

### **MINUTES OF THE MEETING – IEC, IGIDS**

The Ethical committee meet held on 30.09.13 was attended by the following members:

- Dr. Sivapathasundaram, chairman IEC
- Dr. Kingshuk IEC member
- Dr. Sundaramurthy Reddy, IEC member
- Dr. A.R.Srinivasan ,IEC member
- Dr. Swarnapriya , IEC member
- Dr. Mahalakshmi , IEC member
- The Principal, IGIDS
- Dr.B.Pratebha , Member Secretary IEC

The legal expert member Mr.Swaminathan and dental clinician member Dr.Arun were absent for this meeting

Dr.Shiva and Dr.Sukanya recorded the minutes of the meeting. Dr.Vezhavendhan and Dr.Jeelani were also present for the meeting

#### **Objective:**

- To review 8 research protocols that have been submitted to the committee after IRB clearance .
- To offer suggestions if required.
- To finally grant ethical clearance to the proposed research protocols.

#### **Proceedings of the meeting:**

- The meeting commenced at 9: 40 a.m.
- 6 post graduate students (Dr. Pratik, Dr. Rojesh from the department of Orthodontics, Dr. Kayalvizhi, Dr. Madhulika, Dr. Swetha from the department of Oral Medicine) and 2 faculty members, Dr. Srinivasan from the department of Prosthodontics, Dr. Saravana Kumar from the department of Periodontics presented their research projects in a brief power point presentation of 7 minutes each with emphasis on methodology.
- The projects were critically evaluated and modifications suggested.

- Enclosed herewith are the modifications suggested
- A short tea break of 15 mins was taken
- All projects are to be accepted with modifications.
- After thanking the members of Ethical Committee, the session came to a close at 1:10 p.m followed by lunch for the members.

<b>1.Title of the study</b>	Shear Peel Bond Strength of various repetitive re-bonding procedures of metal brackets – a comparative in-vitro study	
<b>Name of the Presenter</b>	Dr. Pratik. S	
<b>QUESTIONS RAISED</b>	<b>EXPLANATION /JUSTIFICATION</b>	<b>SUGGESTIONS OFFERED BY MEMBERS</b>
Dr. Sundaramurthy – Recent reference article was not quoted.	Dr. Nandakumar – the basic procedural information was clearly cited in the key article published in 1999. Further research in this context was not carried out till date.	Members accepted the explanation.
DR.Sundaramurthy – Whether guardian can sign the consent form in case of study group aged below 18 ?	Dr. Nandakumar - Guardian/Warden can sign for hostel students.	Members accepted the explanation.
Dr. Usha - Whether patient's to be informed about the disposal of tooth after study ?		Dr. Sivapathasundaram – Not required.
Dr. Nandakumar - Whether tooth number to be mentioned in the consent form?		Dr. Sivapathasundaram – Not required.

		<u>Other suggestions:</u> To check for grammatical errors and spelling mistakes in the content and the consent form.
<b>Decision of the Board</b>	To be accepted with modification.	
<b>2. Title of the study</b>	Assessment of Enamel characteristics using Commercially available various etching solutions.	
<b>Name of the Presenter</b>	Dr. Rojesh. V. S.	
<b>QUESTIONS RAISED</b>	<b>EXPLANATION /JUSTIFICATION</b>	<b>SUGGESTIONS OFFERED BY MEMBERS</b>
Dr. Sundaramurthy - Where the Scanning Electron Microscope work will be conducted?	Annamalai University	Dr. Sundaramurthy - Facilities used from outside laboratories has to be mentioned in the study protocol.
Dr. Srinivasan – Where will you analyse the reagent's content and its percentage?	Biochemistry department of MGMCRI	To obtain consent from the biochemistry department.
Dr. Srinivasan - Raised question whether viscometer is available in biochemistry.		Dr. Sundaramurthy - To check in biomedical engineering department of Rajiv Gandhi College of Engineering and Technology.

