

**Constitution, Circular, Agenda,  
and Minutes of the Meeting of  
the Ethics Committee in the  
Academic Year  
2020-21**



## ARMY COLLEGE OF DENTAL SCIENCES

Chennapur –CRPF Road, Jai Jawahar Nagar Post, Secunderabad – 500 087, Telangana

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NAAC Accredited 'A' & Certified ISO 9001 : 2015 & ISO 14001 : 2015

### **Constitution of Ethics Committee in the Year 2020-21**

S.NO.	DESIGNATION	NAME	AFFILIATION	ROLE
1	CHAIRPERSON	Lt Gen (Dr) T Ravindranath, AVSM, VSM (retd)		Chairs and conducts meetings
2	MEMBER SECRETARY	Dr. K V Ramana Reddy	Principal, Army College of Dental Sciences	Member Secretary
3	MEMBER	Dr. Prasad Chitra	Head of Department, Department of Orthodontics	Clinician
4	MEMBER	Dr. Mamta Kaushik	Head of Department, Department of Conservatory Dentistry and Endodontics	Clinician
5	MEMBER	Dr. Sanjay Vasudevan	Head of Department, Department of Periodontics	Clinician
6	MEMBER	Dr. V. Krishna Priya	Head of Department, Department of Pedodontics	Clinician
7	MEMBER	Justice Maj Gen. AB Gorthi	Judge Advocate General	Legal Expert
8	MEMBER	Dr (Mrs) Sudha Menon		Psychologist
9	MEMBER	Mrs. Suchitra Menon		Lay Person

The Member Secretary appointed all the members as per schedule Y of ICMR guidelines on 12th November 2018. The new committee will be reconstituted once every 2 years. Lt Gen (Dr) T Ravindranath, AVSM, VSM (retd) is not a faculty member of the Army College of Dental Sciences. He was elected by members of the group on 12 November 2014. This committee will be valid from 12 November 2018 to 12 November 2020.

The committee will review all new research projects and also the ongoing research project at intervals appropriate to the degree of risk to the study subjects. The committee will maintain a list of projects submitted, approved/ disapproved, and each project's outcome.



Principal  
Army College Of Dental Sciences

*[Signature]*  
Principal



**ARMY COLLEGE OF DENTAL SCIENCES**  
**SECUNDERABAD**

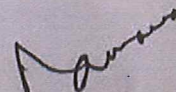
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23 Jan 2021

**CIRCULAR**

**ETHICAL COMMITTEE MEETING**


1. Ethical committee meeting will be held on 30 Jan 2021 (Saturday) from 10.00am onwards in Lecture hall No 4.
2. All Ethics committee members and PG guides are requested to be present for the meeting.

  
(Dr KV Ramana Reddy)  
Principal

**Distribution:-**

1. Registrar - for info please.
2. All PG Departments
3. Adm Supervisor - Ensure proper arrangements
4. Office copy



  
Principal  
Army College Of Dental Sciences



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### **AGENDA**

The EC is set up to ensure that the research protocols that are carried out at the Army College of Dental Sciences, Secunderabad -

- will ensure the safety, rights, and well-being of all trial subjects. Special attention will be paid to trials that may include vulnerable subjects (children, pregnant and nursing mothers, geriatric subjects, disabled subjects, and minorities).
- are found in scientific design, have statistical validity, and are conducted according to the parameters of ICH-GCP as well as local regulatory requirements
- conducted under the supervision of medical persons with the required experience/expertise
- include solely, patients who, through their legally acceptable representation have given informed consent for participation in the research study
- members will maintain the confidentiality of all the discussions during the meeting and sign a confidentiality form at the start of their membership term.

