



Mahatma Gandhi Mission's
MEDICAL COLLEGE

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INSTITUTIONAL ETHICS COMMITTEE (IEC)

Institutional Ethics Committee (IEC) of MGM Medical College, Kamothe

Minutes of the Institutional Ethics Committee (IEC) Meeting

In pursuance of the circular on the subject dated, the Institutional Ethics Committee (IEC) of MGM Medical College, Kamothe assembled for video conference based meeting on **9th Dec 2021 at 10.00AM. (Morning)**, virtually via google meet at the following link

<https://meet.google.com/nmk-rzcu-jdy>

The following functionaries attended the meeting

No	Member	Designation
1	Dr. Pramila Yadav	Chairperson
2	Dr. D. Bhusare	Member
3	Dr. Pradeep Jadhav	Member Secretary
4	Dr. Ipseeta Ray	Convener
5	Dr. R.S. Inamdar	Member
6	Dr. Jaishree Ghanekar	Member
7	Dr. A.D. Urhekar	Member
8	Mrs. Rupali Gujar	Social Scientist
9	Dr. Karuna Ramraje	Legal Expert
10	Ms Usha Mohite	Lay Person

Minutes of the previous IEC meeting held on 30th September 2021 were confirmed unanimously

Minutes of IEC meeting held on 09/12/2021

1 Title: A Study on impact of Covid 19 on eye health – Patients perspectives

Investigators: Dr. Anamika Pandey, Guide: Dr. Faraaz Hussain, Department of Ophthalmology

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- To include details of parameters to be evaluated in methodology

The proposal was approved by the IEC

2 Title: A study on preoperative xylocaine sensitivity test in patients undergoing ocular surgeries

Investigators: Dr. Yogya Reddy, Guide: Dr. Faraaz Hussain, Department of Ophthalmology

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- To include sample size justification
- Declaration form not signed, need to submit the signed copy to IEC

The proposal was approved by the IEC

3 Title: Comparison of onset of action of intrathecal clonidine versus intrathecal fentanyl as adjuvant with hyperbaric bupivacaine under spinal anaesthesia for lower limb orthopedic surgeries

Investigators: Dr. Aradhana Devi, Guide: Dr. Archana Har, Department of Anaesthesiology

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- The study is a comparative study between two adjuvant add-on drugs, no need for control mono-therapy arm, suggested to remove the control arm from the study
- Case record form to include time-points of the study assessment

The proposal was approved by the IEC

4 Title: Knowledge and attitude about the practices of blood transfusion amongst medical interns and residents in a tertiary care hospital

Investigators: Dr. Vinita Rao, Guide: Dr. Sheeta Dhole, Department of IHBT

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- The study methodology and design is not clear, need to mention in details the study methodology and conduct.
- Questionnaire is needs to be validated

The proposal was approved by the IEC

5 Title: Study of co- relation between CRP value in Covid-19 patients and vaccination

Investigators: Dr. Abhilasha, Guide: Dr. Ujwala Maheshwari, Department of Pathology

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- To include details of parameters to be evaluated in methodology
- Administrative permission to be obtained
- Case record form to include data variables as per the study parameters and also mention assessment timepoints.

The proposal was approved by the IEC

6 Title: Profile of psychiatric disorders among Covid-19 patients admitted at Covid designated medical college and hospital

Investigators: Dr. Sneha Raju, Guide: Dr. Darpan Kaur, Department of Psychiatry

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- To include Sample size justification and calculation
- To mention in methodology, from where the patients are going to be recruited or which department or setting the patients will be enrolled.
- Administrative permission to be obtained
- Case record form to include data variables as per the study parameters

The proposal was approved by the IEC

7 Title: A retrospective study on reactions in leprosy at a tertiary care hospital in Navi Mumbai

Investigators: Dr. JincyAmbalathink, Guide: Dr. Shylaja Someshwar, Department of Dermatology

IEC comments and suggestions:

The retrospective study was reviewed and granted clearance

The proposal was approved by the IEC

8 Title: Uncommon in common : interesting variants of basal cell carcinoma

Investigators: Dr. JincyAmbalathink, Guide: Dr. Shylaja Someshwar, Department of Dermatology

IEC comments and suggestions:

The case study was reviewed and granted clearance

The proposal was approved by the IEC

9 Title: A study of lipid profile in patients of alcoholic liver disease

Investigators: Dr. Aman Kathpal, Guide: Dr. Amrit Kejriwal, Department of General Medicine

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Participant information sheet has inadequate information (in detailed to be written and to be submitted
- To include Sample size justification and calculation

The proposal was approved by the IEC

10 Title: Study of the impact of Covid 19 pandemic on nutritional status and mental health of school going children and adolescents

Investigators: Ms. Upasana Dahiya, Guide: Dr. Jeetendra Gavhane, Department of II MBBS Student

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- To include parenteral consent and assent form
- Covid-19 applicable norms to be followed in case of direct interaction with parents or students
- Use validated questionnaire or the questionnaire needs to be validated
- Administrative permission from Dean and respective School principals' to be obtained
- To extend or change the duration of study

The proposal was approved by the IEC

11 Title: To evaluate sub foveal choroidal thickness (SFCT) in DMR using Enhanced depth OCT and comparison with DM parameters

Investigators: Dr. Priyanka Gandhi, Guide: Dr. Faraaz Hussain, Department of Ophthalmology

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Case record form to include data variables as per the study parameters

To submit revised protocol with related documents (consent and Participant information sheet and Case record form) and also submit duly filled IEC application form

The proposal was approved by the IEC

12 Title: Rare cause of chronic visual loss and distress in young choroidal hemangioma

Investigators: Dr. Anamika Pandey, Guide: Dr. Faraaz Hussain, Department of Ophthalmology

IEC comments and suggestions:

The case study was reviewed and granted clearance

The proposal was approved by the IEC

13 Title: Incidence of hill sachs and bankart lesions in shoulder instability

Investigators: Dr. Shounak Modak, Guide: Dr. Priti Kapoor , Department of Radio Diagnosis

