

IRB AND IEC MEET – 18/01/2018

MINUTES OF THE MEETING.

The Institutional Review Board and Institutional Ethical Committee meet held on **18/01/2018** was attended by the following members:

- PRINCIPAL – Dr.Saravanakumar
- Member secretary,IEC – Dr.Pratebha
- Member secretary,IRB - Dr. Yuvraj
- Internal member- Dr.P.S.Manoharan

External expert Members –

- Dr.M.S.Muthu, Prof&Head, Pedodontics,SRMC, Porur,Chennai – chairperson, IEC
- Dr.Gopi Chander, Prof,Prosthodontics,SRM Dental college,Ramapuram,Chennai – Clinician member, IEC
- Dr.Balamurali,Prof, Oral Pathology, MGPGI- Basic dental scientist
- Mr.Ezhumalai, Statistician, SBV University – Senior Statistician
- Mrs.Uma Udayaraj, Layperson member, English professor,KGNC – Lay person
- Mrs.Shahin Sultana, Social scientist
- Dr.Anandh Raj, Dept of Gen Pathology,MGMCRI ,Basic medical scientist, IEC,

Meeting incharges: Dr.Padmaraj and Dr.Aniruddh

Objective:

- To review and approve 15 research projects from UG,PG and faculty.
- To offer suggestions and modifications as necessary.
- To finally certify the projects as approved or otherwise

Proceedings of the meeting:

- The meeting commenced at **10:00 a.m.**
- 15 new research proposals from PGs, UGs and faculty of various departments presented their research proposals followed by discussion for 15 minutes each with emphasis on suggestions and any modification if required.
- The projects were critically evaluated and modifications suggested.
- It was decided by the members the modifications suggested are to be scrutinized by internal IRB following which they will be forwarded to the chairperson for approval and certification
- Apart from the 15 protocols there were three projects which were approved earlier but requiring addition of clinical parameters . It was discussed with the chairperson and it was suggested by him to send the protocols along with the rest of the protocols for approval

- After thanking the members of Institutional Review Board, the session came to a close at 2.00 p.m.

S.no	Department	Topic	Presenter
1.	ORAL PATHOLOGY	ORAL CANDIDA SPECIES ISOLATION AND THEIR ANTIFUNGAL SUSCEPTIBILITY PATTERN IN HIV PATIENTS	Dr. Gayathri
	SPEAKER/MEMBER	QUERIES/ SUGGESTIONS	Presenter
1	Dr.M.S.Muthu	Are you comparing the medium?is it an objective Can you differentiate the species? Drug for testing efficacy should be confirmed Title translation to tamil in consent form should be understandable Why Kappa statistics? Some form of documentation for data entry should be there.	No,after allowing it to grow in the medium ,isolate the species in non albicans. Agreement between two methods
2	Dr.Gopichander	WHAT IS THE PATIENT BENEFIT?	Judicious use of antifungal makes the virus resistant.so particular use of antifungals would be required
3	Dr.Balamurali		
4	Mr.Ezhumalai	Sample size is based on convenience sampling, Z test may be added to compare % between 2 drugs	From key article
5	Mrs.Uma Udayaraj		
6	Dr.Anand	Title can be modified, so that HIV patients should not be included(Eg:Patients with retroviral +VE), Categorize the species	
7	Dr.Shahin Sultana	Nomenclature for HIV patients should be changed.Consent form for taking photographs	
8	Dr.R.Saravanakumar		
9	Dr.Manoharan	Separate data sheet for collection, Consent form to be paraphrased	
10	Dr.Pratebha	Consent form should include consent for photographs,change as patients living with HIV/AIDS	
11	Dr.Yuvraj		
	Final Remarks	Accept with modifications METHODOLOGY, CONSENT FORM, DRUGS USED AND DATA SHEET should be modified,patients identity to be blinded	Accepted with modification for both IRB& IEC

