

Minutes of the 5th Annual Institutional Ethical Meeting Govt. Dental College & Hospital (IEC GDCH), Ahmedabad

Date: 18th February 2017

Time: 9.30 am to 1.00 pm

Venue: Committee Room, Dean Office, Govt. Dental College & hospital, Ahmedabad-380016

The following attended the IEC meeting:

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|--------------------------|-----------------------|
| 1. Dr. Sunil Kumar | Chairperson |
| 2. Dr. Girish Parmar | Dean & Co-Chairperson |
| 3. Dr. Jigna Shah | Member Secretary |
| 4. Mr. S.M. Soni | Legal Advisor |
| 5. Mrs. Geeta Goswami | NGO |
| 6. Dr. Geetha Asthana | Committee Member |
| 7. Dr. Jayshankar Pillai | Committee Member |

Dr. Girish Parmar, Dean Govt. Dental College & Hospital, warmly welcomed the Chairperson Dr. Sunil Kumar, Senior Deputy Director, NIOH, Ahmadabad. Other committee members & all researchers. He stated the purpose of the meeting to follow the ethical norms with concern study to all researchers. The committee was felt that the dignity & privacy of each participant should be maintained.

The researchers (Ph.D. students and Post graduates) were instructed to present their summary of project individually in terms of methodology, overviews, importance of study & ethical criteria regarding the subject. All participants presented their studies with documents pertaining to CRF (Case record Form), Informed Consent Form & withdrawal Form dually filled for each case as well as undertaking form.

A strong discussion was done on each and every topic presented by participants. Committee had strictly warned all participants not to change topic or title, its methodology and presented synopsis. The study needs to be initiated within one year of issuing of this approval. In case the study is not initiated within time, the IEC expects to be informed about the reason for the same and a fresh approval will have to be obtained subsequently. The IEC GDCH expects to be informed about the progress of the study (every 6 months), any Serious Adverse Events (S.A.E.) occurring in the course of the study and if any changes are made in the protocol or CRF/ consent form the IEC GDCH needs to be informed about this in advance and an additional permission is required to be taken. The IEC GDCH also expects you to submit summary and outcomes of a copy of the final Dissertation study report & to get the study completion certificate before submit to Gujarat University. Study approval certificate and completion certificate (all copies) are needed to be attached in dissertation.

Committee is asked to consider for use of old/ left over dental materials by investigators, the IEC, GDCH give the post fact of approval. Committee instructed all Ph.D. students to appoint Co guide wherever it is necessary and same to be approved by Gujarat University.

Reference Study No: S.1

Subject of Study: Evaluation of clinical use of demineralized dentin graft in the extraction socket

Principal Investigator: Dr. Jigar Dhuvad

Co-Investigators: Dr. Deval Mehta

Department: Oral Surgery

COMMENTS: discussion was on to mention subject sample no. approximately 200 and also asked to discuss with biostatistician to decide sample.

Reference Study No: S.2

Subject of Study: Evaluation of patterns of tobacco use and tobacco use cessation (TUC) through behavior counseling (BC), Motivational interviewing (MI) amongst urban school children of Ahmedabad city: A survey

Principal Investigator: Dr. Meef R. Ramatri

Co-Investigators: Dr. Mahesh Chavda

Department: External Ph.D Student

COMMENTS: discussion was on to mention subject sample no. approximately 200 and also asked to discuss with biostatistician to decide sample. ICF form is to be submitted. For minors in case of age is less than 14 years, parent consent is mandatory and asked to follow the guidelines of KAT

Reference Study No: S.3

Subject of Study: Strengthening preventive prosthodontics by integrating tobacco cessation within routine prosthodontic care: current scenario and future prospects

Principal Investigator: Dr. Rachana Shah

Co-Investigators: Dr. Rupal Shah

COMMENTS: committee had asked to mention age group and decide sample size with consult biostatistician. At least 5 % of OPD of Department must be included in study. An adhoc approval is given to presented study topic.