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- To include Sample size justification
- Administrative permission to be obtained

The proposal was approved by the IEC

14 Title: Correlation of lower limb venous Doppler findings with CT severity score in patients with Covid infection

Investigators: Dr. Pranjal Sharma, Guide: Dr. Priti Kapoor , Department of Radio Diagnosis

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- To include Sample size justification
- Administrative permission to be obtained

The proposal was approved by the IEC

15 Title: Correlation between use of inotropes in thrombolysed myocardial infarction patients and their survival

Investigators: Dr. Kalluri Sai, Guide: Dr. Jaishree Ghanekar, Department of General Medicine

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- To include details of parameters to be evaluated in methodology and outcomes to be assessed
- Mention of randomization and method of allocation of the groups in methodology
- To include Sample size justification and calculation
- Case record form to include data variables as per the study parameters

The proposal was approved by the IEC

16 Title: Preparedness, planning and response to a mass- casualty incident: Then and now

Investigators: Dr. Sreekala Radhakrishnan, Guide: Dr. Mayank Dhir, Department of Emergency Medicine

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Administrative permission
- Case record form to include data variables as per the study parameters

The proposal was approved by the IEC

17 Title: Reliability of FABER test in correlation with alpha angle in diagnosis of femoroacetabular impingement

Investigators: Dr. Shrey Binyala, Guide: Dr. Nilesh Vishwakarma, Department of Orthopaedics


IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Participant information sheet to be submitted along with language translations (Marathi and Hindi)

The proposal was approved by the IEC


Member Secretary

Dr. Pradeep Jadhav


Convener

Dr Ipseeta Ray


Chairperson

Dr . Pramila Yadav



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INSTITUTIONAL ETHICS COMMITTEE (IEC)

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Minutes of the Institutional Ethics Committee (IEC) Meeting

In pursuance of the circular on the subject dated:, the Institutional Ethics Committee (IEC) of MGM Medical College, Kamothe assembled for video conference based meeting on **10th Dec 2021 at 10.00AM. (Morning), virtually** via google meet at the following link

<https://meet.google.com/vah-oucs-uzi>

The following functionaries attended the meeting

No	Member	Designation
1	Dr. Pramila Yadav	Chairperson
2	Dr. D. Bhusare	Member
3	Dr. Pradeep Jadhav	Member Secretary
4	Dr. Ipseeta Ray	Convener
5	Dr. R.S. Inamdar	Member
6	Dr. Jaishree Ghanekar	Member
7	Dr. A.D. Urhekar	Member
8	Mrs. Rupali Gujar	Social Scientist
9	Dr. Karuna Ramraje	Legal Expert
10	Ms Usha Mohite	Lay Person

Minutes of IEC meeting held on 10/12/2021

1 Title: Major amputations in Covid 19 pandemic: A sword that cuts hearts and body parts – A pandemic within a pandemic

Investigators: Dr. Pooja Agarwal, Guide: Dr. Sameer Kadam, Department of General Surgery

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- To include sample size justification
- Participant information sheet is inadequate with information

The proposal was approved by the IEC

2 Title: A study of penetrating injuries of abdomen in a tertiary care hospital of Maharashtra

Investigators: Dr. Pooja Agarwal, Guide: Dr. Ali Reza, Department of General Surgery

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Participant information sheet to be submitted with local translations

The proposal was approved by the IEC

3 Title: Adverse dermatological reactions among healthcare workers during the Covid-19 pandemic

Investigators: Dr. Tanya Pandey, Guide: Dr. Shylaja Someshwar, Department of Dermatology

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Self designed questionnaire needs to be validated or use a validated questionnaire
- Consent form to be submitted

The proposal was approved by the IEC

4 Title: Cervical lymphadenopathy : A clinic pathological study

Investigators: Dr. Meghna Sehgal, Guide: Dr. Lisha Suraj, Department of General Surgery

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Retrospective study so consent form not required
- Administrative permission to be taken
- NOC or Co-guide from pathology suggested as the study looks into the clinicopathology aspects

The proposal was approved by the IEC

5 Title: Role of magnetic resonance angiography in patients with watershed zone brain infarcts: A retrospective analysis

Investigators: Dr. Animesh Chhabra, Guide: Dr. Abhay Gursale, Department of Radio Diagnosis

IEC comments and suggestions:

- The investigator was absent for the meeting, the proposal was not reviewed

The proposal was not reviewed in this IEC meeting, will be placed in next IEC meeting

6 Title: Prospective study on selection of newer modalities of skin dermatomes instruments to cause operative surgeon comfort and study the donor site morbidity in selected cases of 20% surface tissue loss

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Mention time points, assessment outcomes and followup duration in the study protocol
- Informed consent and Participant information sheet not submitted , need to submit to IEC

The proposal was approved by the IEC

7 Title: Resistive index and flow volume : determinant of early failure in arteriovenous fistulas

Investigators: Dr. Prajakta Vedak, Guide: Dr. Sameer Kadam, Department of General Surgery

IEC comments and suggestions:

The study was reviewed and granted clearance

The proposal was approved by the IEC

8 Title: Study of gall bladder carcinoma and its clinicopathological correlation (A retrospective study in a tertiary care hospital

Investigators: Dr. Gargi Gupta, Guide: Dr. Reeta Dhar, Department of Pathology

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Retrospective study so consent form not required
- Administrative permission to be taken
- NOC or Co-guide from respective department (surgery) from where the cases of gall bladder carcinoma patients were primarily treated.

