

Tagore Dental College and Hospital

Minutes – 20th Institute Ethics Committee Meeting – 31-08-2021

The meeting started at 10.30am at the board room , Tagore Dental College with the Member Secretary Dr.S. Jimson welcoming all the members.

The following members attended the ethical committee meeting through Zoom Portal .

1. Dr.C.Saravanan (Chairperson)
 2. Dr.S.Jimson ((Secretary)
 3. Dr.M.R.Srinivasan
 4. Dr.Geetha
 5. Dr.K.B. Prasanna
 6. Dr.Miriam Samuel
 7. Dr.I.Kannan
 8. Mr.I. Raja Samuel
 9. Rev.D. Sagariya
- Minutes of the 19th Ethics Committee meeting was presented and approved.
 - Dr.Saravanan, Professor, Department of Oral and Maxillofacial Surgery, SRM Dental College & Hospital, Kattangulathur, Chennai chaired the meeting and gave a brief description about the conduct of the meeting.

There were a total of 12 presentations to be discussed in the meeting.

1. The 1st presentation was by **Ms.Pooja N.R. CRRI, Department of Oral Pathology** under the guidance of **Dr.Sai Krishna, HOD and Professor, Department of Oral Pathology**, on the study title **“Estimation of age by assessment of dentin translucency”**

The following comments were observed by the committee. The principal investigator was asked to do the following changes and resubmit the study.

- To do calculation of adequate sample size based on prior studies
- To take adequate precautions to mask the identity of the individuals who contributed extracted materials.

- To change the method of sampling to non random
 - To mention the amount of forensic value / inference the study findings carry
 - To consider adding the level of attritions / abrasions / erosions in the study.
2. The 2nd presentation was by **Ms.Preetha G.and Ms.Pavithra S., CRRI, Department of Oral Pathology**, under the guidance of **Dr.L.S.Makesh Raj, Associate Professor, Department of Oral Pathology**, on the study title “**Assessment of popular tobacco cessation android application using the ABACUS app behavior change scale tool.**”

The following comments were observed by the committee. The principal investigator was asked to do the following changes and resubmit the study

- To do the following changes in the study methodology
 - To mention how assessment of human behavioral changes are going to be done
 - To mention the end use of the objective of the study to public health
 - To include applications in both iOS and Android.
 - To have a primary and secondary objective
3. The 3rd presentation was by **Ms.A.Bharghavi and Ms. P.T. Abinaya, CRRI, Department of Periodontics**, under the guidance of **Dr.Priyadharshini, Reader, Department of Periodontics**, on the study title “**Estimation of prevalence of different periodontal condition amongst individuals visiting the department of Periodontics-TDCH; a retrospective study**”

The following comments were observed by the committee. The principal investigator was asked to do the following changes and resubmit the study for presentation as the Guide was not present in the meeting for the presentation.

- To mention the need to do a retrospective study
 - To make it a community based study to find the prevalence
 - To justify the need of the study
 - The analysis plan is not clear.
 - What are the proposed steps to delink the identifiers of the participants?
4. The 4th presentation was by **Ms.Suhasini R. and Ms. Sivaranjini S. CRRI Department of Pedodontics** under the guidance of **Dr. Gayathri, Senior Lecturer, Department of Pedodontics** on the study title “**Parental acceptance of different behavior management techniques used in pediatric dentistry- a cross sectional study.**”

The following comments were observed by the committee. The principal investigator was asked to do the following changes and resubmit the study.

- To change the study title.
- To justify the need for questionnaire feedbacks.
- To prepare patient information sheet and informed consent
- To justify the need for simple random sampling method.
- Data collection tool has identifiers and please make sure privacy/confidentiality is ensured.
- To change the exclusion criteria.
- To change the term “cognitive behavioral therapy”.

5. The 5th presentation was by **Mr.Akhileshwaran**, CRRI, Department of Periodontics under the guidance of **Dr.Juala Catherine, Senior Lecturer, Department of Periodontics** on the study title “**Comparative evaluation of ph changes in gingivitis and Periodontitis**”

The following comments were observed by the committee. The principal investigator was asked to do the following changes and resubmit the study.

- To do the following changes in the study methodology
 - To State the study design
 - To find alternative methods of measuring pH accurately other than litmus paper
 - To make more additions to the inclusion criteria such as minimum number of teeth in the arch or partially edentulous arch
 - The data collection instrument seems to be incomplete

6. The 6th presentation was by **Ms.Harshitha Balaji**, CRRI, Department of Orthodontics, under the guidance of **Dr.Rajesh Raman, Senior Lecturer, Department of Orthodontics** and **Dr.Balaji.K, Head of the Department of Orthodontics**, on the study title “**Evaluation of salivary levels of cariogenic bacteria in patients during orthodontic treatment with fixed appliance versus thermoplastic aligners - an observational prospective study**”

The following comments were observed by the committee. The principal investigator was asked to do the following changes and resubmit the study.