S.no	Department	Topic	Presenter
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2	OMFS	COMPARISION OF ROPIVACAINE AND BUPIVACAINE IN POSTOPERATIVE PAIN MANAGEMENT FOR OPEN REDUCTION OF MANDIBULAR FRACTURE – DOUBLE BLINDRANDOMIZED CLINICAL STUDY	Dr. Adersh
	SPEAKER/MEMBER	QUERIES/ SUGGESTIONS	Presenter
1	Dr.M.S.Muthu	Null hypothesis should be changed.CONSORT guidelines should be adhered to. CPRM registry should be done. If planning as RCT it should be checked with CONSORT. Sample of 28 patients in each group should be similar to the other group wrt case selection.	Once GA effect is lost, usually bupivacaine is given but in this study ropivacaine is given.
2	Dr.Gopichander	What type of fracture?how can you group all mandibular fracture into one pain scale?	
3	Dr.Balamurali	VAS is checked in 4 th ,6 th ,8 th hourly, literature review for routine use of ropivacaine and bupivacaine	
4	Mr.Ezhumalai	Simple random sampling cannot be used. Randomization can be done not Simple random sampling.Write specifically what statistics you are going to do and apply randomization procedure	
5	Mrs.Uma Udayaraj		
6	Dr.Anand	What is scale of measurement used	VAS
7	Dr.Shahin Sultana	Study termination should be clearly mentioned.	
8	Dr.R.Saravanakumar		
9	Dr.Manoharan	Operator and evaluator is blinded?Complexity of fracture and assessment should be done,inclusion criteria to be defined clearly	
10	Dr.Pratebha	Information and monitoring to the clinical trial committee, sampling technique is wrong, RCT should be block randomization	
11	Dr.Yuvraj		
	Final Remarks	Accepted with modification, to report to Clinical trial monitoring committee. To be scrutinized by Internal review board for modifications suggested by the members	

S.no	Department	Topic	Presenter
3	OMFS	COMPARATIVE STUDY BETWEEN THREE DIMENSIONAL TITANIUM DOUBLE Y PLATE AND SQUARE PLATE FOR THE MANAGEMENT OF PARASYMPHYSIS FRACTURE OF MANDIBLE- A RANDOMISED CONTROLLED TRIAL	Dr.Ranjitha
	SPEAKER/MEMBER	QUERIES/ SUGGESTIONS	Presenter

1	Dr.M.S.Muthu	Is this randomized controlled trial? If so CTR registry and CONSORT guidelines should be done. The outcome should be specific.No statistics mentioned for the test	Block randomization.
2	Dr.Gopichander	Wide age criteria for patients then how can you select patients acc to inclusion criteria?	
3	Dr.Balamurali		
4	Mr.Ezhumalai	Independent t test should be mentioned in the protocol,statistical analysis to be modified after consultation	
5	Mrs.Uma Udayaraj		
6	Dr.Anand	CTRI registration to be done since clinical trial	
7	Dr.Shahin Sultana		
8	Dr.R.Saravanakumar		
9	Dr.Manoharan	Operating time is the outcome? If already midline discrepancy then intercuspatation should be a better objective Any specific indications for Y plate or square plate?	No it can be interchangeably used.
10	Dr.Pratebha	Intercuspatation should be chosen instead of Class I occlusion, test for each variable to be included, modify consent forms	
11	Dr.Yuvraj		
	Final Remarks	Accepted with modification, title, occlusion details to be checked,CONSORT guidelines to be checked,describe randomization,allocation and concealment and statistical analysis	

S.no	Department	Topic	Presenter
4	ortho	ANGULATION ERRORS IN LATERAL CEPHALOGRAM AND ITS INFLUENCE IN ORTHODONTIC DIAGNOSIS – “AN INVITRO STUDY”	Dr.Arul
	SPEAKER/MEMBER	QUERIES/ SUGGESTIONS	Presenter
1	Dr.M.S.Muthu	Will sample size of 3 skulls in each group be sufficient. Study variables should be modified.	
2	Dr.Gopichander		
3	Dr.Balamurali	Objectives should be made clear	
4	Mr.Ezhumalai	In such small cases, resource equation if used 5 can be group size Instead of one observer is going to measure, make intra and inter observer as a objective. Why repeating for left and right side?	Dolphin software to be plotted. Not to be repeated for right and left side, it is only for sagittal.