The proposal was approved by the IEC

Case study

9 Title: Need of awareness about over the counter steroid intake – A case series

Investigators: Dr. Anamika Pandey, Guide: Dr. Faraaz Hussain, Department of Ophthalmology

The proposal was tentatively approved by the IEC subject to the following:

- To submit patient consent form for publication

The proposal was approved by the IEC

10 Title: Unusual etiologies of an unusual problem primary aortic mural thrombus

Investigators: Dr. PappuVamsu, Guide: Dr. Sameer Kadam, Department of General Surgery

IEC comments and suggestions:

The case study was reviewed and granted clearance

The proposal was approved by the IEC

11 Title: Rare association of dome shaped macula with high myopia and megalocornea

Investigators: Dr. Priyanka Gandhi, Guide: Dr. Faraaz Hussain, Department of Ophthalmology

IEC comments and suggestions:

The case study was reviewed and granted clearance

The proposal was approved by the IEC

12 Title: Asymmetric and incomplete vogtkoyanagiharadasyndrome : patient's perceptive dilem

Investigators: Dr. Priyanka Gandhi, Guide: Dr. Faraaz Hussain, Department of Ophthalmology

IEC comments and suggestions:

The case study was reviewed and granted clearance

The proposal was approved by the IEC

13 Title: Labs, signs and history – unraveling the mystery

Investigators: Dr. Priyanka Gandhi, Guide: Dr. Reshma Ramakrishanan, Department of Ophthalmology

IEC comments and suggestions:

The case study was reviewed , title to include case study

The proposal was approved by the IEC

14 Title: Unilateral posterior uveitis in a young jia male

Investigators: Dr. Priyanka Gandhi, Guide: Dr. Faraaz Hussain, Department of Ophthalmology

IEC comments and suggestions:

The case study was reviewed and granted clearance

The proposal was approved by the IEC

15 Title: Venom induced consumptive coagulopathy

Investigators: Dr. Lakshmi Monika, Guide: Dr. Mitesh Thakkar, Department of General Medicine

IEC comments and suggestions:

The case study was reviewed and granted clearance

The proposal was approved by the IEC

16 Title: Young male losing vision: presenting with severe endogenous endophthalmitis

Investigators: Dr. Anamika Pandey, Guide: Dr. Faraaz Hussain, Department of Ophthalmology

IEC comments and suggestions:

The case study was reviewed and granted clearance

The proposal was approved by the IEC

17 Title: Hamartoma of optic disc : a unique presentation leading to diagnosis of Neurofibromatosis-2

Investigators: Dr. Yogya Reddy, Guide: Dr. Faraaz Hussain, Department of Ophthalmology

IEC comments and suggestions:

The case study was reviewed and granted clearance

The proposal was approved by the IEC

18 Title: Spectrum of ophthalmic findings in 3 recurrent pituitary adenoma: case series

Investigators: Dr. Yogya Reddy, Guide: Dr. Faraaz Hussain, Department of Ophthalmology

IEC comments and suggestions:

Summary of the case study to be submitted

The proposal was approved by the IEC

19 Title: Malarial retinopathy :falci not so fan-see

Investigators: Dr. Yogya Reddy, Guide: Dr. Reshma Ramakrishanan, Department of Ophthalmology

IEC comments and suggestions:

The case study was reviewed and granted clearance

The proposal was approved by the IEC

20 Title: Triple trouble case report of sudden onset VKH in a young female with hit of SLE and a recent herpes zoster infection

Investigators: Dr. Yogya Reddy, Guide: Dr. Varshav Gore, Department of Ophthalmology

IEC comments and suggestions:

The case study was reviewed and granted clearance

The proposal was approved by the IEC

21 Title: OMG: steroid hackneyed

Investigators: Dr. Yogya Reddy, Guide: Dr. Varshav Gore, Department of Ophthalmology

IEC comments and suggestions:

The case study was reviewed, suggested to include full form in the title

The proposal was approved by the IEC

22 Title: Granulomatous mastitis mimicking tuberculous mastitis: A series of cases in a tertiary care hospital

Investigators: Dr. Navdeep Kaur, Guide: Dr. Ujwala Maheshwari, Department of Ophthalmology

IEC comments and suggestions:

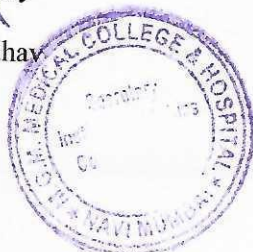
Administrative permission to be obtained

The proposal was approved by the IEC

Note - One project the investigator was absent, will be placed in the next subsequent meeting.

~~Member Secretary~~

~~Dr. Pradeep Jadhav~~



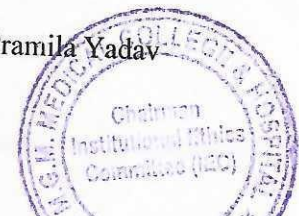
Convener

Dr Ipseeta Ray



Chairperson

Dr . Pramila Yadav





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Institutional Ethics Committee (IEC) of MGM Medical College, Kamothe

Minutes of the Institutional Ethics Committee (IEC) Meeting

In pursuance of the circular on the subject dated: 05.1.2022, the Institutional Ethics Committee (IEC) of MGM Medical College, Kamothe assembled for video- conference based meeting at 10 am on **12.1.2022 via google meet platform (link bcd-fafv-jfc)**. The following functionaries attended the meeting:

No	Member	Designation
1	Dr. Pramila Yadav	Chairperson
2	Dr. D. Bhusare	Member
3	Dr. Pradeep Jadhav	Member Secretary
4	Dr. Ipseeta Ray	Convener
5	Dr. R.S. Inamdar	Member
6	Dr. Jaishree Ghanekar	Member
7	Dr. A.D. Urhekar	Member
8	Mrs. Rupali Gujar	Social Scientist
9	Dr. Karuna Ramraje	Legal Expert
10	Ms Usha Mohite	Lay Person

Minutes of the previous IEC meeting held on 10th Dec 2021 were confirmed unanimously

Minutes of IEC meeting held on 11/01/2022

Institutional Ethics Committee (IEC) suggestions and comments

Title: Utility and validation of MAA tape (Mother's Assessment for action) for diagnosis of nutritional vulnerability and management of children (6 months to 5 years)

Investigators: Dr. Ashlesha Tawde, Guide: Dr. Prasad Waingankar, Department of Community Medicine

IEC comments and suggestions:

