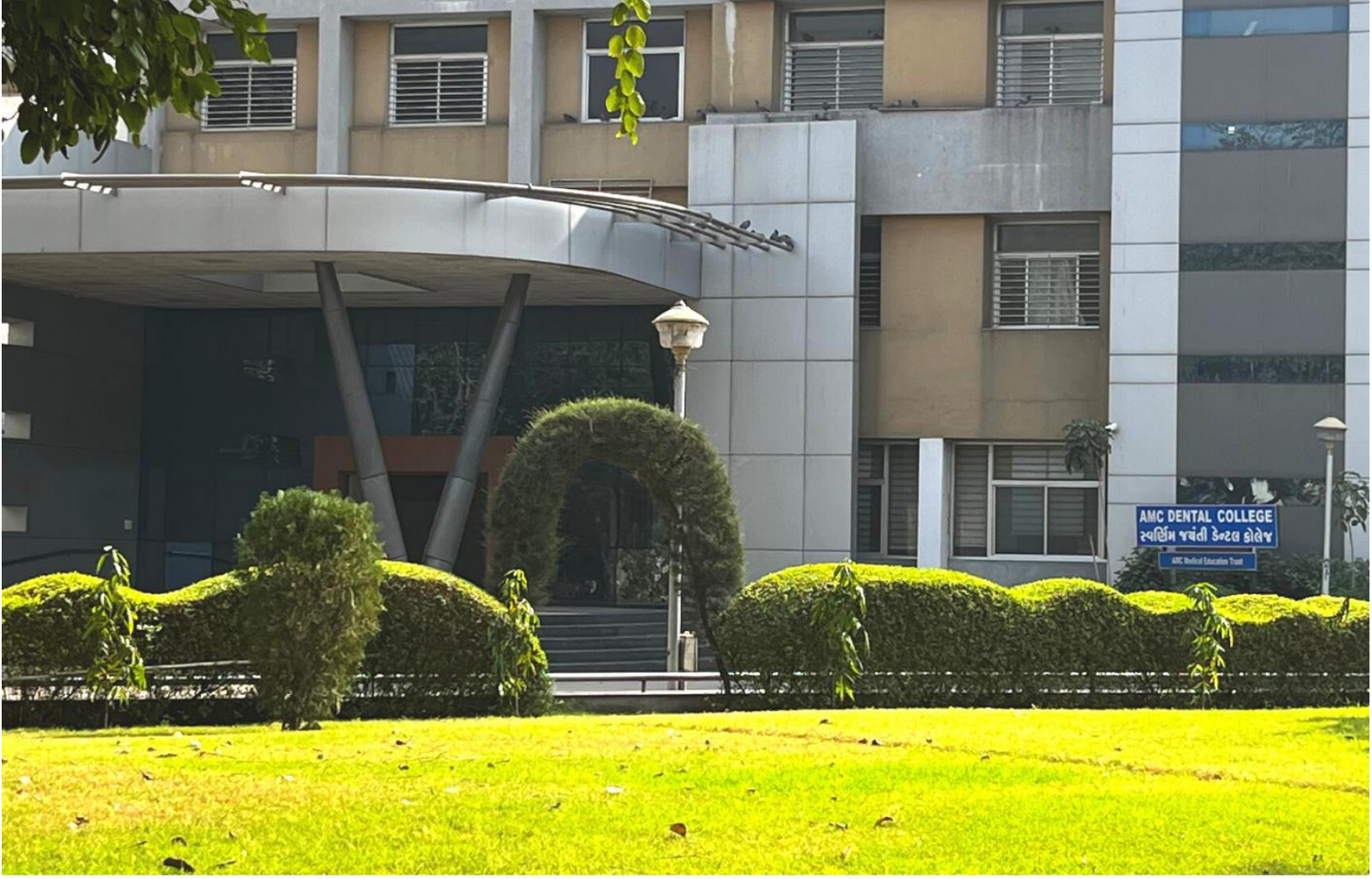

AMC DENTAL COLLEGE

Khokhra, Ahmedabad 380008

Affiliated to Gujarat University

SELF STUDY REPORT (CYCLE 1) 2022-2023

CRITERIA: 3: Research, Innovations and Extension

KEY INDICATOR: 3.3: Research Publications and Awards

METRIC: 3.3.1: The Institution ensures implementation of its stated Code of Ethics for research.

Index

IEC REGISTRATION AND COMPOSITION

File No. ECR/1242/AMC Dental/Indt/GJ/2014

Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Office of Drugs Controller General (India)
Central Drugs Standard Control Organization

FDA Bhawan, Kotla Road,
New Delhi – 110 002, India
Dated: 13/05/2015

To,

The Chairman,
Institutional Ethics Committee,
AMC Dental College & Hospital,
Bhalakia Mill Compound, Khokhra,
Ahmedabad, Gujarat-380008, India.

SUB: - Ethics Committee Registration no. ECR/236 /Indt/GJ/2015 issued under Rule 122DD of the Drugs & Cosmetics Rules1945.

Sir/Madam,

Please refer to your application no. Nil dated Nil submitted and your response dated 05.03.2015 to this office for the Registration of Ethics Committee.

Based on the documents submitted by you, this office hereby registers the INSTITUTIONAL ETHICS COMMITTEE, AMC DENTAL COLLEGE & HOSPITAL situated at BHALAKIA MILL COMPOUND, KHOKHRA, AHMEDABAD, GUJARAT-380008, INDIA with Registration number ECR/236 /Indt/GJ/2015 as per the provisions of Rule 122DD of the Drugs and Cosmetics Rules, 1945 subject to the following conditions:

1. **The Ethics Committee shall review and approve only the study protocols and related documents of Bioavailability/Bioequivalence studies of the approved drug molecules and also carry ongoing review of such studies.**
2. The Ethics Committee shall review and accord its approval to Bioavailability/Bioequivalence studies and also carry ongoing review of such studies at appropriate intervals, as specified in Schedule Y and the Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for safeguarding the rights, safety and well being of the trial subjects.
3. In the case of any serious adverse event occurring during Bioavailability/Bioequivalence studies, the Ethics Committee shall analyze and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y.
4. The Ethics Committee shall allow inspectors or officials authorized by the Central Drugs Standard Control Organization to enter its premises to inspect any record, data or any document related to Bioavailability/Bioequivalence studies and provide adequate replies to any query raised by such inspectors or officials, as the case may be, in relation to the conduct of Bioavailability/Bioequivalence studies.