Reference Study No: S.4

Subject of Study: To assess the efficacy of zygotic buttress as a source of anchorage in orthodontics – a clinical study

Principal Investigator: Dr. Amit Bhattacharya

Co-Investigators: Dr. Kalyani Trivedi, Dr. Renuka Patel

Department: Orthodontia

COMMENTS: discussion was made on selection criteria of patients and surgical complications and how to combat situation and under whose guidance?

Reference Study No: S.5

Subject of Study: Psychosocial impact on oral health related quality of life through the course of orthodontic treatment in Gujarat
Principal Investigator: Dr. Rahul Trivedi
Co-Investigators: Dr. Dolly Patel, Dr. Falguni Mehta
Department: Orthodontia

COMMENTS: author is recommended to increase subject sample upto 500.

Reference Study No: S.6

Subject of Study: Gender determination from dental pulp tissue by microscopic methods (detection of Barr bodies and F bodies) using different forensic parameters.
Principal Investigator: Dr. Tapan Modi
Co-Investigators: Dr. Jyoti Chavda
Department: Oral pathology

COMMENTS: discussion was on to mention source of patient sample in material methods and instructed to take samples from college itself. Author is also asked to change patient consent form accordingly.

Reference Study No: S.7

Subject of Study: A study of histopathologic changes in follicle of impacted mandibular third molar
Principal Investigator: Dr. Pratik Rupakar
Co-Investigators: Dr. Jyoti Chavda
Department: Oral pathology

COMMENTS: author is instructed to take age group of patient between 16 to 25 years as tooth follicle is present only at that time. Author has to mention radiographs type and technique in material and methods. He is also instructed to work under guidance of Ph.D guide as author is private practitioner.

Reference Study No: S.8

Subject of Study: Stature estimation by odontometric parameters – an analytical study
Principal Investigator: Dr. Yesha Jani
Co-Investigators: Dr. Shilpa Parikh
Department: External Ph.D Student

Reference Study No: S.9

Subject of Study: Altered taste perception and salivary properties in patients with arecanut and tobacco related habits – a comparative study
Principal Investigator: Dr. Roseline Patel
Co-Investigators: Dr. Jigna Shah
Department: External Ph.D Student

COMMENTS: Author is asked to verify if any studies on this had been done or not as very few researches are available on this. Author is also asked to incorporate taste perception scale in study.

Reference Study No: S.10

Subject of Study: Periodontal infection as a possible risk factor for pre-term and low birth weight infants – An epidemiological case control study

Principal Investigator: Dr. Neeta V. Bhavsar

Co-Investigators: Dr. Sakshee Trivedi

Department: Periodontia

COMMENTS: Author is asked to done 3 scale on annual income not on kuppuswami scale and to calculate subject as per statistically required and also asked to search patient from civil hospital.

An adhoc approval is given to presented study topic.

Reference Study No: S.11

Subject of Study: Axial Pulp-tooth ratio of Maxillary and mandibular Canines assessed using of Cone-beam computed tomography for dental age estimation: A retrospective, cross-sectional study.

Principal Investigator: Dr. Jayshankar Pillai

Co-Investigators: Dr. Girish Parmar, Dr. Sukhdev Mishra

Department: Oral pathology

COMMENTS: Author is asked to take consent and inform about radiation exposure that is going to give patients also educate about effects of radiation and inform first to patients.

An adhoc approval is given to presented study topic.

Reference Study No: S.12

Subject of Study: Proteomic analysis of human whole saliva for gender determination and age estimation: A 2D gel Electrophoresis study.

Principal Investigator: Dr. Jayshankar Pillai

Co-Investigators: Dr. Girish Parmar, Dr. Sukhdev Mishra

Department: Oral pathology

An adhoc approval is given to presented study topic.

