



### 5<sup>th</sup> Institutional ethical committee – minutes

The 5<sup>th</sup> IEC meeting was convened on 25. 7. 15 and the following members were present for the meeting:

- Dr . Ranganathan, chairperson, IEC, IGIDS
- Dr. Stephen S, medical expert member , IEC, IGIDS
- Dr. Lokesh S, Medical expert member , IEC, IGIDS
- Dr.Srinivasan, Social science expert member , IEC, IGIDS
- Dr. Shanmugam J, research expert member , IEC, IGIDS
- Dr . Sathya Narayanan , PG-coordinator, IGIDS
- Dr. Pratebha, member secretary, IEC, IGIDS
- Dr. Ramesh S, Meeting assistant, IEC, IGIDS

Dr. Ranu kumari, dental expert member, Dr. Rajkumar, Dental expert member, and Dr. Muthumanikam , non medical member were absent for the meeting. Their letters of absence were presented to the chairperson.

- ✓ The meeting commenced at 9.35 am. The member secretary welcomed the new members on the IEC panel and introduced the members to the Chairperson.
- ✓ 22 research projects were to be scrutinised as per the program schedule of which 18 projects were scrutinised for ethical issues( 7 ICMR STS projects and 11 non ICMR projects). Three studies were not presented -

Reasons:

- Dr. Yoga- absent and had authorised another post graduate to present but chairperson insisted on the concerned investigator to do presentation
- Dr. Venugopal and Krishnapriya (final yr student) : have discontinued their projects
- ✓ All IEC members were given assessment forms for each project to document their opinion and to be able to reach a consensus regarding ethical clearance for the concerned project.
- ✓ The chairperson met the guides of ICMR STS projects ,and the following were some general **suggestions** he gave:
  - consent / assent forms are mandatory for paediatric patients
  - permission letters from schools or in case of extra mural projects, letters from concerned institutes are to be obtained before the start of study
  - to tailor make the consent form for the research project
  - to check whether the statistical software used is appropriate and non-pirated
- ✓ Dr. Lokesh and Dr. Stephen emphasised that in case of projects where patients' clinical laboratory data are being used, it is mandatory to get a consent from the patient for using his/her clinical data
- ✓ The **suggestions** of IEC members for individual projects (18 projects) is enclosed below
- ✓ Tea and snacks were provided around 10.30 and the meeting closed with a lunch at 2.30 pm





**INSTITUTIONAL ETHICAL COMMITTEE**

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**Minutes of individual research projects – 5<sup>th</sup> IEC meeting**

**1.Name of the investigator:** Ramya (final yr student) ICMR STS project

**Title of the project:** Comparative Evaluation of Proximal Contacts in Amalgam Restorations Done Using Sectional Matrix and Circumferential Matrix System- An In-Vitro Study.

**Suggestions:**

none ( no ethical issues)

**Decision:** Approved



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**Minutes – 5<sup>th</sup> IEC meeting**

**2. Name of the investigator:** M.Halitha Banu

**Title of the project:** Self Negligence and Awareness Among Oral Precancerous and Cancer Patients - A Cross Sectional Questionnaire Study

**Suggestions:**

1. Dr. Srinivasan – questions need to be more qualitative than quantitative in nature
- 2Dr. Ranganathan: -suggested to include pretest counselling and then post test counselling  
- Title revision : to keep it as “a questionnaire study”
3. Dr. Lokesh – suggested to check use of valid statistical software package to avoid piracy issues
4. Dr. Ranganathan and Dr. Lokesh: to consider removal of psychological and social counselling

**Decision:** accepted with modifications





**Minutes – 5<sup>th</sup> IEC meeting**

**3. Name of the investigator:** Nivetha V

**Title of the project:** Knowledge and Attitude Regarding Infant Oral Health Care among Anganwadi Workers of Puducherry - A Cross Sectional Study.

