward with this study
4. You should have a consent in your questionnaire mentioning their marks will be assessed

Dr. Athulya

1. How will you assess to different colleges
2. You will need to obtain permissions for the same

Dr. Chary

1. Which assessment will you consider internal assessment or university exam
2. Which year students will you consider
3. Is the marks obtained directly proportional to sleep quality

Dr. Liya

1. Many confounding factors are involved to get outcome of the study. How will you overcome this?
2. Consider all the factors before proceeding with the study

Dr. Nebu

1. Expand Research Problem
2. Add smart objectives for aims and objectives
3. If any vulnerable group is included in the study provide justification (Eg students, pregnant women)

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

Reply Comment

1. As per the advice from the IRB we are not planning to include students from outside the institution.

2. Academic performance will be obtained by from the marks students get in the university examination.

3. Definite plan has been made regarding the study.

4. It has been mentioned in the consent form that the marks of the students will be taken as a part of the study.

5. The study has been modified in a way that only students from our institution are included.

6. Answer same as that of the fifth question.

7. University assessment marks will be taken to avoid potential confounding factors.

8. First semester to seventh semester students will be invited to participate in the study.

9. We plan to assess the sleep quality of the students and then compare it with their academic performance at appoint of time. Previous studies have shown that poor sleep quality is associated with poor academic performance among undergraduate medical students.

10. The confounding factor mentioned in the IRB was that the assessment tool for academic performance shall not be the internal assessment marks because there will be wide variation in the evaluation and award of internal assessment marks among the different medical colleges inside the same university itself. In order to address this problem, we are modifying the study so that only medical students from our institution will be included in the study and also the university examination marks rather than the internal assessment examination marks will be taken as the parameter to assess the academic performance.

11. The confounding factors will be definitely considered and all attempts will be made to rectify them.

12. There has been an increased prevalence of poor sleep quality and excessive daytime sleepiness among medical students. Previous studies have shown that poor sleep quality and excessive daytime sleepiness both have a relationship with their academic performance. Our research problem is “what is the effect of poor sleep quality (found out by the Pittsburgh sleep Quality Index) and excessive daytime sleepiness (assessed by Epworth Sleep scale) on the academic performance of undergraduate medical students”.

13. Aim: To assess the quality of sleep and day time sleepiness among undergraduate medical students and its relationship with their academic performance.

Primary objective: To determine the sleep quality and daytime sleepiness among undergraduate medical students.

Secondary objective: to assess the relationship between poor sleep quality and excessive daytime sleepiness with their academic performance.

14. No vulnerable group (children, pregnant women) are included in this study. Undergraduate medical students from first to seventh semesters are invited to participate in this study.

Written informed consent will be send through mail to all students in the respective semesters as mentioned above, before the commencement of the study. Only those who are willing to participate by filling the consent form will be included in the study. Since the principal investigator being a faculty in the Phase I subjects, a co- investigator from phase II will be conducting the survey for phase I students.

IRB Study Reference No: 10/2022

Protocol Title: Correlates of the suicide crisis syndrome in major depression: A Multicentric Exploratory study

Principal Investigator: Dr. Roy Abraham Kallivayalil

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

Dr. Melvin

1. Since it's a Multicentric study, who will be collecting the data
2. Choice of patients should be carefully considered.

Reply Comments

1. The Co- Investigators
2. Will strictly follow the inclusion and exclusion criteria

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

IRB Study Reference No: 11/2022

Protocol Title: A study to evaluate safety and efficacy of endoxifen in patients with bipolar I disorder

Principal Investigator: Dr. Roy Abraham Kallivayalil

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

Dr. Melvin

1. Is this a regulatory study? Has any approval been taken from the DCGI office for this study as a post marketing study?

2. Are all study staff trained in Good clinical practice? Please furnish the GCP training certificate of all study team members.

3. Sponsor needs to provide insurance so that in case SAE happens, compensation may be paid for the same through insurance

4. The patient information sheet is missing in English and Malayalam.

5. The consent form in Malayalam is missing. Kindly check. I was not able to find it.

6. Has this trial been registered in CTRI?

7. Is this a multi-centric study? Which are the other sites? Have they obtained IEC clearance?

8. When patients are asked to stop taking regular medication and switch over to study medication, how do you propose to monitor any potential adverse events occurring due to stoppage of therapy?