Reference Study No: S.13

Subject of Study: Gonial angle, inter-gonial and inter-condylar measurements in dentate and edentulous mandible for gender determination and age estimation: A cross-sectional, radiographic analysis.

Principal Investigator: Dr. Rupal Shah

Co-Investigators: Dr. Girish Parmar, Dr. Bhavyata Darji, Dr. Jayshankar Pillai, Dr. Sukhdev Mishra
Department: Prosthodontia

An adhoc approval is given to presented study topic.

Reference Study No: S.14

Subject of Study: The Impact of Behavioural Risk Factors and Health Promoting Behaviour on Periodontal Health among Adults in Gujarat: A Cross Sectional Study

Principal Investigator: Dr. Dinta kakkad

Co-Investigators: Dr. Neeta Bhavsar

Department: External Ph.D Student

Reference Study No: S.15

Subject of Study: Relevance of a smile zone shape to architect immaculate esthetic values in Indian population.

Principal Investigator: Dr. Poonam Mahendra

Co-Investigators: Dr. Rupal Shah

Department: External Ph.D Student

COMMENTS: Author is asked to report Ph.D guide at every 3 months for progress report, include different state in material methods rather than states of all over India.

Reference Study No: PR.1

Subject of Study: Evaluation of reliability of hamular-notch incisive papilla plane in establishing the occlusal plane in different age group and in dentulous & edentulous patients - an in vivo study

Principal Investigator: Dr. Najmunnisha Sabugar

Co-Investigators: Dr. Rupal Shah

An adhoc approval is given to presented study topic.

Reference Study No: PR.2

Subject of Study: Effect of occlusal vertical dimension on lip positions at smile - an in vivo study

Principal Investigator: Dr. Dhara Kotak

Co-Investigators: Dr. Rupal Shah

An adhoc approval is given to presented study topic.

Reference Study No: PR.3

Subject of Study: Envisaging and investigating a co relation between dentition status and malnutrition propensity in gujarati population

Principal Investigator: Dr. Kiran Hadiya

Co-Investigators: Dr. Sanjay Legdive, Dr. Rupal Shah

An adhoc approval is given to presented study topic.

Reference Study No: PR.4

Subject of Study: Comparative evaluation of efficacy two different acupressure points in reduction of gagging - an in vivo study

Principal Investigator: Dr. Dharmendra Sindha

Co-Investigators: Dr. Sanjay Legdive, Dr. Rupal Shah

COMMENTS: Author is instructed to increase sample size.

An adhoc approval is given to presented study topic.

Reference Study No: PR.5

Subject of Study: Comparative analysis of posterior alveolar slope angulation of maxillary denture and its role in speech intelligibility- an in vivo study

Principal Investigator: Dr. Dharmendra Sindha

Co-Investigators: Dr. Sanjay Legdive, Dr. Rupal Shah

An adhoc approval is given to presented study topic.

Reference Study No: PR.6

Subject of Study: Evaluation of occlusal plane parallelism at different levels of ala-tragal lines in different age groups using photographic and cephalometric method in dentulous and edentulous patients - an in vivo study.

Principal Investigator: Dr. Dipika Sutariya

Co-Investigators: Dr. Sanjay Legdive, Dr. Rupal Shah

COMMENTS: Author is instructed to increase sample size per group 30 patients

An adhoc approval is given to presented study topic.

Reference Study No: PR.7

Subject of Study: Study and comparison of the border outline of edentulous maxillary arch produced by different border molding material.

Principal Investigator: Dr. Sejal Mehta

Co-Investigators: Dr. Rupal Shah

An adhoc approval is given to presented study topic.

Reference Study No: OP.1

Subject of Study: Significance of Vitamin D level in patients having Autoimmune diseases

Principal Investigator: Dr. Chintan Parmar

Co-Investigators: Dr. Jyoti Chavda



Department: Oral pathology

COMMENTS: Author is instructed to increase sample size per group 30 patients
An adhoc approval is given to presented study topic.