**Suggestions:**

1. Dr. Ranganathan – either sampling size or method should be changed
  - To keep information of participants anonymous ( no name, address, and centre name to be recorded)
  - Raised concern over feasibility of completing study
  - To randomize centres
  - To collect data first, then analyse the data and subsequently terminate the study
2. Dr. Lokesh - to produce written permission letters from government and consent from the participants

**Decision:** Accepted with modifications





**Minutes – 5<sup>th</sup> IEC meeting**

4. **Name of the investigator:** Poornima .U

**Title of the project:** Comparing the Efficacy of Turmeric with Chlorhexidine Disinfectant in Reduction of Microbes on Alginate Impression Material

**Suggestions:**

- Dr. Ranganathan – Consent from laboratory needed.
- Define turmeric solution
- Revise inclusion / exclusion criteria

**Decision:** accepted with modification





**Minutes – 5<sup>th</sup> IEC meeting**

5. **Name of the investigator:** Vinitha Kumari

**Title of the project:** Awareness of Probiotics Among Dental Practitioners of Puducherry-questionnaire study

**Suggestions:**

1. Dr.Ranganathan – raised doubts over whether general practioners will be aware of probiotics as it still remains a concept used more in the west  
-To modify questionnaire accordingly if required

**Decision:** accepted with modification





**Minutes – 5<sup>th</sup> IEC meeting**

6. **Name of the investigator:** Ashok kumar

**Title of the project:** Effectiveness and Efficiency of Innovative Non Projection Visual Dental Health Education Aids Among 12 Year and 15 Years Old School Children – A Cross Sectional Case Control Study.

**Suggestions :**

- Dr. Ranganathan and Dr. Srinivasan: It is inappropriate to use both effectiveness and efficiency . Avoid efficiency . Use only effectiveness
- Do not mention cross sectional study. Just keep it as questionnaire study

**Decision:** accepted with modification





### Minutes – 5<sup>th</sup> IEC meeting

7. **Name of the investigator:** Katherina Sushmita Barman

**Title of the project:** Oral Health Literacy Intervention Among Caregivers of HIV Positive Children  
– An Altruistic Step in Dental Care for Smile from Within.

**Suggestions:**

Dr. Ranganathan- remove “Baseline personal information” in HIV associated studies

- To justify why impact is measured after a 2 month period
- Permission letters to be documented.

**Decision:** accepted with modification







**Minutes – 5<sup>th</sup> IEC meeting**

8. **Name of the investigator:** Dr. Uma devi

**Title of the project:** Estimation of Salivary Glucose, pH, Flow Rate in Gestational Diabetes Mellitus.

**Suggestions:**

Dr. Ranganathan and Dr. Stephen –

- fructosamine test is more indicative in pregnant women.

- Dr.Lokesh and dr. Ranganathan- mention the procedure for disposal of biologic samples taken for study

- also to obtain consent from patient for utilisation of their clinical data

**Decision:** Approved





**Minutes – 5<sup>th</sup> IEC meeting**

9. **Name of the investigator** : Dr. Abhishek Shaji Varghese

**Title of the project:** Prevalence of Dental Fear and its Relationship to Dental Caries and Gingival Disease Among School Children in Puducherry – A Cross Sectional Study.

**Suggestions:**

Dr. Ranganathan- to justify why the age group 6 - 12 yrs has been chosen?

**Decision:** Approved





**Minutes – 5<sup>th</sup> IEC meeting**

10. **Name of the investigator:** Dr. Annamary Kattakayam

**Title of the project:** Color Preference and its Association to Emotions Among School Children of Puduchery-A Cross Sectional Study.

**Suggestions:**

Dr. Ranganathan - no need for validating MDAS questionnaire as it is prevalidated

- How are you ruling out the possibility of color blindness in children??

- Sample to be divided into male and female to avoid bias in color preference

Dr. Lokesh - To Correct/ modify information sheet question format as appropriate to this study

**Decision:** Approved





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**11. Name of the investigator:** Dr.Gayathri.K

**Title of the project:** Use of Dental Anxiety Questionnaire and Clinical Approaches: A National Survey of Pediatric Dentists.