5. The licensing authority shall be informed in writing in case of any change in the membership or the constitution of the ethics committee takes place.

6. All the records of the ethics committee shall be safely maintained after the completion or termination of the study for not less than five years from the date of completion or termination of the trial (Both in hard and soft copies).

7. If the Ethics Committee fails to comply with any of the conditions of registration, the Licensing Authority may, after giving an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefore, suspend or cancel the registration of the Ethics Committee for such period as considered necessary.

8. This registration shall be in force for a period of three years from the date of issue, unless it is sooner suspended or cancelled.

9. Ethics Committee shall consist of not less than seven members and is subject to a maximum of 15. One among its members, who is from outside the institute, shall be appointed as chairman, one member as a Member Secretary and rest of the members shall be from Medical, Scientific, Non Medical and Non-scientific fields including lay public.

10. The committee shall include at least one member whose primary area of interest or specialization is Non-scientific and at least one member who is independent of the institution besides; there should be appropriate gender representation on the Ethics Committee.

11. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

12. Members should be conversant with the provisions under Schedule Y, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

13. For review of each protocol the quorum of Ethics Committee shall be at least five members with the following representations:

    i. Basic medical scientist (preferably one pharmacologist)
    ii. Clinician
    iii. Legal expert
    iv. Social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person.
    v. Lay person from community

14. The members representing medical scientist and clinicians should have Post graduate qualification and adequate experience in their respective fields and aware of their role and responsibilities as committee members.

15. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.

16. There should be no conflict of interest. The members shall voluntarily withdraw from the Ethics Committee meeting while making a decision on an application which evokes a conflict of interest which may be indicated in writing to the Chairman prior to the review and be recorded so in the minutes. All members shall sign a declaration on conflict of interest.

17. Subject experts or other experts may be invited to the meetings for their advice. But no such expert shall have voting rights.

18. This certificate is issued to you on the basis of declaration/ submission by you and that registration is sought for Independent Ethics Committee.

19. Ethics Committee should review such number of protocols of Bioavailability/Bioequivalence studies of approved drug molecules which should be commensurate to the infrastructure and facilities available with them.

20. Status report of the functioning of the Ethics Committee should be submitted to the CDSCO headquarters and concerned zonal office on quarterly basis.

21. The details of funding support and amount of honorarium, if any, payable to the ethics committee members should be defined in the Standard Operating Procedure (SOP) of the committee and records to this extent shall be maintained.

22. Ethics committee should have dedicated office with required infrastructure and supporting staff.

However, it is informed that this Ethics Committee can carry out periodic review of ongoing clinical trials already approved by them prior to 30.01.2013

(Dr. V.G. Somani)
Joint Drugs Controller (I) & Licensing Authority

File No. EC/20/000179

सत्यमेव जयते

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 10-Jun-2020

To

The Chairman
institutional ethics committee
AMC MET DENTAL COLLEGE AND HOSPITAL
Bhalakiya Mill Compound,opp,anupam Cinema
Khokhra AHEMDABAD Ahmedabad Gujarat - 380006
India

Subject: Ethics Committee Registration No. ECR/236/Indt/GJ/2015/RR-20 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/NEW/INST/2020/8440 dated 05-Jun-2020 submitted to this Directorate for the Registration of Ethics Committee.

Please find enclosed registration of the Ethics Committee in Form CT-02 vide Registration No. ECR/236/Indt/GJ/2015/RR-20. The said registration is subject to the conditions as mentioned below:

Yours faithfully

VENUGOPAL GIRDHARILA L SOMANI

(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

Conditions of Registration

1. The registration is **valid for a period of five years from the date of its issue**, unless suspended or cancelled by the Central Licencing Authority. Provided that if the application for renewal of registration is received by the Central Licencing Authority ninety days prior to the date of expiry, the registration shall continue to be in force until an order is passed by the said authority on such application.

2. Ethics committee shall **update their SOPs in view of New Drugs and Clinical Trials Rules 2019** for review and accord approval to a Clinical Trials, Bio-availability or Bio-equivalence study protocols and to oversee the conduct of clinical trial to safeguard the rights, safety and well-being of trial subjects.

3. This certificate is issued to you on the basis of declaration/submission made by you.

4. Composition of the said Ethics Committee is as per the Annexure.

5. No clinical trial or bioavailability or bioequivalence protocol and related documents shall be reviewed by an Ethics Committee in meeting unless at least five of its members as detailed below are present in the meeting, namely:-

(i) medical scientist (preferably a pharmacologist);
(ii) clinician;
(iii) legal expert;
(iv) social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or

theologian or a similar person;
(v) lay person.

6. The Ethics Committee shall have a minimum of seven and maximum of fifteen members from medical, non-medical, scientific and non-scientific areas with at least,
(i) one lay person;
(ii) one woman member;
(iii) one legal expert;
(iv) one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.

7. One member of the Ethics Committee who is not affiliated with the institute or organization shall be the Chairperson, and shall be appointed by such institute or organization and one member who is affiliated with the institute or organization shall be appointed as Member Secretary of the Ethics Committee by such Institute or organization.

8. The Ethics Committee shall consist of at least fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted.

9. The committee shall include at least one member whose primary area of interest or specialisation is non-scientific and at least one member who is independent of the institution.

10. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

11. Members should be conversant with the provisions of New Drug and Clinical Trials Rules, 2019, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

12. The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialization, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.

13. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.