### **Procedures**

The applicant of the proposal (generally the principal investigator) is required to submit at a minimum 7 copies of his/ her application letter and 7 copies of the following documents, 15 days before a scheduled meeting:

- i. final protocol with all amendments
- ii. investigators brochure and any other safety-related information available
- iii. the informed consent form and patient information sheet in English and the relevant translated languages and their back- translations with appropriate translation certificates
- iv. letter of approval from the drug controller general of India
- v. current CV of the principal investigator
- vi. study protocols agreement between the sponsor and principal investigator
- vii. certificate of insurance

### **The Committee expects from the principal investigator:**

- a report of the clinical trial on an annual basis or more frequently if so directed
  - a report of each serious adverse event in the study
  - to be kept informed of amendments/ revisions to any study-related document as well as patient safety-related information
  - to be kept informed of study completion and discontinuation with reasons.
  - to submit justification for approval to restart studies discontinued earlier
-




The ethics committee is to be notified of any payments proposed to be made to study patients towards reimbursement of incidental expenses.


- the committee will meet **as and when required**. Advance notice 15 days before each meeting will be sent out to the EC members, along with the agenda.
- the requisite quorum of 10 members is required to be present at each review meeting.
- It is preferable that at least one of the Ethics Committee members not affiliated with the institute be present during each review meeting.
- A copy of the EC composition and operating procedures for the research project will be made available, if required the member secretary, designated by the chairperson, will record the minutes of the meeting and circulate the same to the members within two weeks after the meeting.
- A study team member or Principal Investigator may be called to the meeting to present the study or answer specific queries. However, if he/ she will not participate in the decision-making /voting process of that study even if he/she is a regular member of the EC
- A study team member including the principal investigator will be deemed an interested party with regards to the review.
- the study team members' nonparticipation in the decision-making/voting process will be recorded in the response letter from the EC
- The decision of the committee will be taken by a majority vote after the quorum requirements are fulfilled to recommend/ reject /suggest modifications for repeat review or advice for appropriate steps. If subject experts are invited to offer their views, they will not take part in the voting process.
- The committee will give its opinion on the project in one of the following ways:
  - Approval
  - Disapproval
  - Modification before approval
  - Discontinuation of a previously approved project

The study will be ambiguously identified by protocol title and number in all cases. All documents reviewed will be listed in the response letter, which will also state the list of members present and the date of the meeting at which the study was reviewed.

- The chairman/member-secretary will convey the decision of the committee to the principal investigator in writing.
- Should an amendment to study-related documents be administrative and not involve study design or safety criteria, it may be provisionally approved in writing, by the
- chairman/ member -Secretary of the committee without calling the full meeting. The chairman /member-secretary will inform other members of the committee of the amendment and his /her decision during the subsequent regular meeting of the committee. The decision will be rectified and minuted.
- Correspondence between the EC and the principal investigator/ study team and other relevant records (response letter, minutes of meetings, composition, etc) will be retained for a minimum period of 3 years after completion of the trial.



  
Principal  
Army College Of Dental Sciences

  
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## Minutes of the Ethics Committee Meeting held on 30 Jan 2021

Chairperson Prof Yogeshwari presided over the virtual meeting along with the member secretary, Dr. KV Ramana Reddy, and other members of the Ethics Committee.

The first presentation was by **Dr. ASWANI**, Department of Oral & Maxillofacial Surgery. Title: Comparison of Pre-emptive Analgesic Effect of Ibuprofen & Ketorolac in Third Molar Surgery

Questions raised by the committee were

1. How will you ensure blending?
2. Which pain scale are you using?
3. How will you check with the patient for pain control?

The next presentation was by **Dr. ANJANA**, Department of Oral & Maxillofacial Surgery. Title: Comparison of Efficacy of Cartridge versus Multidose Lignocaine Local Anaesthetic Vials

Questions raised by the committee were

1. Is the concentration of adrenaline in LA the same in both or different?
2. How will you ensure that there is no bias?
3. What is double-blinding?
4. Which test are you going to use for statistical analysis?