**Suggestions:**

Dr. Ranganathan- do not use the term “South Indian population” instead use “dentists from the following states”

Dr. Srinivasan- online survey- no need for consent forms –the first question of the form can assess the willingness to participate in the study

- Question no.6- modify scales/ ratings

- To modify questionnaire

**Decision:** accepted with modification





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**12. Name of the investigator:** Dr.Amudhavalli .V

**Title of the project:** Prosthodontics Practices Among Non Prosthodontists in Complete Denture Treatment in Puducherry – A Cross Sectional Survey.

**Suggestions:**

Dr. Ranganathan and Dr. Stephen- to not use the term “cross sectional survey” – keep it as questionnaire study

- questionnaire to be modified

Dr. Srinivasan-questionnaire does not contain questions on whether patient is happy with dentures delivered- to include it

Dr. Ranganathan- question no.5 is not specific

**Decision:** accepted with modification





**Minutes – 5<sup>th</sup> IEC meeting**

**13. Name of the investigator:** Deva meena

**Title of the project:** To Determine the Relationship of Occlusal Plane to Campers Plane Variation and Occlusal Plane to Mandibular Plane in Dentate Patients - A Cross-Sectional Study.

**Suggestions:**

- Mention study as retrospective in title

**Decision:** Approved





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**14. Name of the investigator:** Dr.Yoga

**Title of the project:** Assessment of Age and Sex with Anthropometric Measurements of Ear –A Cross Sectional Study

**Decision:** investigator absent. To resubmit and present the project for ethical clearance.



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**Minutes – 5<sup>th</sup> IEC meeting**

**15. Name of the investigator:** Vijayashanthi .S

**Title of the project:** Comparative Evaluation of Effect of Sugar Substitutes, Xylitol and Stevioside on the Cariogenic Biofilm Formation and Antimicrobial Effect on Streptococcus Mutans – An In Vitro Study

**Decision:** approved







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16. Krishnapriya. V & 17. Dr. Venugopal – projects discontinued therefore not scrutinised



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**18. Name of the investigator:** Dr. Deepika.S

**Title of the project:** Does Changing the Order of Injection in the Extraction of Mandibular Molars Reduce Post Extraction Complication. - Prospective Comparative Study.

**Suggestions:**

Dr. Ranganathan - instead of changing the order of injections change the needle.

- SOP cannot be changed unless there is evidence for patient benefit
- Changing of order increases risk of carrying infection into deeper tissue and spaces.

**Decision:** Repeat review with modification/ rejected





**Minutes – 5<sup>th</sup> IEC meeting**

19. **Name of the investigator:** Dr.Lucky kumara

**Title of the project:** The Effect of Temperature of the Irrigating Solution on Third Molar Surgery - A Prospective Study.

**Suggestions:**

Dr. Ranganathan – 4 degree is freezing temperature of water. Possibility of severe ischemia and vasoconstriction in tissues and therefore not recommended

The investigator and guide produced articles for use of water at 12 degree in spinal surgeries. IEC members have asked for rationale behind use of 12 degree temperature and if satisfactory this may be used intra orally.

**Decision:** repeat review with modification





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**20. Name of the investigator:** Dr.Lakshmi priya

**Title of the project:** Dental Age Estimation by Comparing Demirjian's and Nolla's Methods Among Children Attending Indira Gandhi Institute of Dental Sciences- A Retrospective Study.

**Decision:** Approved



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**21. Name of the investigator:** Dr.Lakshman

**Title of the project:** Comparison of Nasal Index Among Under Graduate Students of Indira Gandhi Institute of Dental Sciences – A Cross Sectional Study.

**Decision:** Approved



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**22. Name of the investigator:** Dr.Sivasanthosh

**Title of the project:** Age Related Changes in Relative Position of Mental And Mandibular Foramen on A Panoramic Radiograph- A Retrospective Study.

**Decision:** Approved

Dr B Pratebha

Member Secretary, Institutional Ethics Committee, IGIDS, SBV

Date: 17.08.2015

Dr Ranganathan

Chairman, Institutional Ethics Committee, IGIDS, SBV

Date: 18.08.2015



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