14. The Ethics Committee may associate such experts who are not its members, in its deliberations but such experts shall not have voting rights, if any

15. No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the Clinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no conflict of interest.

16. While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson. The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.

17. Any change in the membership or the constitution of the registered Ethics Committee shall be intimated inwriting to the Central Licencing Authority within thirty working days.

18. The Ethics Committee shall review and accord approval to a Clinical trial, Bioavailability and Bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause (B) of Table 1 of the Third Schedule of New Drugs and Clinical Trials Rules, 2019 and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules, Good Clinical Practices Guidelines and other applicable regulations.

19. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7: provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be: provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site.

20. Where a Bioavailability or Bioequivalence study centre does not have its own Ethics Committee, bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the protocol from the Ethics Committee registered under rule 8:Provided that the approving Ethics Committee shall in such case be responsible for the study at the centre:Provided further that both the approving Ethics Committee and the centre, shall be located within the same city or within a radius of 50kms of the bioavailability or bioequivalence study centre.

21. Ethics committee shall indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licencing Authority.

22. Ethics committee shall make, at appropriate intervals, an on-going review of the trials for which they have reviewed the protocol. Such a review may be based on the periodic study progress reports fumished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites.

23. Where any serious adverse event occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee shall analyse the relevant documents pertaining to such event and forward its report to the Central Licencing Authority and comply with the provisions of Chapter VI, New Drugs and Clinical Trials Rules, 2019.

24. The Ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts wherever required, for deciding relatedness and quantum of compensation, as per condition no (22) mentioned above.

25. Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the Ethics committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licencing Authority.

26. Ethics committee shall comply with the requirements or conditions in addition to the requirements specified under the Drugs & Cosmetics Act, 1940 and New Drugs and Clinical Trials Rues, 2019, as may be specified by the Central Licencing Authority with the approval of the Central Government, to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.

27. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial.

28. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial.

29. Funding mechanism for the Ethics Committee to support their operations should be designed and approved to ensure that the committee and their members have no financial incentive to approve or reject particular study.

30. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.

31. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained.

32. The Ethics Committee shall allow any officer authorized by the Central Licencing Authority to enter, with or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects.

33. Where Central Licencing Authority is of the opinion that Ethics Committee fails to comply with any provision of the Drugs and Cosmetics Act, 1940and New Drugs & Clinical Trials Rules, 2019, it may issue show cause notice to such Ethics Committee specifying therein such non-compliances and the period within which reply shall be furnished by such Ethics Committee. After consideration of the facts and reply given by the Ethics Committee, the Central Licencing Authority may take one or more actions specified under provision of Rule 14, Chapter III of New Drugs and Clinical Trials Rules, 2019.

Annexure

File No. EC/20/000179

सत्यमेव जयते

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 10-Jun-2020

Composition of the Ethics Committee:-

Sr. No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1	Mr. Satyajeet Desai	LLB (Master of Laws (LL.M.))	Legal Expert
2	Mr. Mahendra Joshi	LLB (Master of Laws (LL.M.))	Legal Expert
3	Dr. Supriya Malhotra	MBBS (MD-Pharmacology)	Basic Medical Scientist
4	Ms. Priti Adani	bds (Not Applicable)	Social Scientist
5	Ms. HIMANI Shah	B. COM (Not Applicable)	Lay Person
6	Dr. Ramita Vijay Sood	BDS (MDS IN ORAL AND MAXILLOFACIAL SURGERY)	Member Secretary
7	Dr. ASHA Shah	MBBS (md medicine)	Chair Person
8	Dr. Rajendra Aghnihotri	BDS (msc anatomy)	Scientific Member
9	Dr. Kinnari Rajpura	BDS (mds)	Basic Medical Scientist
10	Dr. Dolly Patel	BDS (mds in orthodontics)	Clinician
11	Dr. Bela Dave	BDS (mds)	Clinician
12	Dr. Darshna Shah	BDS (mds)	Clinician

VENUGOPAL GIRDHARILAL SOMANI

(Dr. V.G. Somani)
Drugs Controller General (I) &
Central Licensing Authority

IRB REGISTRATION AND COMPOSITION

INSTITUTIONAL REVIEW BOARD

AMC DENTAL COLLEGE

KHOKHRA-AHMEDABAD

Sr. No.	Name of Member	Qualification	Role/ Designation in Institutional Review Board
1	Dr. Dolly Patel	Dean, HOD, MDS (Orthodontics)	INSTITUTIONAL HEAD
2	Dr. Ramita Sood	HOD, MDS (Oral & Maxillofacial Surgery)	HEAD OF RESEARCH WING
3	Dr. Ina Patel	HOD, MDS (Prosthodontics)	CHAIRMAN
4	Dr. Bela Dave	HOD, MDS (Periodontics)	SCIENTIFIC AND RESEARCH ANALYST
5	Dr. Anjali Kothari	HOD, MDS C(onservaive & Endodontics)	MEMBER SECRETARY
6	Dr. Ekta Malvania	Reader, MDS (PCD)	STATISTICIAN
7	Dr. Kosha Rupareliya	Sen. Lecturer, MDS (OMDR)	CLINICIAN
8	Dr. Vinay Rao	Sen. Lecturer, MDS (Conservaive & Endodontics)	CLINICIAN
9	Dr. Mahesh Jain	Sen. Lecturer, MDS (Orthodontics)	CLINICIAN
10	Dr. Parth Khamar	Sen. Lecturer, MDS (Pedodontics)	CLINICIAN
11	Falguni Vinod Joshi	Diploma in Arch. Assist, BA, U. Visharad Music	NON- SCIENTIFIC MEMBER

Dr. INA B. PATEL
Prof & HOD
Dept. of Prosthodontics & Crown & Bridge
AMC Dental College & Hospital
Khokhara, Ahmedabad

- IRB is Registered under the IEC of AMC Dental College and Hospital

MINUTES OF MEETINGS
IEC 2023

MINUTES OF MEET OF IEC - 2023
(CLINICAL TRIAL AND DISSERTATION)

DATE: 25-10-23
TIME: 2.15pm
VENUE: AMC conference hall
DETAIL: Approval of PG's and PhD's Dissertation

IEC members present.