5	Mrs.Uma Udayaraj		
6	Dr.Anand	Repeat review with methodology	
7	Dr.Shahin Sultana	Questionnaire need not be given.why questionnaire?	
8	Dr.R.Saravanakumar		
9	Dr.Manoharan		
10	Dr.Pratebha	Measurements to be repeated by different examiners(Inter examiner variability)	
11	Dr.Yuvraj	Inter and intra examiner variability in plotting landmarks can be added	
	Final Remarks	REPEAT REVIEW WITH MODIFICATION; DEFERRED FOR HOD OPINION Objective to be changed,protocol to be modified accordingly.only one skull can be chosen with different examiners plotting	

S.no	Department	Topic	Presenter
5	Ortho	COMPARATIVE ASSESSEMENT OF CONVENTIONAL AND SELF-LIGATING BRACKETS ON THE EFFECT OF MAXILLARY AND MANDIBULAR INTERMOLAR AND INTERCANINE DISTANCE	Dr.Pazhanisamy
	SPEAKER/MEMBER	QUERIES/ SUGGESTIONS	Presenter
1	Dr.M.S.Muthu	Patient level blinding does not apply.CONSORT guidelines should be applied. Methodology should be more specific and outcome measures should be stronger. Categorization according to time Standardization for inter canine and intermolar width	
2	Dr.Gopichander		
3	Dr.Balamurali	Adhere to CONSORT guidelines	
4	Mr.Ezhumalai	Self ligating and conventional brackets will be intervention not variables Assessor can be blinded. Add variables (maxillary and mandibular)	
5	Mrs.Uma Udayaraj		
6	Dr.Anand		
7	Dr.Shahin Sultana		
8	Dr.R.Saravanakumar		
9	Dr.Manoharan	Standardized measurements should be checked.If not tip of canine	

		what will be the point?	
10	Dr.Pratebha	Modifications in methodology, add maxillary and mandibular as variables	
11	Dr.Yuvraj		
	Final Remarks	REPEAT REVIEW WITH MODIFICATION ,DEFERRED FOR HOD OPINION, CONSORT Guidelines, methodology,check parameters chosen and consent form to be translated in regional language	

S.no	Department	Topic	Presenter
6.	ortho	EVALUATING THE RATE AND EFFICIENCY OF TOOTH MOVEMENT IN PROPEL EXCELLERATOR TREATED AND CONVENTIONALLY TREATED PATIENTS:AN IN VIVO STUDY	Dr.Shanaz
	SPEAKER/MEMBER	QUERIES/ SUGGESTIONS	Presenter
1	Dr.M.S.Muthu	Expertise would be required for treatment using propel. Ethical issue is strong. Patient informed consent needs to be specific.	
2	Dr.Gopichander	Consent form to explain the procedure should be detailed	
3	Dr.Balamurali	Deferred, check feasibility of study methodology needs revision	
4	Mr.Ezhumalai		
5	Mrs.Uma Udayaraj		
6	Dr.Anand	Deferred, to clarify on consent form and information sheet	
7	Dr.Shahin Sultana		
8	Dr.R.Saravanakumar		
9	Dr.Manoharan	How to assess anchorage qualitatively?	
10	Dr.Pratebha	Modify Study termination details in protocol	
11	Dr.Yuvraj		
	Final Remarks	Ethical issue to be addressed. To be deferred as of now	

S.no	Department	Topic	Presenter
7	PEDO	COMPARISION OFTHE EFFECTS OF CHEWING GUM CONTAINING CASEIN PHOSHOPEPTIDE-AMORPHOUS CALCIUM PHOSPHATE(CPP-ACP)ANDXYLITOL ON SALIVARYCHARACTERISTICSIN 8-10 YEARS CHILDRENWITH MOLAR INCISOR HYPOMINERALISATION: A RANDOMISED	Dr.NARMATHA