Reference Study No: OP.2

Subject of Study: Immunohistochemical characterization of podoplanin
Principal Investigator: Dr. Vandana Peddiwar
Co-Investigators: Dr. Jyoti Chavda
Department: Oral pathology

An adhoc approval is given to presented study topic.

Reference Study No: OP.3

Subject of Study: in patients having speckled leukoplakia and oral squamous cell carcinoma
Principal Investigator: Dr. Noopur Gajjar
Co-Investigators: Dr. Jyoti Chavda
Department: Oral pathology

COMMENTS: Author is instructed to increase sample size per group 30 patients
An adhoc approval is given to presented study topic.

Reference Study No: OMR.1

Subject of Study: Role of serum immunoglobulins in patients of oral lichen planus and oral lichenoid reaction
Principal Investigator: Dr. Vijay Asrani
Co-Investigators: Dr. Jigna Shah
Department: Oral Medicine & Radiology 1963

An adhoc approval is given to presented study topic.

Reference Study No: OMR.2

Subject of Study: Evaluation of Serum Cortisol and Psychological factors in patients with Oral Lichen Planus

Principal Investigator: Dr. Anand Patel
Co-Investigators: Dr. Jigna Shah
Department: Oral Medicine & Radiology

COMMENTS: Author is instructed to mention patient source from Ortho department.
An adhoc approval is given to presented study topic.

Reference Study No: OMR.3

Subject of Study: Age Determination using Lateral Cephalogram and Orthopantomograph:
A Comparative Study

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Principal Investigator: Dr. Anand Patel
Co-Investigators: Dr. Jigna Shah
Department: Oral Medicine & Radiology

An adhoc approval is given to presented study topic.

Reference Study No: OMR.4

Subject of Study: Detection of maxillary sinus abnormalities using various radiographic techniques

Principal Investigator: Dr. Aateka Mansuri
Co-Investigators: Dr. Jigna Shah
Department: Oral Medicine & Radiology

COMMENTS: author is suggested that patients can be shared with Dr. Pillai Sir Study and vice versa

An adhoc approval is given to presented study topic.

Reference Study No: OMR.5

Subject of Study: Atypical facial pain diagnosis and management

Principal Investigator: Dr. Aateka Mansuri
Co-Investigators: Dr. Jigna Shah
Department: Oral Medicine & Radiology

An adhoc approval is given to presented study topic.

Reference Study No: PER.1

Subject of Study: Vitamin E supplementation, superoxide dismutase status and outcome of sealing and root planing in patients with chronic periodontitis: a randomized clinical trial.

Principal Investigator: Dr. Seltun Selnary
Co-Investigators: Dr. Mahesh Chavda
Department: Periodontia

COMMENTS: Author is instructed to increase sample size per group 30 patients
An adhoc approval is given to presented study topic.

Reference Study No: PER.2

Subject of Study: Inter- relationship between pre-diabetes, gutka chewing and periodontal inflammatory conditions

Principal Investigator: Dr. Seltun Selnary
Co-Investigators: Dr. Neeta Bhavsar

COMMENTS: Author is instructed to increase sample size per group 30 patients
An adhoc approval is given to presented study topic.

Reference Study No: PER.3

Subject of Study: Estimation of nitric oxide as inflammatory markers in periodontitis

Principal Investigator: Dr. Pooja Udhgawala

Co-Investigators: Dr. Mahesh Chavda

COMMENTS: Author is instructed to increase sample size per group 30 patients
An adhoc approval is given to presented study topic.

Reference Study No: PER.4

Subject of Study: Flapless Implant Surgery: A Clinical Evaluation

Principal Investigator: Dr. Bandish Jhala

Co-Investigators: Dr. Neeta Bhavsar

COMMENTS: : Author is instructed to increase sample size per group 30 patients
An adhoc approval is given to presented study topic.