1) Dr. Dolly Patel
2) Dr. Asha shah
3) Dr. Mahendra Joshi
4) Dr. Ramita Sood
5) Dr. Darshana shah
6) Dr. Supriya Malhotra
7) Dr. Himani shah
8) Dr. Rajendra Agnihotri
9) Dr. Priti Adani
10) Dr. Ina Patel
11) Dr. Bela Dave
12) Dr. Kinnari Rajpura

THESIS OF PHD'S:

1) Title: Prevalence of occupational burnout amongst oral and maxillofacial surgeons in west India.
Primary investigator**:** Dr. Nishit shah
Mentor: Dr. Ramita Sood
Comments:
1.Add in inclusion:
- Those willing to give consent.
- General dental practitioners to be excluded
- All confounding factor to be included.
- Dr's who already show signs of depression to be excluded.

2.Benefit of study:
- Any help to surgeon who have diagnosed with depression.
- major and minor surgeons in demographic details.

3.Changes to be made:
- Only write initials of doctors involved in study not the name.
- Questionnaires need to be validated.

Remarks: **Approval pending till, corrections are made.**

2) Title: Study of periodontal health among non-hospitalized psychiatric patient.
Primary investigator**:** Dr. Kinjal Desai.
Mentor: Dr Bela Dave.
Comments:
- Find out how many percentages involve in psychiatric clinic.
- Who can be considered as psychiatric patient?

- Informed consent is different for psychiatric patient and is not to be filled by them.
- Exclude schizophrenic patient.

Exclusions:
- Patient who is on any Drugs affecting periodontal health.
- Change term psychiatric used, whenever needed.
- Change the Title first and then go ahead.
- Change groups to less than five years.

Remarks: **Approval pending, need to present again.**

THESIS OF POST-GRADUATES

1) Title: Efficacy of prolotherapy in temporomandibular joint derangement -A prospective Clinical study.
Primary investigator: Dr Mustafa Kurani.
Mentor: Dr Ramita Sood.
Comments:
- What is clicking? Is it significant?
- Inclusion criteria having with reduction or without reduction.
- Complication that can occur? -swelling, post operation pain.
- On procedure be done – la/ga: la.
- Is MRI compulsory? Yes.

Remarks: **Approved**

2) Title: Anatomically guided implant site preparation technique in posterior molar region- A prospective clinical study
Primary investigator: Dr Nisarg Trivedi.
Mentor: Dr Ramita Sood.
Comments:
- What will be the expense?
- What is the follow up period?

Remarks: **Approved**.

3) Title: Efficacy of gas combination cryotherapy for management of benign odontogenic lesion of jaw – A prospective Clinical study.
Primary investigator: Dr Shyam Chauhan.
Mentor: Dr Shital Patel.
Comments:
- What kind of study -prospective
- Do you get enough patient from OPD -yes.

Remarks: **Approved**.

4) Title: To evaluate effectiveness of injectable platelet rich fibrin alone versus injectable platelet rich fibrin with microneedling for gingival augmentation in mandibular anterior thin gingival phenotype: a split month comparative study.

Primary investigator: Dr Aazin Fatima Bukhari.
Mentor: Dr Bela Dave.
Comments:

- Likely outcome by comparing PRF v/s PRF + microneedling.

Remarks: **Approved**.

5) Title: To evaluate effectiveness of platelet rich fibrin alone versus platelet rich fibrin with ascorbic acid with open flap debridement in treatment of stage 3 periodontal -a comparative study.
Primary investigator: Dr Priya Kasundra.
Mentor: Dr Bela Dave.
Comments:

- Amount of ascorbic acid?
- What is the benefit -avoid use of bone graft.

Remarks: **Approved**.

6) Title: Comparation study for extraction socket presentation with synthetic hydroxyapatite present alone and along with platelet rich fibrin -a split mouth in vivo study.
Primary investigator: Dr Sirsha Bhattacharjee.
Mentor: Dr Ashish Kaur
Comments:

- Objectives-primary and secondary.

Remarks: **Approved**.

7) Title: Comparative study of Clinical efficacy between chlorhexidine and chlorhexidine plus hyaluronic acid mouthwash in patient of chronic periodontitis. -Short study
Primary investigator: Dr Sirsha Bhattacharjee
Mentor: Dr Ashish Kaur
Comments: None

Remarks: **Approved**.

Read
25/10/23

Minutes of Meet of IEC - 2023 (Clinical trial anddissertation)

DATE: 23-03-23
TIME: 2.15pm
VENUE: AMC conference hall
DETAIL: Approval of Clinical trials and PG Dissertation

Points discussed:

1. All the presenters were asked to present their thesis in proper format.
2. TIME allotted for presentation was 10 mins for each individual.
3. Presentation should include Title, aims/objective, inclusion and exclusion criteria, materials and method, discussion, parameters for evaluation and conclusion.
4. Participants were informed that during the event of study, they have to submit progress reports every 6 months.

List of attendees: (IEC members)

1. Dr. Dolly Patel
2. Dr. Asha shah
3. Dr. Ramita Sood
4. Dr. Supriya Malhotra
5. Dr. Kinnari Rajpura
6. Dr. Bela Dave
7. Dr. Priti Adani
8. Dr. Mahendra Joshi

Thesis discussed were:

1. Title: Evaluation and comparison of cold atmospheric pressure plasma jets efficiency against E.Faecalis and its biofilm in root canal sterilization- in vitro study.
Primary investigator: Dr. Parth Khamar
Remarks:

- Will it cause gas embolism?

Since, it creates o2 stress and reduces the bacterial environment, it comes out in form of flame and not gas. Therefore, would not go beyond orifice.

- What are future prospects of study?

It might eliminate the need of root canal.