		CONTROLTRIAL	
	SPEAKER/MEMBER	QUERIES/ SUGGESTIONS	Presenter
1	Dr.M.S.Muthu	Remineralizing ability/indicators for it should be measured.then only remineralizing capacity can be found. Salivary parameters can be compared ,no need to check efficacy for this. CONSORT guidelines need to be adhered	Categorization of mild,severe group.severe group would be removed.
2	Dr.Gopichander	Hypo mineralized patients when given block of sugar/salt, unless some changes happen in the media how can changes be expected in patients	
3	Dr.Balamurali	Sample selection needs to be addressed.	
4	Mr.Ezhumalai	Add repeated measures of ANOVA	
5	Mrs.Uma Udayaraj		
6	Dr.Anand	How ph is tested?is it gold standard method? Validation of chewing gum to be necessary	Using GC check saliva.
7	Dr.Shahin Sultana	Through the school and parents, permission needs to be obtained. Why particular school? Socio economic strata might be influential Consent form should be strong.	From results of prevalent study, schools were chosen.
8	Dr.R.Saravanakumar		
9	Dr.Manoharan		
10	Dr.Pratebha		
11	Dr.Yuvraj		
	Final Remarks	Title to be modified(efficacy),CONSORT guidelines	

S.no	Department	Topic	Presenter
8	PEDO	CORRELATION OF CHILD'S COLOUR PERCEPTION TO EMOTION, BEHAVIOUR AND DENTAL ANXIETY DURING DENTAL PROCEDURES	Dr.Swarna
	SPEAKER/MEMBER	QUERIES/ SUGGESTIONS	Presenter
1	Dr.M.S.Muthu	What is non invasive treatment? Restoration ?	Only ART type intervention would be used
2	Dr.Gopichander	Sample size evaluation	It is 100, 91 was the original
3	Dr.Balamurali		
4	Mr.Ezhumalai		
5	Mrs.Uma Udayaraj		
6	Dr.Anand	Sample selection ? what about colour blind?	Color blind to be excluded
7	Dr.Shahin Sultana	Special child would be excluded? To be discussed with HOD.Should be	

		mentioned as children with special health care needs	
8	Dr.R.Saravanakumar		
9	Dr.Manoharan	What is the application?	Colour might influence the patient anxiety
10	Dr.Pratebha		
11	Dr.Yuvraj		
	Final Remarks	ACCEPTED and APPROVED	

S.no	Department	Topic	Presenter
9	pedo	ASSOCIATION BETWEEN TASTE PERCEPTION, FOOD PREFERENCE AND EARLY CHILDHOOD CARIES AMONG 3-6 YEAR OLD CHILDREN - A CROSS-SECTIONAL STUDY	Dr.Eswari
	SPEAKER/MEMBER	QUERIES/ SUGGESTIONS	Presenter
1	Dr.M.S.Muthu	Pictures are specific and data would be voluminous. Development	
2	Dr.Gopichander	Sample of questionnaire?	Food groups would be examined.
3	Dr.Balamurali	Validation and reliability check of questionnaire	
4	Mr.Ezhumalai		
5	Mrs.Uma Udayaraj		
6	Dr.Anand	Accept with modifications	
7	Dr.Shahin Sultana		
8	Dr.R.Saravanakumar		
9	Dr.Manoharan		
10	Dr.Pratebha		
11	Dr.Yuvraj		
	Final Remarks	ACCEPTED WITH MODIFICATIONS .Title to include “questionnaire”. To validate the questionnaire	

S.no	Department	Topic	Presenter
10	Cons endo	COMPARATIVE EVALUATION OF TITANIUM BASED AND STAINLESS STEEL BASED ULTRASONIC TIPS IN CREATING SECONDARY FRACTURES DURING RETRIEVAL OF SEPARATED NITI FILE FRAGMENTS – AN IN VITRO STUDY	Dr.nandhini
	SPEAKER/MEMBER	QUERIES/ SUGGESTIONS	Presenter