- Participant Information sheet and Consent Forms in English, Hindi and Marathi to be submitted
- Add details regarding nutritional counselling in methodology section of study protocol
- Administrative permission to conduct the study needs to be obtained and a copy to be submitted to IEC

M.Sc. BATCH 2021-2022

Institutional Ethics Committee (IEC) suggestions and comments

Anatomy Department

Title: Anatomical Variations In Thyroid Gland And Its Vasculature: A Cadaveric Study

Investigators: Bhairvi Dinesh Jangid, Guide: Dr. Charushila Shinde, Department of Anatomy

IEC comments and suggestions:

- Case Record Form to be prepared and submitted
- Details of evaluation parameters to be added to the methodology section of study protocol

Physiology Department

Title: Impact Of Lockdown Restrictions On Physical And Mental Well Being In Adult Population Not Infected With Covid-19

Investigators: Verma Priyanka, Guide: Dr. Ashita Phadnis, Department of Physiology

IEC comments and suggestions: -

- Validated tools to assess physical and mental wellbeing in adult population not infected with covid-19 needs to be added
- Participant Information sheet needs to be elaborated incorporating details of study procedure, benefits of study.
- The questionnaire designed by Investigator to assess physical and mental wellbeing in adult population not infected with covid-19 needs to be validated after conducting a pilot study

Title: To Assess The Nerve Conduction Study At Wrist In Long & Short Duration Computer Operators

Investigators: Thembe Pooja, Guide: Dr. Priyanka Rane, Department of Physiology

IEC comments and suggestions:-

- Cost of Investigation of Nerve Conduction Study should not be borne by the participants as it is not a routine investigation indicated for the study participants. The same should be added to the participant information sheet.
- In the Exclusion criteria add the drugs that are known to affect the Nerve Conduction

Title: Assessment Of Sleep Hygiene And Insomnia In Patients With Anxiety Disorders

Investigators: Saniea Pius Dsilva, Guide: Dr. Rita Khadkikar, Department of Physiology

IEC comments and suggestions:-

- Mention whether the scales used in the study was copyrighted scales or not. If yes then permission from authors needs to be taken and a copy of the same submitted to IEC

Title: The Study Of Effect Of Tobacco Smoking On Kidney Functions Of Hypertensive Patients.

Investigators: Suvarna Samant, Guide: Dr. YasodaKattimani, Department of Physiology

IEC comments and suggestions:-

- Operational definition of individuals who were Smoking must be included in the methodology section (frequency/duration of smoking)
- Patient Information sheet is inadequate, needs to be prepared fresh and translated to local languages
- Sample size calculation and justification to be added to study protocol

Biochemistry Department

Title: To Study The Association Between Vitamin B12 Deficiency And Hypothyroidism.

Investigators: Mondal Rafika, Guide: Dr. Santosh Gawali, Department of Biochemistry

IEC comments and suggestions:-

- Mention the total sample size in the protocol
- Informed Consent Form not as per the standard guidelines. Needs to be prepared and resubmitted
- Patient Information sheet has not been prepared and submitted
- Language translations of Patient Information sheet needs to be done

Title: To Study Plasma Cholinesterase And Rbc Cholinesterase With Severity Of Organophosphorus Poisoning

Investigators: Mondal Rofika, Guide: Dr. Badade Z.G, Department of Biochemistry

IEC comments and suggestions:-

- Sample size calculation and justification to be added to study protocol
- Cost of Investigation of RBC Cholinesterase should not be borne by the participants as it is not a routine investigation indicated for the study participants. The same should be added to the participant information sheet
- Informed Consent Form not as per the standard guidelines. Needs to be prepared and resubmitted
- Patient Information sheet needs to be prepared and submitted
- Language translations of Patient Information sheet needs to be undertaken

Title: To Study Incident of Hypomagnesemia in Critically Ill Patients.

Investigators: Shivtarkar Priyanka, Guide: Dr. Parineeta Samant, Department of Biochemistry

IEC comments and suggestions:-

- Add the title and evaluation parameters (MICU stay duration, APACHE-II, Outcome, mechanical ventilation duration) to the case record form
- Sample size calculation and justification to be added to study protocol

Title: To Study The Lipid Profile And Oxidative Stress In Non-Alcoholic Fatty Liver Disease With Obesity And Without Obesity.

Investigators: Sawant Pooja, Guide: Dr. Kavita More, Department of Biochemistry

IEC comments and suggestions:-

- Sample size calculation and justification to be added to study protocol
- Cost of Investigation of oxidative stress markers should not be borne by the participants as it is not a routine investigation indicated for the study participants. The same should be added to the participant information sheet

Pharmacology Department

Title: Drug Utilization Pattern Of Anti-Fungal Agents For Infection Caused By Dermatophytes In Dermatology Outpatient Department Of A Tertiary Care Hospital

Investigators: BaradaNayna, Guide: Dr.P.N.Khandelwal, Department of Pharmacology

IEC comments and suggestions:-

- No details regarding how cost variation will be calculated mentioned in the protocol. The cost variation to be added to the methodology as well as Case record form

Title: A Prospective Study of Adverse Drug Reactions of Antimicrobial Agents In Department Of Surgery In Tertiary Care Hospital

Investigators: MrunalVekhande, Guide: Dr. Santosh Gursale, Department of Pharmacology

IEC comments and suggestions:-

- Assent form not in proper format, needs to be prepared and resubmitted
- Age group to be added to the inclusion criteria
- Submit a copy of scales to be used for the study. Mention whether the scales are copyrighted scales. If yes then permission from authors needs to be taken and a copy of the same submitted to IEC

Microbiology Department

Title: Antifungal Susceptibility Testing Of Aspergillus Isolated From Nasal Washings Of Post Covid Patients In Tertiary Care Hospital.