		<u>Other suggestions:</u> To check for grammatical errors and spelling mistakes in content and consent form.  **Recommended to use positive terminologies in the consent form.
<b>Decision of the Board</b>	To be accepted with modification.	

<b>3. Title of the study</b>	Effect of 1% clotrimazole on salivary levels of candida and on non-homogenous leukoplakia.	
<b>Name of the Presenter</b>	Dr. Kayalvizhi	
<b>QUESTIONS RAISED</b>	<b>EXPLANATION /JUSTIFICATION</b>	<b>SUGGESTIONS OFFERED BY MEMBERS</b>
Dr. Sivapathasundaram - Raised ethical issue for not treating non homogenous leukoplakia which was categorised as control group.	No satisfactory explanation given	Dr. Sivapathasundaram - Treatment should be provided to all leukoplakia patients.  Dr. Swarnapriya - Suggested to change comparative study into observational study without control group or to select appropriate control group  Dr. Sivapathasundaram – Or else to compare the patients before and after treatment.

Dr. Sivapathasundaram - Post treatment biopsy is not ethically accepted unless any visible clinical alteration noticed.	No satisfactory explanation given	Dr. Sivapathasundaram - suggested to perform exfoliative cytology using cytobrush instead.
		One of the board members suggested including drug history.
<b>Decision of the Board</b>	To be accepted with modification.	
<b>4. Title of the study</b>	Prevalence of Temporomandibular disorders in patients attending OPD in the department of Oral Medicine???	
<b>Name of the Presenter</b>	Dr. Madhulika.	
<b>QUESTIONS RAISED</b>	<b>EXPLANATION /JUSTIFICATION</b>	<b>SUGGESTIONS OFFERED BY MEMBERS</b>
Dr. Sundaramurthy - Is 3 months duration sufficient for the study?	Not sure.	Recommended to conduct the study for 6 months.
Dr. Srinivasan -Whether to exclude patients with metabolic disorders?	Yes.	Dr. Srinivasan - To Include metabolic disorder in exclusion criteria.
Dr. Sivapathasundaram - Whether dental status will be included?	Not sure	To record dental status in case history, to register using impression and if required along with radiographs.

		Brief information about the role of doctor, the study, the procedure to be done and the benefit to the patient to be mentioned in the consent form.
<b>Decision of the Board</b>	To be accepted with modification.	

<b>5. Title of the study</b>	Responsiveness of pain scales: a comparison of three pain intensity measures with pain assessment Questionnaire in patients with odontogenic pain – A cross sectional comparative study.	
<b>Name of the Presenter</b>	Dr. Shwetha	
<b>QUESTIONS RAISED</b>	<b>EXPLANATION /JUSTIFICATION</b>	<b>SUGGESTIONS OFFERED BY MEMBERS</b>
Dr. Sundaramurthy - What is the purpose of the study, does it have any benefit to the patient?	Dr. Nandakumar - To check the objectivity of the pain scale. No direct benefit to the study group patient but based on the results, it may benefit the patient community as a whole.	Accepted.
Dr. Srinivasan - How is it differing from other similar studies	Pain scale is tried in odontogenic pain for the first time.	
Dr. Sivapathasundaram - How much time will be taken to fill a Questionnaire?	Maximum 15 minutes including the time taken to explain the patient about the Questionnaire.	
Dr. Mahalakshmi - Raised question that illiterate patient may not be aware of drugs what they are consuming.	Accepted that most of the OPD patients are illiterate.	Advised to include literate and illiterate patients and record their educational status. To adequately explain illiterate patients the questions asked in order to obtain the relevant answer.