9. Which brand of endoxifen is being used? Has the investigator's brochure/package insert been provided for it?

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

Reply Comments

1. Has any approval been taken from the DCGI office for this study as a post marketing study?
   Yes, this is a regulatory study. DCGI approval has already been taken.
2. Document attached. Are all study staff trained in Good clinical practice? Please furnish the GCP training certificate of all study team members.
   The site will provide GCP certification for all the study team (PI, CO-I and Study Coordinator)
3. Sponsor needs to provide insurance so that in case SAE happens, compensation may be paid for the same through insurance.
   Insurance has been already purchased. Refer attachments.
4. The patient information sheet is missing in English and Malayalam.
   Attached
5. The consent form in Malayalam is missing. Kindly check. I was not able to find it.
   Attached
6. Has this trial been registered in CTRI?
   Yes
7. Is this a multi-centric study? Which are the other sites? Have they obtained IEC clearance?
   Yes, it is a multicentric study.
8. When patients are asked to stop taking regular medication and switch over to study medication, how do you propose to monitor any potential adverse events occurring due to stoppage of therapy?
   In the course of any adverse event PI will manage the subject as per protocol
9. Which brand of endoxifen is being used? Has the investigator's brochure/package insert been provided for it? Sponsor is INTAS pharmaceuticals.
   Zonalta, the investigator’s package is attached.

IRB Study Reference No: 12/2022

Protocol Title: Perception and knowledge regarding end of life care practices and certifying death among medical interns in medical colleges of south Kerala

Principal Investigator: Dr Sharon Raj Eliza

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments: Nil

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

IRB Study Reference No: 13/2022

Protocol Title: The role of social empowerment and community participation in supporting older people during a crisis situation

Principal Investigator: Dr. Sherin Susan Paul

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments: Nil

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

IRB Study Reference No: 14/2022

Protocol Title: Common food preferences of community dwelling older adults and the elements that shape them.

Principal Investigator: Dr. Betsy A Jose

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments: Nil

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

IRB Study Reference No: 15/2022

Protocol Title: Conventional hands-on training versus video assisted demonstration to teach suturing skill for MBBS students.

Principal Investigator: Dr. Robinson George

Primary reviewer of IRB: Comments from IRB Member
Motion:
Comments: Nil

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

II. PROTOCOL CHANGES : Nil

III. RETROSPECTIVE REVIEW: Nil

IV. OTHER ISSUES DISCUSSED: Nil

The meeting ended at 2:00pm

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Member Secretary
Institutional Review Board

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

PUSHPAGIRI COLLEGE OF DENTAL SCIENCES
PUSHPAGIRI
MEDICITY
TIRUVALLA-7

IRB: 03/2022 **18th August, 2022**

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 head 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 Resarch 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 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. Philip Mathew	Associate Professor of Department of Community medicine	Member
Dr. Stephen James	M Tech	Member
Dr. Arun Mammechen	Associate Professor from Amrita School of Dental Sciences**.**	External Subject Expert

Members Absent with apologies: NIL

Non-Voting Member: NIL

Members alternating: NIL

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

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 fill the second and thrid objective?
2. Will you be giving seperate 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 seperate 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 hetrogenous 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 multicentic 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

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 investigaors list and centre of study.
3. Who is the coorinator 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 obejective – 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 refrence 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:

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

PUSHPAGIRI COLLEGE OF DENTAL SCIENCES
PUSHPAGIRI
MEDICITY
TIRUVALLA-7

INSTITUTIONAL REVIEW BOARD MEETING

No: IRB/01/2022 11th, January, 2022

AGENDA

This is to inform you that the meeting of the IRB will be held on 11th January, 2022 **@ 10:00am (Tuesday) through Google meet platform.** All members are requested to attend the meeting.

General Discussion: Previous Meeting Minutes Approval Welcoming of Dr. Melvin, Associate Professor from SRM Medical College Hospital and Research Centre			
S.No.	**Name of the Principal Investigator**	**Title of the Proposal**	**Time Slot**
1.	**Dr. Nebu George Thomas**	Prevalence of Oral Manifestations post COVID-19 among the adult population of the state of Kerala, India.	10:15am
2.	**Dr. Prameetha George Ittycheria**	Assessment of Survival Rate, Success rate and patient satisfaction of Dental Implants	10:30am
3.	**Dr. Sajit Varghese**	Comparison of Peyton's four-step approach with conventional bedside technique in teaching clinical examination skills to MBBS students – An interventional study	10:45am
4.	**Dr. Kiran R**	Effectiveness of Direct Observation of Procedural Skills (DOPS) as formative assessment in surgical hand scrub among interns in Orthopaedics – an interventional study	11:00am
5.	**Dr. John Joseph**	Atypical clinical presentation and late diagnosis: A retrospective study of complicated and uncomplicated appendicitis in pediatric age groups.	11:15am
6.	**Dr. Manoj Gopal V**	Tacking of lax transversalis fascia and seroma in laproscopic direct inguinal hernia repair in a tertiary care centre in South Kerala-A retrospective study	11:30am