Reference Study No: PER.5

Subject of Study: Clinical effectiveness of diode laser as an adjunct to non-surgical periodontal treatment: a randomized control study.

Principal Investigator: Dr. Ramya P.

Co-Investigators: Dr. Neeta Bhavsar

COMMENTS: : Author is instructed to increase sample size per group 30 patients
An adhoc approval is given to presented study topic.

Reference Study No: PER.6

Subject of Study: Omega 3 fatty acids as a host modulator in chronic periodontitis patients: a randomised, double-blind, placebo-controlled, clinical trial.

Principal Investigator: Dr. Mayuri Rathod

Co-Investigators: Dr. Mahesh Chavda

COMMENTS: : Author is instructed to increase sample size per group 30 patients and asked to remove word clinical trial from subject title.
An adhoc approval is given to presented study topic.

Reference Study No: PER.7

Subject of Study: Use of Hydrogen Peroxide mouthwash as an adjunct to Chlorhexidine mouthwash : A clinical and microbiological study

Principal Investigator: Dr. Pratik Patel

Co-Investigators: Dr. Neeta Bhavsar

COMMENTS: : Author is instructed to increase sample size per group 30 patients
An adhoc approval is given to presented study topic.

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Reference Study No: CO.1

Subject of Study: Comparative evaluation of use of different direct pulp capping agents -an in vivo study

Principal Investigator: Dr. Jaiprathiksha V Iyer

Co-Investigators: Dr. Girish Parmar

Department: Conservative & Endodontics

An adhoc approval is given to presented study topic.

Reference Study No: CO.2

Subject of Study: Comparison of efficacy of mepivacaine -tramadol combination and mepivacaine alone with the gold standard-lignocaine on the success of inferior alveolar nerve block in mandibular molars with symptomatic irreversible pulpitis – a randomized clinical trial”

Principal Investigator: Dr. Purna Jeloka

Co-Investigators: Dr. Sunita Garg

Department: Conservative & Endodontics

An adhoc approval is given to presented study topic.

Reference Study No: CO.3

Subject of Study: Quantitation of resin infiltration technique for management of white spots of fluorosis by a novel technique of computerised digital image analysis: A case series

Principal Investigator: Dr. Seema Chavda

Co-Investigators: Dr. Sunita Garg

Department: Conservative & Endodontics

An adhoc approval is given to presented study topic.

Reference Study No: OS.1

Subject of Study: Gender determination and age estimation from extracted posterior teeth: An odontometric and morphologic analysis

Principal Investigator: Dr. Bipin Sadhvani

Co-Investigators: Dr. Tejas Gadhvi

Department: Oral Surgery

COMMENTS: : Author is instructed to increase sample size as much as possible

An adhoc approval is given to presented study topic.

Reference Study No: OS.2

Subject of Study: Autogenous Buccal fat Vs Dermal fat as an interpositional material in the treatment of temporomandibular joint ankylosis

Principal Investigator: Dr. Vipul Nagavadiya

Co-Investigators: Dr. Sonal Anchlia

Department: Oral Surgery

COMMENTS: : Author is instructed to increase sample size as much as possible
An adhoc approval is given to presented study topic.

Reference Study No: OS.3

Subject of Study: Versatility of orbita plate in the management of mandible body fracture -a novel prospective study

Principal Investigator: Dr. Dhruvi Shukla

Co-Investigators: Dr. Sonal Anchlia

Department: Oral Surgery

COMMENTS: : Author is instructed to increase sample size as much as possible
An adhoc approval is given to presented study topic.

Reference Study No: OS.4

Subject of Study: Changing trends in oro facial space infection.

Principal Investigator: Dr. Rohit Parmar

Co-Investigators: Dr. Sonal Anchlia

Department: Oral Surgery

COMMENTS: : Author is instructed to increase sample size as much as possible
An adhoc approval is given to presented study topic.