Investigators: MamtaEpili, Guide: Dr. Anahita Hodiwala, Department of Microbiology

IEC comments and suggestions:-

- Justification of the sample size needs to be added to protocol
- Signature of LAR and Impartial Witness needs to be added to Informed consent Form

Title: Bacteriological Profile And Antimicrobial Susceptibility Pattern Of Lower Respiratory Tract Infections In Covid Positive Patients

Investigators: Khadharbee J Bhaba, Guide: Dr. S.A.Samant, Department of Microbiology

IEC comments and suggestions:-

- Age group to be mentioned in Inclusion criteria
- Signature of LAR needs to be added to Informed consent Form
- Add the study title in the CRF

Title: Microbiological Surveillance Of Operation Theatres Using Various Sampling Techniques In A Tertiary Care Hospital At Navi Mumbai

Investigators: Jaulkar Pallavi, Guide: Dr. Samir Pachpute, Department of Microbiology

IEC comments and suggestions:-

- Administrative permission from Medical Superintendent to be taken to conduct the study and a copy submitted to IEC
- Study proforma to be prepared and submitted

Title: Bacteriological Profile With Special Reference To Esbl Producing E.Coli In Cases Of Asymptomatic Uti Among Pregnant Women Attending Tch.

Investigators: Alfiya Mohammad, Guide: Dr.Harapriya Kar, Department of Microbiology

IEC comments and suggestions:-

- The title needs to be modified. Tch is not a standard abbreviation. It needs to be expanded and the full form 'Tertiary care Hospital' needs to be added to study title.
- Signature of LAR needs to be added to Informed consent Form
- Administrative permission from dept of Obstetrics and Gynecology to be obtained

Title:The Antimicrobial Effect OfTulsi (OcimumTenuiflorum) On *Streptococcus Pneumoniae* Isolated From Sputum Samples Of Patients With Lower Respiratory Tract Infection In A Tertiary Care Hospital.

Investigators: AnujaSagare, Guide: Dr.Harapriya Kar, Department of Microbiology

IEC comments and suggestions: -

- Age group to be mentioned in Inclusion criteria
- Add the sign of Impartial Witness in the Assent form
- Details of method of extraction of OcimumTenuiflorum needs to be mentioned. Add details of dose range that will be used for study.
- Signature of LAR needs to be added to Informed consent Form

Title: A Study On The Bacteriological Profile And Antimicrobial Susceptibility Pattern Of Surgical Infections In A Tertiary Care Hospitals, Navi Mumbai

Investigators: Surve Rashmi, Guide: Dr. Samir Pachpute, Department of Microbiology

IEC comments and suggestions:-

- Age group to be mentioned in Inclusion criteria
- Signature of LAR needs to be added to Informed consent Form
- Add the study title in the CRF
- Assent form to be prepared and a copy of Assent form to be submitted

Title: Clinicomycological Study of Onychomycosis In Patients Attending To Dermatology Department At Tertiary Care Hospital.

Investigators: Parnika Patil, Guide: Dr.S.A.Samant, Department of Microbiology

IEC comments and suggestions:-

- Age group to be mentioned in Inclusion criteria
- Signature of LAR needs to be added to Informed consent Form
- Case record form to be prepared and submitted

Title: Clinico-Microbiological Study Of Catheter Associated Urinary Tract Infection (Cauti) And Associated Risk Factors In Patients Admitted In Tertiary Care Hospital In Navi Mumbai.

Investigators: Herita Britto, Guide: Dr.Deepashri Naik, Department of Microbiology

IEC comments and suggestions:-

- Add the title of the study to Case record form
- Age group to be mentioned in Inclusion criteria
- Signature of LAR needs to be added to Informed consent Form

Title: Clinico-Microbiological Profile of Central Line Associated Blood Stream Infection (Clabsi) And Associated Risk Factor Among Patients Admitted In A Tertiary Care Hospital, Navi-Mumbai

Investigators: Shreya Kadam, Guide: Dr.Deepashri Naik, Department of Microbiology

IEC comments and suggestions:-

- Risk factors to be assessed not mentioned in the CRF.. To be added
- Add the title of the study to Case record form
- Age group to be mentioned in Inclusion criteria
- Signature of LAR needs to be added to Informed consent Form

Title: To Study The Multidrug-Resistant Pseudomonas Infections From Wound Swabs And Pus Samples Of Patients In A Tertiary Care Hospital.

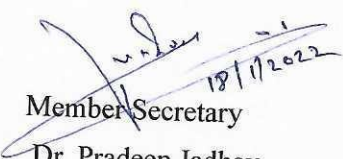
Investigators: Nidhi Narayan, Guide: Dr. Neha Singh, Department of Microbiology


IEC comments and suggestions:-


- Age group to be mentioned in Inclusion criteria
- Signature of LAR and Impartial Witness needs to be added to Informed consent Form

- Add the title of the study to Assent form
- Objective 1 regarding how prevalence and Incidence will be determined needs to be mentioned.

The meeting ended with thanks to the chair. Date of next meeting to be decided


Member Secretary
Dr. Pradeep Jadhav


Convener
(Dr Ipseeta Ray)


Chairperson
Dr . Pramila Yadav



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INSTITUTIONAL ETHICS COMMITTEE (IEC)

Institutional Ethics Committee (IEC) of MGM Medical College, Kamothe

Minutes of the Institutional Ethics Committee (IEC) Meeting

In pursuance of the circular on the subject dated:, the Institutional Ethics Committee (IEC) of MGM Medical College, Kamothe assembled for video conference based meeting on **18th February 2022 (Friday) at 10.00AM. (Morning)**, virtually via google meet at the following link

<https://meet.google.com/jcx-ydkw-qge>

The following functionaries attended the meeting

No	Member	Designation
1	Dr. Pramila Yadav	Chairperson
2	Dr. D. Bhusare	Member
3	Dr. Pradeep Jadhav	Member Secretary
4	Dr. Ipseeta Ray	Convener
5	Dr. R.S. Inamdar	Member
6	Dr. Jaishree Ghanekar	Member
7	Dr. A.D. Urhekar	Member
8	Mrs. Rupali Gujar	Social Scientist
9	Dr. Karuna Ramraje	Legal Expert
10	Ms Usha Mohite	Lay Person