7.	**Dr. Manoj Gopal V**	Limberg's Flap Procedure for sacrococcygeal pilonidal sinus in a tertiary care centre – a retrospective study	11:45am
8.	**Dr. John P S**	A Comparative study on the effect of therapeutic ultrasound supplemented with citicholine versus therapeutic ultrasound and placebo in non-union of fractures.	12:00pm
9.	**Dr. Punya Chandran**	Assessment of the sleep quality and daytime sleepiness among the undergraduate medical students and its relationship with their academic performance.	12:15pm
10.	**Dr. Roy Abraham Kallivayalil**	Correlates of the suicide crisis syndrome in major depression: A Multicentric exploratory study .	12:30pm
11.	**Dr. Roy Abraham Kallivayalil**	A study to evaluate safety and efficacy of endoxifen in patients with bipolar I disorder	12:45pm
12.	**Dr Sharon Raj Eliza**	Perception and knowledge regarding end of life care practices and certifying death among medical interns in medical colleges of south Kerala	01:00pm
13.	**Dr. Sherin Susan Paul**	The role of social empowerment and community participation in supporting older people during a crisis situation	01:15pm
14.	**Dr. Betsy A Jose**	Common food preferences of community dwelling older adults and the elements that shape them	01:30pm

IRB: 02/2021 **7th September, 2021**

Meeting Date: 7th September, 2021

Minutes of the IRB committee on: 7th September

1. Due to the prevailing Covid -19 pandemic situation, the IRB meeting was scheduled on an online platform (Zoom) on 7th April, 2021. The IRB Members and the Principal investigators were given the zoom link before head and were requested to join at 12pm on 7th September, 2021. 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

S.No.	Name	Primary Scientific or Non-scientific Specialty	Role in IEC
1	Dr Harikumar B Nair	Primary	Chairperson
2	Dr Nebu George Thomas	Primary	Member Secretary
3	Rev Dr. Mathew Mazhavancheril	Primary	Member
4	Dr Vikram Gowda	Primary	Member
5	Dr Liya Roslin Joseph	Primary	Member
6	Dr Philip Mathew	Primary	Member
7	Dr Krishnan Namboodiri	Primary	Member
8	Dr Athulya G Asokan	Primary	Member
9	Dr Tressia Alias Princy Paulose	Primary	Member
10.	Dr T M Chary	Primary	Member
11.	Adv. Minu Mathews	Primary	Member
12.	Mr Lijo George	Primary	Member
13.	Fr. Sibin Mathew	Primary	Member
14.	Dr Nibu Varghese	Primary	Member
15.	Dr. Melvin	Primary	Guest – 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: 15 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: 01/2021

Protocol Title: A comparative study on the effect of Calcium and Vitamin D supplements versus citicholine in fracture healing

Principal Investigator: Dr. John P S

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments :

1. Choline is easily in our body so should there be a group with high protein and without citicholine?
2. A suggestion was given to consider protein intake factor.
3. Can a 4th group be considered supplementing only with Vitamin C, as Vit V increases the choline level in body?
4. Does this study require a CTRI registration?
5. Can we have randomization in methodology as the present study appears as a non –randomized trial?

6. The study title does not reflect tibial fracture.
7. Can we have a third group without Vitamin D- calcium/ citicholine supplementation?
8. Are you recording the other factors not responsible for healing of fracture?

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

IRB Study Reference No: 02/2021

Protocol Title: Mitral Annulus Calcifications: An Echocardiographic Study

Principal Investigator: Dr. Rajan Joseph Manjuran

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

1. As you are invited to participate in this study, will you be getting authorship for this study?
2. Patient doing echocardiography without doing lipid profile/ renal parameters, will that be a concern?
3. Will you be supporting any patients for doing the above said investigations?
4. By doing this study, are you expecting regional difference in the results?

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

IRB Study Reference No: 03/2021

Protocol Title: Perception and perspectives of Hospital Infection Control Committee (HICC) members regarding Infection Prevention and Control (IPC) Guidelines, 2020 and strategies to improve its adoption by healthcare facilities.

Principal Investigator: Dr. Philip Mathew

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments :

1. Is this study a qualitative study?
2. How are you going to choose those 12 sample in your study and is it across Kerala?
3. The 12 sample selected sufficient for the study?
4. Is there any reason for restricting your study only to qualitative aspect?