Reference Study No: OS.5

Subject of Study: Dredging - conservative surgical method for large cystic lesions of the jaws

Principal Investigator: Dr. Nisarg Patel

Co-Investigators: Dr. Sonal Anchlia

Department: Oral Surgery

COMMENTS: : Author is instructed to increase sample size as much as possible
An adhoc approval is given to presented study topic.

Reference Study No: OS.6

Subject of Study: Two needle single puncture arthrocentesis of temporomandibular joint

Principal Investigator: Dr. Shishir Kumar

Co-Investigators: Dr. Sonal Anchlia

Department: Oral Surgery

COMMENTS: : Author is instructed to increase sample size as much as possible
An adhoc approval is given to presented study topic.

Reference Study No: OS.7



Subject of Study: Intraarticular AUTOLOGUS blood injection in treatment of chronic subluxation of temporomandibular joint

Principal Investigator: Dr. Vikas Sharma

Co-Investigators: Dr. Sonal Anchlia

Department: Oral Surgery

COMMENTS: : Author is instructed to increase sample size as much as possible
An adhoc approval is given to presented study topic.

Reference Study No: OS.8

Subject of Study: Modified subbrow incision – A novel approach to surgical management of nasal fractures

Principal Investigator: Dr. Hardi Domadia

Co-Investigators: Dr. Sonal Anchlia

Department: Oral Surgery

COMMENTS: : Author is instructed to increase sample size as much as possible
An adhoc approval is given to presented study topic.

Reference Study No: OS.9

Subject of Study: Osteosynthesis using 3D plate in midface fractures

Principal Investigator: Dr. Ramyata Dayatar

Co-Investigators: Dr. Sonal Anchlia

Department: Oral Surgery

COMMENTS: : Author is instructed to increase sample size as much as possible
An adhoc approval is given to presented study topic.

Reference Study No: OR.1

Subject of Study: Assessment and comparison of Pi analysis with other sagittal discrepancy indicators."

Principal Investigator: Dr. Abbas Sanjeliwala

Co-Investigators: Dr. Falguni Mehta

Department: Orthodontia

An adhoc approval is given to presented study topic.

Reference Study No: OR.2

Subject of Study: Assessment of posterior teeth angulation in patients with anterior open bite and normal occlusion

Principal Investigator: Dr. Krushna Pathak

Co-Investigators: Dr. Falguni Mehta

Department: Orthodontia

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An adhoc approval is given to presented study topic.

Reference Study No: OR.3

Subject of Study: Relating dental arch width and vertical facial morphology in adults- a cephalometric, photographic and model study.

Principal Investigator: Dr. Karishma Raval

Co-Investigators: Dr. Renuka Patel

Department: Orthodontia

An adhoc approval is given to presented study topic.

Reference Study No: PED.1

Subject of Study: Influence of rubber dam on physiological parameters of stress during dental treatment of children in age group of 7-10 years. - an in vivo study

Principal Investigator: Dr. Dipak K. Sharma

Co-Investigators: Dr. Shantanu Chaoudhari

Department: Pedodontia

COMMENTS: : Author is instructed to increase sample size as much as possible

An adhoc approval is given to presented study topic.

Reference Study No: PED.2


Subject of Study: Clinical correlation and assessment of accuracy and predictability of age using cameriere's 7 teeth method with Indian specific formula in children


Principal Investigator: Dr. Rupinder Kaur

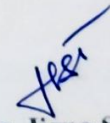
Co-Investigators: Dr. Shantanu Chaoudhari

COMMENTS: : Author is instructed to increase sample size as much as possible

An adhoc approval is given to presented study topic.


Dr. Sunil Kumar
Chairperson
IECGDCH
Ahmedabad


Dr. Girish Parmar
Co-Chairperson & Dean
IECGDCH
Ahmedabad


Dr. Jigna Shah
Member Secretary
IECGDCH
Ahmedabad