Minutes of IEC meeting held on 18/2/2022

Institutional Ethics Committee (IEC) suggestions and comments

1) Title: Cross-sectional questionnaire based observational study on prevalence of self-medication among the adult population in India during the Covid-19 lockdown. (ICMR – STS)

Investigators: Ms. Ananya Bhasin, Guide: Dr. Anahita Hodiwala, II MBBS student

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Suggested to omit the words “Adult population in India” as the study is not pan- India based
- Participant information sheet not submitted to IEC
- Standard consent form for the study to be submitted to IEC

The proposal was approved by the IEC

2) Title: Comparative study on functional outcome of kapandji intrafocal pinning vs percutaneous k-wire fixation in extra- articular distal end radius fracture

Investigators: Dr. Laksh Agrawal, Guide: Dr. Ashok Ghodke, Department of Orthopedics

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- To include sample size justification
- Participant information sheet in local language to be submitted

The proposal was approved by the IEC

3) Title: To study the lipid profile in patients with ischemic stroke

Investigators: Dr. Nidhi Anam, Guide: Dr. Amrit Kejriwal, Department of General Medicine

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- To include sample size justification
- Investigator Undertaking form , the signature of investigators are missing

The proposal was approved by the IEC

4) Title: Association of C-reactive protein with type 2 diabetes mellitus patients

Investigators: Dr. Shreyansh Soni, Guide: Dr. Sandeep Rai, Department of General Medicine

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- To include sample size justification
- In methodology , to mention separately the inclusion and exclusion criteria for the Cases and the Control group
- Participant information sheet to include study title
- Investigator declaration form is submitted incomplete, the signatures of the investigators are missing on it

The proposal was approved by the IEC

5) Title: Study of association of uric acid levels with blood sugar levels and glycosylated haemoglobin levels among patients with type II diabetes mellitus

Investigators: Dr. Niharika Sabnis, Guide: Dr. Sandeep Rai, Department of General Medicine

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Title modified -The investigator has modified the title prior to the meeting. The new revised title protocol and requisite documents to be resubmitted
- Objectives of the study to be refined
- To include sample size justification
- Participant information sheet in local languages are missing , needs to be submitted

The proposal was tentatively approved by the IEC

6) Title: Randomized study comparing the outcomes of laparoscopic and conventional resection of rectal carcinoma with curative intent

Investigators: Dr. Vikas Gupta, Guide: Dr. Mukesh Soni, Department of General Surgery

IEC comments and suggestions: The proposal was reviewed and had major revisions.

- The study included vulnerable groups esp. cancer patients
- Randomization of cancer patients to either intervention needs justification in terms of gold standard technique, complications and safety measure.

- Currently, the protocol standard for the desired intervention is not available in the department.
- The protocol needs to be written in detailed form
- To include sample size justification
- Details of complications and safety measures not mentioned
- Study outcomes needs to be mentioned in detailed with followups
- Participant information sheet in local languages missing, not submitted to IEC
- Patient consent form missing, not submitted to IEC
- CRF is missing, not submitted to IEC
- The participant information sheet should have complete details about the study as per the standard format

The proposal had major revisions and needed more clarification, not approved in the present form. The revised protocol needs to be submitted for further review

7) Title: Cancer screening study, to screen for breast, cervix and head/neck cancers at the community level

Investigators: Dr. Vikas Gupta, Guide: Dr. Mukesh Soni, Department of General Surgery

IEC comments and suggestions: The proposal was reviewed and had major revisions.

- To include sample size justification
- Expected outcomes to be mentioned in protocol
- Site of study details and feasibility of conducting the study at the site
- Co-investigator from OGBY to be included in the study if cervix screening is involved, similarly co-investigator from ENT for screening head neck and oral cavity.
- It was suggested to involve one region (breast lump/cancer screening for the feasibility) and to conduct a prior informed health camp for breast screening for possible cancer detection involving Community medicine department
- The study should involve follow-ups for proper investigation for confirmation of the cancer
- Participant information sheet in local languages missing, not submitted to IEC
- Patient consent form missing, not submitted to IEC
- CRF missing, not submitted to IEC

The proposal had major revisions and needed more clarification, not approved in the present form. The revised protocol needs to be submitted for further review

8) Title: Analyzing the prevalence of different cancers presenting in a tertiary care hospital by starting a hospital based cancer registry

Investigators: Dr. Vikas Gupta, Guide: Dr. Mukesh Soni, Department of General Surgery

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Title and protocol is mismatch. Whether the study is to create cancer registry or conduct a survey is not clear. No clear details are mentioned in the protocol.
- For creating or using registry, administrative permission documents are not submitted
- The details of the registry system along with the security aspect of storing the confidential and privacy data of the patients with accountability need to be submitted
- To include sample size justification
- Site of conduct and patient recruitment from which department details is not mentioned in protocol.
- CRF missing, not submitted to IEC
- Participant information sheet in local languages missing, not submitted to IEC
- Patient consent form missing, not submitted to IEC

The proposal had major revisions and needed more clarification. The revised protocol needs to be submitted for further review

9) Title: Determination of average age from time of onset to diagnosis of diabetic retinopathy

Investigators: Dr. Mohammad Awais, Guide: Dr. Bhaimangesh Naik, Department of General Medicine

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Title modification -Title needs to be revised/ changed as per the aim of the study
- The study objective and outcomes to be defined clearly
- Mention implication of the study in the protocol
- To include sample size justification
- To include co-guide or permission NOC from Geriatric department as site of conduct is mentioned also from geriatric medicine department
- CRF is incompletely prepared
- In Consent form- to add the study title

The proposal was tentatively approved by the IEC

10) Title: Study of correlation between glycosylated hemoglobin and stage of diabetic retinopathy

Investigators: Dr. Praveen Badlani, Guide: Dr. Bhaimangesh Naik, Department of General Medicine

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Investigator Undertaking form , the signature of investigators are missing
- To include sample size justification
- To include co-guide from ophthalmology department as the study involves staging of retinopathy as primary objective
- In consent and participant information sheet- title is missing , to add the study title
- To resubmit the revised protocol and requisite documents