		<u>Other suggestions:</u> **ssssssssssTo convert the negative terms into positive format in the consent form.  To check for spelling mistakes in Tamil version of the consent form.  To include the Questionnaire in Tamil version after validating it.  To include music therapy in pain management if possible.
<b>Decision of the Board</b>	To be accepted with modification.	
<b>6. Title of the study</b>	Prevalence of TMJ disorders among B.D.S. students from IGIDS, Puducherry – a cross-sectional study.	
<b>Name of the Presenter</b>	Dr. Kayalvizhi	
<b>Questions raised</b>	<b>Explanation /Justification</b>	<b>Suggestions offered by members</b>
Dr. Sivapathasundaram - Why to include B.D.S. students specifically? Why not M.D.S. and medical students?	Satisfactory explanation not given.	To include students of SBV university ( dental, medical and nursing)
Dr. Sivapathasundaram - Decision of students not to participate in the study was not considered.	Satisfactory explanation not given.	Advised to include only the volunteers, if needed prior counselling to students can be done to involve them in the study.
<b>Decision of the Board</b>	To be accepted with modification.	

<b>7. Title of the study</b>	Anxiety and attitude of dental students of SBVU for MCQ in Periodontics course.	
<b>Name of the Presenter</b>	Dr. Saravana Kumar	
<b>QUESTIONS RAISED</b>	<b>EXPLANATION /JUSTIFICATION</b>	<b>SUGGESTIONS OFFERED BY MEMBERS</b>
Dr. Srinivasan - When to measure the anxiety level of student, before/ after exam?	After exam as per the guidelines of National Teaching Programme.	Accepted.
Dr. Srinivasan -In the Questionnaire, is it essential to have 5- point grading scale	Had referred the Yes/No pattern used in the key article that was done in Minnesota University.	Dr. Swarnapriya - Explanation not accepted. Recommended to follow 5- point grading scale.
Dr. Srinivasan -Does the intellectual level of the student affect the anxiety level	Yes, it affects. The intellectual level of the students will be assessed based on their previous University Exam marks.	Accepted.
Dr. Srinivasan – whether the difficulty level of the Questionnaire affect the study?	No as the question paper is prepared based on Item Analysis norms.	Accepted.
Dr. Swarnapriya - Both anxiety and attitude level has to be estimated?	Not sure.	Dr. Swarnapriya - Recommended to estimate only the anxiety level of the student.
Dr. Sivapathasundaram - Interest in further Publication.	Only for internal auditing. Not for publication.	
<b>Decision of the Board</b>	To be accepted with modification.	



<b>8. Title of the study</b>	Use of social media for active and passive learning in dental students.	
<b>Name of the Presenter</b>	Dr. Srinivasan	
<b>QUESTIONS RAISED</b>	<b>EXPLANATION /JUSTIFICATION</b>	<b>SUGGESTIONS OFFERED BY MEMBERS</b>
Dr. Sivapathasundaram - Is it essential to recommend social network – facebook among student community?	Only students already using facebook will be included in the study.	Accepted.
Dr. Sivapathasundaram -Can it produce ill-effects?	Not sure.	Necessary precaution has to be taken. Dr. Swarnapriya -To provide psychological counselling to the students. Dr. Srinivasan – To fix the time period to use facebook per day.
Dr. Sivapathasundaram - Why educational blogs can't be used for the same purpose?	Facebook is easily accessible through smart phones. Need for close circuit.	Partially accepted.
Dr. Sivapathasundaram - Has parents been informed about the students being involved in facebook learning?	Will get the parent's consent too.	
Dr. Swarnapriya - Why to involve adolescent/pre-adult I year students?	No satisfactory explanation given.	To involve II year or III year students.
Dr. Swarnapriya - Whether attitude domain is tested in the study?	Not included.	Dr. Swarnapriya - Recommended to include cognitive and attitude domain.
<b>Decision of the Board</b>	To be accepted with modification.	

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



Dr B Pratebha

Member Secretary

Institutional Ethics Committee

IGIDS, SBV

Date: 17.10.2013



Dr B Sivapathasundaram

Chairman

Institutional Ethics Committee

IGIDS, SBV

Date: 18.10.2013