1	Dr.M.S.Muthu	Any other parameters can be added which will add value to the study.	
2	Dr.Gopichander	If already material properties are known why secondary fractures are checked Impact of the study would be low	
3	Dr.Balamurali	Any other modification apart from proven fact.	
4	Mr.Ezhumalai		
5	Mrs.Uma Udayaraj		
6	Dr.Anand		
7	Dr.Shahin Sultana		
8	Dr.R.Saravanakumar		
9	Dr.Manoharan	How can it be assessed?standardization?	
10	Dr.Pratebha	Prevalence of secondary fractures, Ethical clearance not required	Niti base takes longer time to fracture
11	Dr.Yuvraj		
	Final Remarks	APPROVED; Ethical clearance not required. Methodology to be scrutinized by internal review board	

S.no	Department	Topic	Presenter
11	Periodontics	INFLUENCE OF TLR (TOLL LIKE RECEPTOR) AND NOD (NUCLEOTIDE-OLIGOMERISATION DOMAIN PROTIEN LIKE) RECEPTORS POLYMORPHISMS IN CHRONIC PERIODONTITIS IN SOUTH INDIAN POPULATION	Dr.Pratebha
	SPEAKER/MEMBER	QUERIES/ SUGGESTIONS	Presenter
1	Dr.M.S.Muthu	Before raising a flap, routine blood investigation? Odds ratio- to be clarified Would funding be sufficient?	Yes as part of routine blood investigation this sample would be taken for chronic periodontitis Split up of expenses shown.
2	Dr.Gopichander	Why not pilot study for the sample?	
3	Dr.Balamurali		
4	Mr.Ezhumalai	Title of South Indian population, student t test for ILR etc values. Definition for healthy controls to be given TNF alpha use mean+- SD Age in case and control to be same,select matched age and gender controls	If specific other origin patients would be different.
5	Mrs.Uma Udayaraj		
6	Dr.Anand		
7	Dr.Shahin Sultana		
8	Dr.R.Saravanakumar		

9	Dr.Manoharan		
10	Dr.Pratebha		
11	Dr.Yuvraj		
	Final Remarks	APPROVED AND ACCEPTED . To age match cases and controls	

S.no	Department	Topic	Presenter
12	Public health dentistry	EFFICIENCY AND EFFECTIVENESS OF 2% CHITOSAN MOUTHWASH IN- COMPARISON WITH 0.2% CHLORHEXIDINE DIGLUCONATE MOUTHWASH IN PLAQUE REDUCTION – A RANDOMIZED CROSS OVER CONTROLLED TRIAL	Dr.Senthil
	SPEAKER/MEMBER	QUERIES/ SUGGESTIONS	Presenter
1	Dr.M.S.Muthu	Any method for sample size, wash out period of 1 week(certain areas 2days) CONSORT guidelines should be followed, trial registry Consent form should mention that it is new and side effects,clearance from FDA	Convenience sampling , residents as sample
2	Dr.Gopichander	Availability of mouthwash,molecular weight	It is commercially available, low mol wt, but has to be procured from abroad
3	Dr.Balamurali		
4	Mr.Ezhumalai	Sample size justification, minimum 30 for parametric test. Based on review of literature or availability of patients. Research question and hypothesis. Predominately non vegetarian needs to be clarified.	
5	Mrs.Uma Udayaraj		
6	Dr.Anand		
7	Dr.Shahin Sultana		
8	Dr.R.Saravanakumar		
9	Dr.Manoharan	Efficiency and effectiveness of plaque scores (any one can be used)	
10	Dr.Pratebha		
11	Dr.Yuvraj		
	Final Remarks	ACCEPTED WITH MODIFICATION: CONSORT guidelines to be checked, sample size justification	