The proposal was tentatively approved by the IEC

11) Title: Correlation of sofa scoring with mortality

Investigators: Dr. Simran Maheshwari, Guide: Dr. Bhaimangesh Naik, Department of Dr. Babita Ghodke

Medicine

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Title change -Title is incomplete , needs to be revised as per the aim of the study
- The study objective and outcomes to be defined clearly
- The details of the which sofa scoring will be used for prediction needs to be clearly mentioned in methodology
- To include sample size justification
- CRF not submitted
- Participant information sheet need to be refined with adequate information

The proposal was tentatively approved by the IEC

12) Title: Utility of surgical apgar score in predicting postoperative morbidity and mortality in patients undergoing laparotomy – A prospective study

Investigators: Dr. Akshaya Parthiban, Guide: Dr. Ali Reza, Department of General Surgery

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Study outcomes to be mentioned in protocol
- To include sample size justification
- Time points and followup visit with list of complications to be mentioned in case record form

The proposal was approved by the IEC

13).Title: Susceptibility and synergistic property between plant extract and antimicrobial drugs on E.coli (M.Sc Student)

Investigators: Ms. Sohini Sujit, Guide: Dr. Anahita Hodiwala, Department of Microbiology

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Title be modified – to include the plant name in the title
- To mention details of the authenticity of plant or extract in the protocol
- also the details of standard procedure of obtaining standardized extract and its purity assessment (analytical grade)
- CRF is missing , not submitted to IEC

The proposal was approved by the IEC

14) Title: Study of lipid profile in chronic kidney disease patients

Investigators: Dr. Kubal Sahil, Guide: Dr. Jaishree Ghanekar, Department of General Medicine

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- To include sample size justification
- To mention in methodology, the clinical stage of CKD and mention the correlation of lipid levels with the CKD stages

The proposal was approved by the IEC

15) Title: Left ventricular hypertrophy in patients with hypertension

Investigators: Dr. Ravi Patil, Guide: Dr. Babita Ghodke, Department of General Medicine

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- To include sample size justification
- To mention outcome measures in the protocol

The proposal was approved by the IEC

16) Title: To evaluate rpoβ gene and its various mutants in MDR cases by Genexpert method (M.Sc Student)

Investigators: Ms. Jayalakshmi , Guide: Dr. Harapriya Kar, Department of Microbiology

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Administrative permission for accessing the data as the study is retrospective
- To submit CRF form

The proposal was approved by the IEC

17) Title: Differences in applanation tonometry reading depending upon eyepiece and binocularity

Investigators: Dr. Ayushi Ojha , Guide: Dr. Syed Faraaz, Department of Ophthalmology

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- To include sample size justification

The proposal was approved by the IEC

18) Title: Fundus changes and associated OCT based ganglion cell analysis in Tobacco abuse

Investigators: Dr. Ayushi Ojha , Guide: Dr. Syed Faraaz, Department of Ophthalmology

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Title to be modified – the term abuse cannot be used as the study is focused on chronic tobacco consumers. OCT full form to be mentioned in title.
- Operative definition of study terms needs to be mentioned
- To include sample size justification
- CRF is not submitted , to submit CRF form to IEC

The proposal was approved by the IEC

19) Title: Treatment satisfaction and medication adherence in patients with diabetes mellitus attending a tertiary care hospital (M.Sc Student)

Investigators: Mr. Mayuresh Jadhav, Guide: Dr. Pradeep Jaadhav, Department of Pharmacology

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Permission to use copyrighted scales to be obtained and submitted

- Since the scales are Patient related outcomes, a patient feasible guide for understanding the terms and the meaning of the questions was suggested
- It was also suggested to use more patient specific easy questionnaire for the specific condition and drug treatment, if available
- Indirect benefits can be mentioned in the PIS
- In CRF- mention the study title

The proposal was approved by the IEC

20) Title: Chronic hemodialysis patients hospitalized with COVID-19: short – term outcomes

Investigators: Dr. Anjali Patel, Guide: Dr. Mitesh Thakkar, Department of General Medicine

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- To mention the details of short term outcomes in the objectives and methodology
- Administrative permission to access retrospective data to be submitted
- Inclusion criteria- add the term “COVID -19 patients”
- Period of the retrospective study or study period to be mentioned
- List of Co-morbidities and short term outcomes to be added
- In CRF- mention the study title and list of short term outcomes

The proposal was approved by the IEC

21) Title: Prevalence of audiological impairment in children with cleft palate

Investigators: Dr. Neelikattu Aathira, Guide: Dr. Supriya Patil, Department of ENT

IEC comments and suggestions: The proposal was **Rejected/ not approved by the IEC** due to the following:

- The study was a retrospective study , however investigators had already initiated the retrospective study , collected data and complied it before getting administrative permission and ethical clearance

The proposal was Rejected/ Not approved by the IEC

22) Title: Comparative study to analyse the occurrence of post operative hematoma after longitudinal and transverse scrotal incision

Investigators: Dr. Preety Deshpande, Guide: Dr. Prajakta Vedak, Department of General Surgery

IEC comments and suggestions:

- To incorporate efficacy parameter along with assessment of hematoma was suggested as assessment of a single complication does not justify the research
- Also the justification for randomization of patients for the surgical intervention to assess only the complication aspect is weak
- Single surgeon assessment is confounding
- Suggested to include multiple surgeon operated cases with observation study design or analyse retrospective data for the complication
- To include sample size justification
- Signature of LAR in consent form is missing

The proposal is kept on hold till further clarification from investigators

23) Title: The immunomodulatory effect of aqueous extract of simarouba glauca with respect to CD+T cell exhaustion markers in breast cancer

Investigators: Dr. Arpita Singh, Guide: Dr. Ujwala Maheshwari, Department of Pathology

IEC comments and suggestions:

- The investigator was absent for the meeting, the proposal was not reviewed

The proposal was not reviewed in this IEC meeting, will be placed in next IEC meeting

Case report

24) Title: Topiramate – Glaucoma's mate: A different management approach

Investigators: Dr. Priyanka Gandhi, Guide: Dr. Kashyap Thakker, Department of Ophthalmology

IEC comments and suggestions:

Suggested to do a causality assessment by WHO or Naranjo scale for the adverse reaction

The case study was reviewed and granted clearance

The proposal was approved by the IEC

25) Title: Eye – the brain SPY

Investigators: Dr. Ayushi Ojha, Guide: Dr. Reshma Ramakrishanan, Department of Ophthalmology

IEC comments and suggestions:

Title to be modified, title to be specific to the case study and add the word "case series".