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

IRB Study Reference No: 04/2021

Protocol Title: Shortage of specific antimicrobial agents affecting optimal drug procurement and dispensing in hospitals: A qualitative study from Kerala, India

Principal Investigator: Dr. Philip Mathew

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

1. Suggestion: It would be better if you could distribute your study across the region.
2. Do you have a pre-defined questionnaire for collecting the data?
3. How will you be checking the shortage in your study?
4. How will you prevent the shortage?

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

IRB Study Reference No: 05/2021

Protocol Title: Identifying behavioral markers for mental wellbeing through digital phenotyping- Multicentric study

Principal Investigator: Dr. Roy Abraham

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments :

1. Where can you access this application?
2. Who will do the data collection?
3. How will you ensure the confidentially of the data collected?
4. It would be better to include participants who are directly not reporting to you.
5. How do you prevent your data being taken by others as it's a public domain?

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

IRB Study Reference No: 06/2021

Protocol Title: Prevalance of Workplace violence in Kerala -It's Association with Clinical anger among Doctors

Principal Investigator: Dr. Roy Abraham

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

1. Is the sample size for the study decided?
2. Who all are included in the sample size?
3. Do you have any inclusion criteria?
4. It would be better if you can include a good sampling criteria.

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

IRB Study Reference No: 07/2021

Protocol Title: Effectiveness of NiTi springs vs. elastomeric power chain force delivery systems with mini-implant assisted maxillary incisor intrusion in deep bite correction: A randomized controlled trial

Principal Investigator: Dr. Biju Sebastian

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments :

1. How do you prefer to randomize your sample?
2. Are you going to use a software for randomization?
3. How are you going to conceal the information?
4. Are both post delivering system regularly being used in the department?
5. How will you assess the root resorption?
6. Who will bear the expenses?
7. Are you going to include patients who have already started orthodontic treatment?
8. This study require a CTRI registration

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

IRB Study Reference No: 08/2021

Protocol Title: Treatment effect evaluation of Facemask and 2×4 appliance on class lll patients of age 7-9 years: A randomized controlled trial

Principal Investigator: Dr. Biju Sebastian

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

1. Patient information sheet have to be more elaborate.
2. What is Class III patients?
3. Is this Class III a complete term?
4. This study require a CTRI registration

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

IRB Study Reference No: 09/2021

Protocol Title: Effect of online inquiry based learning versus lecture based learning in the academic performance of phase I MBBS students

Principal Investigator: Dr. Amrutha Mary

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments :

1. Will the result lie on the topics been taken?
2. How are you going to assess the knowledge of the students?
3. Will you be informing the students that they are a part of this study?
4. What is your sample size?

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

IRB Study Reference No: 10/2021

Protocol Title: Effect of mnemonics in medical education- A perspective study on entertainment education in first year MBBS students for better memory

Principal Investigator: Dr. Meenu S

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

1. Is there a chance of sharing the same mnemonics between the groups?
2. How are you going to assess the students?
3. Will you conduct the test on the same day after class or an another day?

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

IRB Study Reference No: 11/2021

Protocol Title: Incidence of Covid-19 infection and its associated oral manifestations among oral health care workers.

Principal Investigator: Dr. Lisa Elizabeth Jacob

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

1. Who all are included in your study group?
2. Is this a Multi-centric study?
3. Do you think 213 will be adequate sample size if you are doing a multi-centric study?
4. How long after Covid-19 will you be checking for oral manifestations?
5. It is better to use the term frequency/ prevalence of COVID-19 instead of incidence.
6. It's better to have a clear strategy on how you are going to circulate the Google forms
7. Since there are no co-investigators from other region better to consider this study as a single centric study.
8. Please mention in your title as – A questionnaire Based Study

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

IRB Study Reference No: 12/2021

Protocol Title: Assessment of depression, anxiety and stress among the dental students during the Covid -19 pandemic.

Principal Investigator: Dr. Anju Mathew

Primary reviewer of IRB: Comments from IRB Member

Motion:
Comments:

1. Is there any study carried out in Kerala?
2. As students come under vulnerable population it is better to consider students who do not report to you.
3. It is better if the study is multi-institutional as it adds weightage while going for publication

4. It would be better if a study can be conducted among the faculties.

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

II. PROTOCOL CHANGES : Nil

III. RETROSPECTIVE REVIEW: Nil

IV. OTHER ISSUES DISCUSSED: Nil

The meeting ended at 3:45pm

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Member Secretary
Institutional Review Board

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

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