- How expensive is the study?

Sponsored by Government of India.

- Temperature changes of tooth should be monitored.

Remarks: **Approved**

2. Title: A prospective, multicenter, randomized, open label, active controlled, phase 2 study to evaluate the efficacy, safety and tolerability of fixed dose combination (FDC) ofdoxycycline hyclate and metformin hydrochloride (10%

gel in the treatment of adults with periodontitis.

Primary investigator: Dr. Bela Dave

Comments:

- To rule out lot of Drugs used for medical condition (or else SLE can be excluded.)
- Please add, that there is no H/o any immunocompromised conditions or known H/o any medication.
- Please make amendments to exclude any medical condition

Remarks: **Approved**

3. Title: Is the local anesthetic efficiency of tramadol with adrenaline superior to that of lignocaine with adrenaline for extraction of non-complicated maxillary tooth under supraperiosteal injections- A prospective Clinical trial.

Primary investigator: Dr. Rajan Savani

Mentor: Dr. Shital Patel

Comments:

- How is pain assessed in infection?
- At what frequency is pain assessed?

Patient will be asked to wait for 4-5 hours till withdrawal of the Drug.

Remarks: **Approved**

Blood
23/03/23

MINUTES OF MEETINGS
IRB 2023

MINUTES OF MEETING (IRB 2023)

FOR BATCH (2022-25)

DATE: 01/02/23, 06/02/2023, 09/02/23, 13/02/23
TIME: 2:00 PM-5:00 PM
VENUE:AMC Lecture Hall
DETAIL:
1)Planning to review and evaluate the thesis and short-study protocol of all the first year MDS Postgraduate students,
2) To evaluate short study of three final year students and one third year student who had to represent at Indian council of medical research (ICMR) change the research protocol due to feasibility issues, before beginning of the final study.

PROGRAM ITSELF:

- During the IRB meeting held on 01/02/23, presentation of synopsis of short study of three final year student was conducted and evaluated by the IRB committee members as well as alterations were suggested where-ever necessary.
- During the IRB meeting held on 06/02/23 presentation of synopsis of dissertation of postgraduate students from department of orthodontics (Three 1st year MDS), oral and maxillofacial surgery (Three 1st year MDS), prosthodontics (Two 1st year MDS), was conducted and evaluated by the IRB committee members as well as alterations were suggested where-ever necessary.
- During the IRB meeting held on 09/02/23, presentation of synopsis of dissertation of postgraduate students from department of prosthodontics (One 1st year MDS), periodontics (Three 1st Year MDS), Endodontics (Three 1st Year MDS) and as well as presentation of short study synopsis from department of periodontics (Three 1st Year MDS) was conducted and evaluated by the IRB committee members alterations were suggested where-ever necessary.
- During the IRB meeting held on 13/02/23, presentation of short study synopsis of one third year student and from department of prosthodontics (Three 1st Year MDS), periodontics (One 1st Year MDS) was conducted and evaluated by the IRB committee members alterations were suggested where-ever necessary.

PROGRAM OUTCOME:

- Out of all the students, who made the presentations during IRB meeting, study of following students, three students of oral surgery department, three students of periodontics department (dissertation) and one student of periodontics department (short study) will go for Ethical Committee.

1) Mustafa Kurani
2) Nisarg Trivedi
3) Shyam Chauhan
4) Priya Kasundra
5) Aazinfatima Bukhari
6) Sirsha Bhattacharjee (Dissertation)
7) Sirsha Bhattacharjee (Short study)

CHAIRPERSON: Dr. Ina Patel

During the IRB meeting held on 01/02/23,06/02/2023,09/02/2023,13/02/2023.

Thesis discussed were:

1. Title: Neuromuscular adaptation following twin block appliance: an electromyographic study for anterior temporalis, masseter and orbicularis oris muscle.
   Primary investigator: Dr. Hasti Trivedi (Dept of Orthodontics)
   Mentor: Dr Dolly Patel
   Remarks:
   - Mention pre and post photos of before and after twin block.
   - Use of gnathodynometer.
   - Select sample size according to Drop out ratio.
   - Add in "T" title in adaptation.
   - Take assent form for subjects more than 12 years.

2. Title: Use of digitally designed bracket positioning to compare the accuracy of bracket placement with direct and different indirect bonding techniques: In vivo study
   Primary investigator: Dr. Vrunda shah (Dept of Orthodontics)
   Mentor: Dr Dolly Patel
   Remarks:
   - Modify likely outcome of study
   - Result table will be too many in numbers
   - 30 printed trays should be added
   - Randomization will be there.

3. Title: Evaluation of mandibular morphology using 2d, 3d imaging and 3d printed models indifferent skeletal malocclusion
   Primary investigator: Dr. Vatsal Patel (Dept of Orthodontics)
   Mentor: Dr Roopal Patel
   Remarks:
   - Modify need of study
   - In class 1 and 2 what morphologies are you going to check
   - Keep 3 groups of each class
   - Reform study proforma
   - Radiation consent is essential as a part of study

4. Title: Efficacy of prolotherapy in temporomandibular joint derangement: -a prospective clinical study
   Primary investigator: Dr. Mustafa Kurani (Dept of Oral and Maxillofacial Surgery) (EC)
   Mentor: Dr Ramita Sood
   Remarks
   - Which tmj disorders are going to be included should be mentioned.
   - MRI is compulsory.
   - Vas scale should be replaced as it is compulsory.

5. Title: Anatomically guided implant site preparation technique in posterior molar region-A prospective Clinical study.
Primary investigator: Dr. Nisarg Trivedi (Dept of Oral and Maxillofacial Surgery) (EC)
Mentor: Dr Ramita Sood
Remarks:

- Change the title.
- Techniques sensitive.
- To reduce cost, replace graft with PRF.
- Prosthetic reference should be mentioned.
- In inclusion criteria patient who are deprogrammed should be included.
- For standardization same operator and same implant technique should be involved.