S.no	Department	Topic	Presenter
13	orthodontics	COMPARATIVE EVALUATION OF PLATELET RICH FIBRIN WITH DEMINERALIZED FREEZE DRIED BONE ALLOGRAFT IN PERIODONTALLY ACCELERATED OSTEOGENIC ORTHODONTICS: A THREE ARM RANDOMIZED CLINICAL TRIAL	Dr.Aniruddh
	SPEAKER/MEMBER	QUERIES/ SUGGESTIONS	Presenter
1	Dr.M.S.Muthu	CONSORT guidelines should be followed	
2	Dr.Gopichander	Consent form to be validated	
3	Dr.Balamurali	To increase sample size to 6+ dropout patients	
4	Mr.Ezhumalai	Add 10-20% drop out; ANOVA followed by Post hoc test	
5	Mrs.Uma Udayaraj		
6	Dr.Anand	approved	
7	Dr.Shahin Sultana		
8	Dr.R.Saravanakumar		
9	Dr.Manoharan		
10	Dr.Pratebha	10-20% attrition rate to be added up(drop outs)	
11	Dr.Yuvraj		
	Final Remarks	Accepted with modifications. Consent form to be scrutinized by IEC chairperson	

S.no	Department	Topic	Presenter
14	Public health dentistry	KNOWLEDGE AND AWARENESS ABOUT EFFECTS OF SESAME OIL PULLING AND ITS HEALTH BENEFITS AMONG DENTAL STUDENTS OF IGIDS , PUDUCHERRY: A CROSS SECTIONAL STUDY	krishnapriya
	SPEAKER/MEMBER	QUERIES/ SUGGESTIONS	Presenter
1	Dr.M.S.Muthu	If only measuring these 2 it should be clarified. Questionnaire was designed on own? Knowledge questions should have yes/no Existing/validated questionnaire can be used. These questions are general Remove sesame oil from questionnaire	Since not done on dental students,not all questions were chosen from key article
2	Dr.Gopichander	Outcome measures to be clarified,qualitative parameters can be added	
3	Dr.Balamurali		
4	Mr.Ezhumalai	Statistics part should be modified, to collect some background	

		variable like age,gender,add chi square test	
5	Mrs.Uma Udayaraj		
6	Dr.Anand		
7	Dr.Shahin Sultana		
8	Dr.R.Saravanakumar		
9	Dr.Manoharan	To check methodology	
10	Dr.Pratebha	Questionnaire validation can in itself be a study, validation to be done for this study	
11	Dr.Yuvraj		
	Final Remarks	APPROVED WITH MODIFICATIONS . questionnaire to be validated	

S.no	Department	Topic	Presenter
15	Periodontics	Assessment of Oral Hygiene, Health and Periodontal Status of Parents of Dental Students – A Cross Sectional Study.	Ashna
	SPEAKER/MEMBER	QUERIES/ SUGGESTIONS	Presenter
1	Dr.M.S.Muthu	To modify methodology,	
2	Dr.Gopichander	Collect background data of parents(age,gender,rural/urban) and do chi square test	
3	Dr.Balamurali		
4	Mr.Ezhumalai	Sample size	
5	Mrs.Uma Udayaraj		
6	Dr.Anand	Qualitative component as a questionnaire can be added	
7	Dr.Shahin Sultana		
8	Dr.R.Saravanakumar		
9	Dr.Manoharan	Purpose of this study will it influence the result, the positive results would mean ? will it be qualitative? Better oral hygiene might be because of other characteristics than students sharing oral hygiene measures with parents	
10	Dr.Pratebha		
11	Dr.Yuvraj		
	Final Remarks	ACCEPTED WITH MODIFICATIONS. To be scrutinized by the internal review board	

I hereby state that I have verified the minutes of the meeting and found it to be in order.

Handwritten signature of B. Pratebha in blue ink, written in a cursive style.

Dr B Pratebha

Member Secretary, Institutional Ethics Committee, IGIDS, SBV

Date: 14.03.2018

Handwritten signature of M.S. Muthu in blue ink, written in a cursive style, enclosed in a rectangular box.

Dr M S Muthu

Chairman, Institutional Ethics Committee, IGIDS, SBV

Date: 15.03.2018