- To consult a microbiologist whether cariogenic bacteria can be extracted from 1 ml of saliva.
- To consider doing as a study with two groups – 1 group of aligners and 1 group of normal fixed appliance.
- To include a consent for the parents.

7. The 7th presentation was by **Ms.Durgalakshmi, CRRI Department of Oral and Maxillofacial Surgery**, under the guidance of **Dr.Lokesh B. Reader, Department of Oral and Maxillofacial Surgery**, on the study title “**Pattern and causes of tooth extraction in patients reporting to dental hospital**”

The following comments were observed by the committee. The principal investigator was asked to do the following changes and resubmit the study.

- To justify the age group segregation.
- To remove the term “quantitative”.
- To justify sample size calculation.
- To mention about the usefulness of study to the society.
- To remove all the exclusion criteria.
- Participant information sheet is missing; Informed consent form needs revision.

8. The 8th presentation was by **Mr. Prithvirajan G. CRRI**, Department of Oral Pathology under the guidance of **Dr. Jai Santosh Manikandan, Senior Lecturer, Department of Oral Pathology** on the study title “**Use of incisive papilla in gender determination - a cross sectional study.**”

The following comments were observed by the committee. The principal investigator was asked to do the following changes and resubmit the study.

- To modify the informed consent specific to hiding the personal identity of the patient
- Rationale is not convincing. Information provided is inadequate to justify the research gap
- Justification of sample size is absent
- Analysis is not clear.

9. The 9th presentation was by **Dr.Krishanaeshwari, Professor, Department of Anatomy**, under the guidance of **Dr.D.H.Gopalan, Department of Anatomy** on the study title **Prevalence of styloid process elongation on panoramic radiography in south Indian population**

The following comments were observed by the committee. The principal investigator was asked to do the following changes and resubmit the study.

- To make changes in the study title, to change the term South Indian Population to Tertiary care Dental Hospital.
- To change the study methodology.
- To take adequate precautions to mask the identity of the individuals.

- How many records are expected to be analyzed?
- Hospital-based studies estimate “frequency” of the outcome (styloid process elongation) and may not reflect “prevalence” in the community.

10. The 10th presentation was by **Dr.Pavithra B. II yr PG, Department of Prosthodontics, under the guidance of Dr.C.J.Venkatakrishnan, Head of Department and Dr.Jacob Mathew Philip, Reader, Department of Prosthodontics** on the study title **“Assessment of the air microbial analysis during prosthodontic abutment preparation: estimating the bacterial count in the aerosols”**

The following comments were observed by the committee. The principal investigator was asked to do the following changes and resubmit the study.

- To make changes in the study title
- To change it as observational study.
- The cases need to be done in a single room and a single chair.
- To adhere to disinfection and sterilization protocols and mention about the methodology.
- To make sure the waterline needs to be disinfected prior to the beginning of assessment.
- To standardize the methodology and justify randomization and control.
- To change the term clinical trial study.
- To remove the exclusion criteria.
- The study can also be done in small space bridges containing only two teeth preparation.
- Participant information sheet is missing; Informed consent form needs revision.
- SPIRIT guidelines need to be followed to write the full-length proposals.
- “Randomization” is unclear.

11. The 11th presentation was by **Ms.Geethanjali, CRRI, Reader, Department of Oral Medicine and Radiology** under the guidance of **Dr.N.Balaji, Reader, Department of Oral Medicine and Radiology** on the study titled **“Prevalence of oral mucosal lesion in dental patients with tobacco smoking, chewing and mixed habits- a cross sectional study.”**

The following comments were observed by the committee. The principal investigator was asked to do the following changes and resubmit the study.

- The mix of exposure and outcomes in the title is misleading (prevalence of lesions among those with tobacco exposure).
- The study rationale is unclear.
- Basis for sample size is missing, to justify the sample size collection.
- To modify the case sheet and rename it as Data collection Sheet.
- To consider doing the study as three groups, control, tobacco users and tobacco and alcohol users.
- To incorporate smoking and drinking habits.
- Participant information sheet is missing
- Analysis plan is unclear
- “Random” selection is mentioned in the protocol, however, it is not clear how this will be done

12. The 12th presentation was by **Dr. Anandh B.** Reader , Department of Oral and Maxillofacial Surgery under the guidance of **Dr.S. Jimson** , Head of Department, **Department of Oral and Maxillofacial Surgery**, on the study title **“Mucormycosis in Covid-19 affected individuals – an observational study”**

No comments were observed by the committee.



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