6. Title: Efficacy of gas combination cryotherapy for management of benign odontogenic lesionof jaw- A prospective Clinical study
Primary investigator: Dr. Shyam Chauhan (Dept of Oral and Maxillofacial Surgery) (EC)
Mentor: Dr Shital Patel
Remarks:

- Last 3 option of parameter to be assessed should be specified.
- Long term data is needed.

7. Title: Co-relative analysis of width of anterior maxillary teeth with the width of first three fingersand nail form to tooth form of left hand- a comparative study.
Primary investigator: Dr Kresha Shah (Dept of Prosthodontics)
Mentor: Dr Ina Patel
Remarks:
No changes suggested

8. Title: Evaluation of co-relation between midline of face and mouth with various anatomic landmarks- a cross sectional study
Primary investigator: Dr. Priya Joshi (Dept of Prosthodontics)
Mentor: Dr Ina Patel
Remarks:
No changes suggested

9. Title: Comparative evaluation of the effect of accelerated aging on the microhardness and color stability of commercially available flexible denture base materials: an in vitro study.
Primary investigator: Dr Neha Sonagara
Mentor: Dr Kinjal Solanki
Remarks:

- Standardization of sample should be there.
- Polishing may affect microhardness test.

10. Title: To evaluate effectiveness of platelet rich fibrin alone versus platelet rich fibrin with ascorbic acid with open flap debridement in treatment of stage iii periodontitis- a comparative study

Primary investigator: Dr. Priya Kasundra (Dept of Periodontics) (EC)

Mentor: Dr Bela Dave

Remarks:

- For all results RVG should be taken
- Specify criteria for grade 3
- Density of bone should be checked at grey level
- Standardization of use of ascorbic acid

11. Title: To evaluate effectiveness of injectable platelet rich fibrin alone versus injectable platelet rich fibrin with microneedling for gingival augmentation in thin mandibular anterior gingival phenotype- a split mouth comparative study

Primary investigator: Dr Aazin Fatema Bukhari (Dept of Periodontics) (EC)

Mentor: Dr Bela Dave

Remarks:

- Title should be reformed
- Inclusion criteria should include patients having gingival recession
- exclusion should include TFO patients
- Informed consent form should be clear
- study should include control group
- considering Drop out sample size should increase

12. Title: Comparative study of extraction socket preservation with synthetic hydroxyapatite granulesalone and along with platelet rich fibrin- - a split mouth in vivo study

Primary investigator: Dr Sirsha Bhattacharjee (Dept of Periodontics) (EC)

Mentor: Dr Ashish Kaur

Remarks:

- For standardization identical type of teeth should be included 2 gingival index is not necessary
- For sample size consider Drop out ratio
- In inclusion include grade 1 or 2 mobile teeth
- Atraumatic extraction should be there 1 storing of tooth should be done properly

13. Title: Evaluation of push out bond strength of different root repair materials to root dentin atdifferent levels-an in vitro study

Primary investigator: Dr Hetvi Parikh (Dept of Endodontics)

Mentor: Dr Anjali Kothari

Remarks:

- Storing of tooth should be done properly

14. Title: Evaluation of success rate of bypassing the fractured instrument and its correlation with itslocation: an in vitro study

Primary investigator: Dr. Deep Agarwal (Dept of Endodontics)

Mentor: Dr Anjali Kothari

Remarks

- Instead of storing in normal saline tooth should be stored in artificial saliva.
- Mention type of radiograph to be taken to check file in canal before and afterprocedure

15. Title: Spectrophotometric analysis of color stability of different monochromatic compositerestorative material: an in vitro study
Primary investigator: Dr Gunja Malviya (Dept of Endodontics)
Mentor: Dr Neeta PatelRemarks:

- No alteration suggested

16. Title: Short Study-To evaluate awareness of ergonomics in undergraduate students of AMC dental collegequestionnaire survey
Primary investigator: Dr Priya Kasundra (Dept of Periodontics) (EC)
Mentor: Dr Bela Dave
Remarks

- All the questions were direct leading and close ended so no relevant data could be generated
- All the questions were reformed and presented and were passed in IRB

17. Title: Short study-To assess the factors that affect the selection of a dentifrice among a population of arts and commerce undergraduate students in west zone of Ahmedabad: a questionnaire survey
Primary investigator: Dr Aazin Fatima Bukhari (Dept of Periodontics) (EC)
Mentor: Dr Bela Dave
Remarks:

- Likert scale should be introduced in questionnaire.

18. Title: Short Study-Comparative study of Clinical efficacy between chlorhexidine and chlorhexidine plushyaluronic acid mouthwashes in patients of chronic periodontitis: an in vivo study
Primary investigator: Dr Sirsha Bhattacharjee (Dept of Periodontics) (EC)
Mentor: Dr Ashish Kaur
Remarks

- If the patients with stage 2,3 or 4 are taken result can vary so take only one class
- Study should be double blinded

19. Title: Short Study-Perception, awareness, and attitude towards digital dentistry among general practitioners: -a questionnaire-based survey
Primary investigator: Dr Kresha shah (Dept of Prosthodontics)
Mentor: Dr Ina Patel
Remarks

- Questions 9 and 13 should be reframed.
- In inclusion criteria, include age group, MDS/BDS, urban/rural
- Answers of question should be converted in conclusion

20. Title: Short Study-Evaluation of smile line in relation to gender in Gujarati population-a photographic study

Primary investigator: Dr Priya Joshi (Dept of Prosthodontics)
Mentor: Dr Ina Patel
Remarks:

- Considering Drop out ratio, sample size should be increased.