The next presentation was by **Dr. AYESHA**, Department of Pedodontics and Preventive Dentistry. Title: Comparative evaluation of micro tensile bond strength of restorative materials on SDF and Non-SDF treated teeth: An in vitro study

Questions raised by the committee were

Nil

The next presentation was by **Dr. PREM SHANKAR CHAUHAN**, Department of Pedodontics and Preventive Dentistry. Title: Effectiveness of two types of distraction technique in the management of dental anxiety and pain in 6-12 years old children

Questions raised by the committee were

1. Informed consent to be taken from parents.
2. Duration of using the distraction technique

The next presentation was by **Dr. BHARAT POONIA**, Department of Orthodontics and Dentofacial Orthopaedics. Title: Evaluation of orthodontic tooth movement predictability with customized fixed orthodontic appliances - a prospective cohort study

Questions raised by the committee were

1. How much time will you take to complete the cases?
2. What are the selection criteria for choosing the cases?

The next presentation was by **Dr. MOHD. MUDASSIR MOHINUDDIN**, Department of Periodontics. Title: Association between obesity and periodontitis among undergraduate students of Hyderabad: A Cross-sectional study

Questions raised by the committee were

1. Why study only dental undergraduate students and not all undergraduate students?
2. How will the BMI index be recorded?

3. Informed consent is required.

The next presentation was by **Dr. SNEHA REDDI**, Department of Periodontics. Title: Awareness of periodontal diseases and its management among medical college students in Hyderabad: A Questionnaire-based study

Questions raised by the committee were

1. What is the relationship between systemic disease and periodontitis?
2. How will the questionnaire be prepared?
3. Difference in the knowledge of various years of undergraduates through this questionnaire?

The next presentation was by **Dr. NEHA KUMARI**, Department of Periodontics. Title: Relationship between fingerprint patterns and periodontal status: demographics study

Questions raised by the committee were

1. How will you record the fingerprint?
2. What is the relationship between fingerprint and periodontal disease?

The next presentation was by **Dr. VISHNU**, Department of Conservative Dentistry and Endodontics. Title: Influence of audio & simulated 3D environment of anesthetic efficacy of Lidocaine for Inferior Alveolar Nerve Block in Patients with Irreversible Pulpitis: Randomised Controlled Trial

Questions raised by the committee were

1. How would you convince the patient to the study?
2. Would songs and videos selection be based on patients' choices?
3. How will you use virtual reality glasses?

The next presentation was by **Dr. NEHA CHAUHAN**, Department of Conservative Dentistry and Endodontics. Title: Comparative evaluation of the remineralizing capacity of various agents on artificial caries using Scanning Electron Microscope – Energy dispersive X-Ray Analysis: An Invitro Study

Questions raised by the committee were

1. What is the clinical significance of the study?
2. Availability of materials and reagents?
3. How will you test the remineralization of the teeth?

The next presentation was by **Dr. AMIT KUMAR**, Department of Conservative Dentistry and Endodontics. Title: To Evaluate the clinical performance of reinforced glass Ionomer materials in Class II restorations – A 12-month Randomized Controlled Clinical Trial

Questions raised by the committee were

1. What is your stance on enrolment of pregnant patients and radiographic exposure risk?
2. Would medically compromised patients be included?
3. Inclusion or exclusion of medically challenged patients?
4. What would be the method of evaluation of results?
5. Would modified USPHS criteria be used?



The next presentation was by **Dr. ANOUSHKA MENON**, Department of Prosthodontics, and Crown and Bridge. Title: Surface modifications' effect on the translucency and opalescence of high translucency monolithic zirconia- an invitro study.

Questions raised by the committee were

1. Standardization protocols for surface modifications
2. Rationale behind grinding of sandblasting discs.
3. Device to be used to check translucency and opalescence.

The next presentation was by **Dr. AP RAVI**, Department of Prosthodontics, and Crown and Bridge. Title: Comparative evaluation of tensile bond strength of vinyl siloxane ether with different tray materials using two tray adhesives

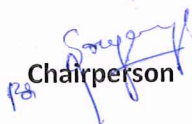
Questions raised by the committee were

1. Difference between polyvinyl siloxane and vinyl siloxane ether impression material
2. How do we check tensile strength?
3. Different types of adhesives.


The next presentation was by **Dr. BALJINDER KAUR**, Department of Prosthodontics and Crown and Bridge. Title: Comparing marginal and internal fit of composite veneers fabricated with conventional, CAD-CAM, 3 D printing using two different resin cement.

Questions raised by the committee were

1. How to measure the marginal and internal fit?
2. Which resin cement are you using and why?
3. How would sectioning of the tooth be done?

  
Chairperson



  
Principal  
Army College of Dental Sciences