- In exclusion criteria -other than Gujarati population

21. Title: Short study- To evaluate the correlation between the Mesio-distal width of the maxillary anterior teethand different measurements of the distal maxillary arch width.
Primary investigator: Dr Neha Sonagara (Dept of Prosthodontics)
Mentor: Dr Kinjal Solanki
Remarks:

- Apply some formula in your study

22. Title: Short Study-Tooth enamel regeneration
Primary investigator: Parishi Marfatia (ICMR) (EC) final year
Remarks:

- Mention the type of study
- Require more sample size
- Methodology is not clear
- Check feasibility issues
- Better work on first two objectives
- Approximate expenditure should be considered

23. Title: Short Study-Estimation of prevalence of internet addiction and pathological gambling in undergraduateuniversity students-a cross-sectional study
Primary investigator: Kautuki Kharabe (ICMR) final year
Remarks:

- Modify the aim
- Answers should be in quantitative form and outcome of study should be qualitative form
- For judging answers help of psychiatric department should be taken
- Pathological gambling is a strong word and should be avoided

24. Title: Short Study-Neonatal line width and its association with certain maternal sociobiological factors
Primary investigator: Manushi Thakkar (ICMR) final year
Remarks

- Feasibility issues
- First step is to find correlation between neonatal line and mother's stress and then proceed for other findings

25. Title: Short Study-Effectiveness of herbal medications over synthetic Drugs in endodontic treatments asintracanal medicaments
Primary investigator: Het Brahm Bhatt (ICMR) third year
Remarks

- Measure mic (minimum inhibitory concentration)
- Precise concentration should be used in the study
- Title shall be reframed

13/2/23

MINUTES OF MEETINGS
IEC 2022

MINUTES OF MEET OF IEC 2022-2023
(POST GRADUATES'DISSERTATION)

DATE: 12-12-22
TIME: 2.15pm
VENUE: AMC conference hall
DETAIL: Approval of PG Dissertation

Points discussed:

1. All the PGs were asked to present their thesis in proper format.
2. Time allotted for presentation was 10 mins for each individual
3. Presentation should include title, aims/objective, inclusion and exclusion criteria, materials and method, discussion, parameters for evaluation and conclusion.
4. Participants were informed that during the event of study, they have to submit progress reports every 6 months.

List of attendees: (IEC members)

1. Dr. Dolly Patel
2. Dr. Asha shah
3. Dr. Ramita Sood
4. Dr. Supriya Malhotra
5. Dr. Kinnari Rajpura
6. Dr. Bela Dave
7. Dr. Priti Adani
8. Dr. Mahendra Joshi

Thesis discussed were:

1.Title: Implant placement in narrow ridge arch using peizosurgery and screw expanders – a prospective Clinical study.
Primary investigator: Dr. Ragini Tiwari
Mentor: Dr. Ramita Sood
Comments:

- Discussing procedure and cost.
- If the cost would be borne by patient? Yes

Remarks: **Approved**

2.Title: Use of botulinum toxin-a for pain relief on mouth opening after surgical intervention in oral submucous fibrosis — a randomized controlled trial"
Primary investigator: Dr. Anupama Chauhan
Mentor: Dr. Ramita Sood
Comments:

- How will Botox help patient? Muscle relaxation

Remarks: **Approved**

3.Title: Comparative study of efficacy of injectable platelet rich fibrin and hyaluronic acid for interdental papillary reconstruction: a split mouth vivostudy
Primary investigator: Dr. Archana Prajapati

Mentor: Dr. Ashish Kaur
Comments:

- Is the study blinded? yes

Remarks: **Approved**

4.Title: Evaluation of bone healing and alveolar ridge preservation by guided bone regeneration using collagen membrane as barrier in an immediate extraction socket - prospective Clinical study.
Primary investigator: Dr. Pranali Patel
Mentor: Dr. Ramita Sood
Comments: None
Remarks: **Approved**

Rsood
12/02/22

MINUTES OF MEET 2022
REVISED PROTOCOL –CLINICAL TRIAL
(ONLINE)

DATE: 06-08-22
TIME: 10:00 AM
VENUE: AMC Conference Hall

Points discussed:

1. All the presenters were asked to present their thesis in proper format.
2. Time allotted for presentation was 10 mins for each individual
3. Presentation should include title, aims/objective, inclusion and exclusion criteria, materials and method, discussion, parameters for evaluation and conclusion.
4. Participants were informed that during the event of study, they have to submit progress reports every 6 months.

List of attendees: (IEC members)

1. Dr. Dolly Patel
2. Dr. Asha shah (online)
3. Dr. Rajendra Agnihotri (online)
4. Dr. Supriya Malhotra(online)
5. Dr. Kinnari Rajpura
6. Dr. Bela Dave
7. Dr. Priti Adani (online)
8. Dr. Mahendra Joshi(online)

Trial discussed:

1.Title: A randomized, double blind, multicentric, placebo controlled parallel study to evaluate the efficiency and safety of tranexamic acid mouthwash of morning side healthcare limited (UK) to reduce bleeding in subject undergoing tooth extraction who are on drug affecting hemostasis

Primary investigator: Dr. Ramita Sood

Comments:

- Number of subjects for seeing in our center: 60-70
- Is aspirin to be stopped? No
- Outcome: benefit to the subject who are on medication affecting hemostasis

Remarks:**Approved**

6/08/22

MINUTES OF MEETINGS
IRB 2022

MINUTES OF MEET 2022
(POSTGRADUATES DISSERTATION)

DATE: 07-10-2022,08-10-2022,09-10-2022
TIME: 2:00 PM-5:00 PM
VENUE:AMC Lecture Hall-2

Points discussed:

1. All the PGs were asked to present their thesis in proper format.
2. Time allotted for presentation was 10 mins for each individual.
3. Presentation should include title, aims/objective, inclusion and exclusion criteria,materials and method, discussion, parameters for evaluation and conclusion.
4. Participants were informed that during the event of study, they have to submit progress reports every 6 months.

List of attendees: (IRB members)

1. Dr. Dolly Patel
2. Dr. Ina Patel
3. Dr. Ramita Sood
4. Dr. Kinnari Rajpura
5. Dr. Bela Dave
6. Dr. Anjali Kothari
7. Dr. Bhadra Shah
8. Dr. Sona Sheth
9. Dr. Niyanta Joshi
10. Dr. Roopal Patel
11. Dr. Shital Patel
12. Dr. Ekta Malvania
13. Dr. Parth Khamar

Thesis discussed were:

1.Title: To evaluate and compare the properties of nano ceramic composite resins with contemporary composite resins: an in vitro study
Primary investigator: Dr Kavita Sule
Mentor: -Dr. Anjali Kothari Comments:

- Title was changed
- Validation of instrument to be used
- Method of sterilization should be modified

2.Title: An in vitro analysis for potency and behavior of different whitening agents on enamel color and surface roughness
Primary investigator: Dr. Viraj Talsania
Mentor: Dr. Anjali Kothari
Comments:

- Proper font size

formatting of objectives should be done

3.Title: Analysis of dynamic cyclic fatigue resistance of different endodontic nickel titanium instruments after autoclave sterilization: an in vitro study

Primary investigator: - Dr. Shwetika Patel

Mentor: Dr. Neeta Patel

Comments:

- No changes suggested

4.Title: Evaluation of the role of cranio- facial pattern for developing obstructive sleep apnea in young adults: a prospective study

Primary investigator: - Dr. Akash Dalal

Mentor: Dr. Dolly Patel

Comments:

- There should be customized values of hyoid developing obstructive bone in all groups
- According to class 1, 2 and 3, it should be time-based study
- Polysomnography for severe compromise of airway obstruction should be done

5.Title: Profile trait changes at peak height velocity in girls and boys: longitudinal study

Primary investigator: Dr Stela Kapoor

Mentor: Dr. Roopal Patel

Comments:

- Considering Drop-out ratio sample size should be increased by 20%
- Feasibility issue should be considered

6.Title- Clinical efficacy of heat activated nickel titanium wire versus super elastic nickel titanium wire for initial alignment: a comparative study

Primary investigator: - Dr Zeel Desai

Mentor: Dr. Dolly Patel

Comments:

- Title is altered, will present in next IRB

7.Title: use of botulinum toxin -a for pain relief on mouth opening after surgical intervention in oral submucous fibrosis-randomized controlled trial

Primary investigator: - Dr. Anupama Chauhan

Mentor: Dr. Ramita Sood

Comments:

- Methodology should include study and control group both. (ec)

8.Title: Implant placement in narrow ridge arch using piezo surgery and screw expanders -a prospective Clinical study

Primary investigator: - Dr. Ragini Tiwari

Mentor: Dr. Ramita Sood

Comments:

- Resolve any feasibility issue
- Modify sample size (EC)

9.Title: ls the local anesthetic efficiency of tramadol adrenaline superior to that of lignocaine with adrenaline for extraction of non-complicated maxillary tooth under supra-periosteal injection -a prospective Clinical study
Primary investigator: -Dr. Rajan Savani
Mentor: Dr. Shital Patel
Comments:

- Method of injection is not mentioned (EC)

10. Title: - evaluation of bone healing and alveolar ridge preservation by guided bone regeneration using a collagen membrane as a barrier in an immediate extraction socket-a prospective Clinical study
Primary investigator: - Dr Pranali Patel
Mentor: Dr. Ramita Sood
Comments:

- No need of IOPA, CBCT will do.
- No need of raising full thickness flap (EC)

11. Title: A cross sectional study to evaluate co-relation between philtrum width and maxillary central Incisor width in Gujarati population
Primary investigator: - Dr. Manali shah
Mentor: Dr. Ina Patel
Comments:

- From inclusion criteria remove word ethnicity and native instead mention that both the parents should be Gujarati
- Standardization procedure for lip measurement should be used.
- Lips should be competent, rapid test and phonetics should be used

12. Title: To compare the effectiveness of 1% metformin gel and platelet rich fibrin and platelet rich fibrin alone in open flap debridement for intrabony defect: an in vivo study.
Primary investigator: Dr. Kruti Bhavsar
Mentor: Dr. Bela Dave
Comments:

- Topic is altered will present in next IRB

13. Title: Comparative evaluation of no vertical accuracy of three different interactional recording materials before and after wing two different disinfecting solution with two different methods-as in vitro study
Primary investigator: Dr. Pankti Panchal
Mentor: Dr. Kinjal Solanki
Comments:

- No suggestions
- Three options so split mouth is not possible

14. Title: To determine the orientation of anterior occlusal plane in relation to inner canthus and orientation of posterior occlusal plane in relation to outer canthus and its co- relation with extra-oral facial landmark in dentate subjects an in vivo study
Primary investigator: - Dr. Param Shukla
Mentor: Dr. Ina Patel

Comments:

- Instrument used for facial measurement should have lacking mechanism in inclusion criteria 1 molar should be present with class i molar relation
- Title changed: as an adjunct
- Will go to iec for further approval

15. Title: Comparative evaluation of marginal integrity of pattern fabricated from inlay casting wax, inlay margin wax combination and two different light cure pattern resin systems at time interval at 1 hour, 9 hours and 24 hours-an in vitro study
Primary investigator: Dr. Rujul shah
Mentor: Dr. Ina Patel
Comments:
- Title should be changedpassed
- Will go to IEC for further Approval

16. Title: Comparative study of efficacy of injectable platelet rich fibrin and hyaluronic acid for interdental papillary reconstruction: a split mouth vivo study.
Primary investigator: -Dr. Archana Prajapati
Mentor: Dr. Ashish Kaur
Comments:
- Will go to EC
- No changes suggested
- No need for RVG

17. Title: To compare efficacy of demineralized freeze-Dried bone allograft versus concentrated growth factor in the treatment of intrabony defect an in vivo study
Primary investigator: Dr Drashti shah
Mentor: -Dr. Bela Dave
Comments:
- Will go to EC
- Plaque index not mentioned
- Change outcome of the study objective
- Mention curvature

9/10/22

DR DOLLY PANKAJ PATEL

Digitally signed by DR DOLLY PANKAJ PATEL
Date: 2024.03.07 16:49:48 +05'30'