The case study was reviewed and granted clearance

The proposal was approved by the IEC

26) Title: Red alert! Cherry red spot in the eye of a child with termors and neuroregression : a diagnostic conundrum

Investigators: Dr. Ayushi Ojha, Guide: Dr. Syed Faraaz, Department of Ophthalmolgy

IEC comments and suggestions:

The case study was reviewed and granted clearance

The proposal was approved by the IEC

27) Title: Latent refractive error correction : correct or not so correct

Investigators: Dr. Ayushi Ojha, Guide: Dr. Syed Faraaz, Department of Ophthalmolgy

IEC comments and suggestions:

The case study was reviewed and granted clearance

The proposal was approved by the IEC

28) Title: Patient care and caring for the patient : social impact of COVID 19

Investigators: Dr. Ayushi Ojha, Guide: Dr. Syed Faraaz, Department of Ophthalmolgy

IEC comments and suggestions:

Title to be modified – to be specific to the case

The case study was reviewed and granted clearance

The proposal was approved by the IEC

29) Title: Spontaneous suprachoroidal hemorrhage in a 2 year old child with clotting factor deficiency

Investigators: Dr. Ayushi Ojha, Guide: Dr. Syed Faraaz, Department of Ophthalmolgy

IEC comments and suggestions:

The case study was reviewed and granted clearance

The proposal was approved by the IEC

30) Title: Childhood bullous pemphigoid : A rare entity

Investigators: Dr. Kopal Vadera, Guide: Dr. Shylaja Someshwar, Department of Dermatology

IEC comments and suggestions:

The case study was reviewed and granted clearance

The proposal was approved by the IEC

31) Title: Ipsilateral verrucous epidermal nevus with woolly hair nevus: A Unique association

Investigators: Dr. Kopal Vadera, Guide: Dr. Meghana Phiske , Department of Dermatology

IEC comments and suggestions:

The case study was reviewed and granted clearance

The proposal was approved by the IEC

32) Title: Watch it while you pump it

Investigators: Dr. Ayushi Ojha, Guide: Dr. Reshma Ramakrishanan, Department of Ophthalmology

IEC comments and suggestions:

Title to be modified – to be specific to the case

The case study was reviewed and granted clearance

The proposal was approved by the IEC

33) Title: Lichen planus in a male child

Investigators: Dr. Sumit Ahuja, Guide: Dr. Meghana Phiske, Department of Dermatology

IEC comments and suggestions:

The case study was reviewed and granted clearance

The proposal was approved by the IEC

34) Title: Meconium Pseudocyst: A rare neonatal surgical emergency

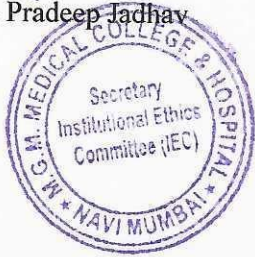
Investigators: Dr. Samit Doshi, Guide: Dr. D. Bhusare, Department of General Surgery

IEC comments and suggestions:

The case study was reviewed and granted clearance

The proposal was approved by the IEC

~~Member Secretary~~ 23/12/22
Dr. Pradeep Jadhav

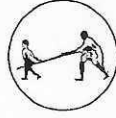


Ipseta Ray
Convener
Dr Ipseta Ray



Pramila Yadav
Chairperson
Dr . Pramila Yadav





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E-mail: mgmethics@gmail.com
Registration number - EC/NEW/INST/2021/2255

Ethics Committee relating to Biomedical and Health Research with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research (DHR)

In pursuance of the circular on the subject dated: **23.3.2022**, the Institutional Ethics Committee (IEC) of MGM Medical College, Kamothe assembled for video conference based meeting on 31st March 2022 **at 1:30 PM** Pharmacology Seminar room 2nd Floor MGM Medical College Building.

The following functionaries attended the meeting

Sr. No.	Name	Designation of member in Ethics Committee
1	Dr. Pramila Yadav	Chairman
2	Dr. Padmaja Kanchi	Member /Co-Chairperson
3	Dr. D. Bhusare	Member- Clinician
4	Dr. Pradeep Jadhav	Member Secretary
5	Dr. Ipseeta Ray	Basic Medical Scientist
6	Dr. R.S. Inamdar	Basic Medical Scientist
7	Dr. Jaishree Ghanekar	Member - Clinician
8	Mrs. Amruta Sachin Dhavale	Lay Person
9	Mrs. Rupali Gujar	Social Scientist
10	Dr. Sheela Hosamani	Legal Expert

Minutes of IEC meeting held on 31/03/2022

- The first induction meeting of the newly reconstituted MGM Institutional Ethics Committee (IEC) was conducted on **31/03/2022**
- The members were introduced to each other and the general rules and policies of the Ethic committee were briefed and discussed.
- Dr. R S Inamdar (Internal Member) has resigned from College and won't be continuing as a part of ethics member; the members have nominated Dr. Santosh Gawali as replacement for the same.
- Appraisal of SOP, Common formats, ICMR Guidelines and Policies of MGM IEC, Navi Mumbai was briefed to the members. It was decided that the common forms may be circulated directly to all the HOD of medical College.
- Following research protocols were reviewed by the committee

1 Title: A case control study of platelet indices in chronic liver disease

Investigators: Dr. Salman Shaikh, Guide: Dr. Amrit Kejriwal, Department of General Medicine

IEC comments: The proposal was tentatively approved by the IEC subject to the following:

- Revise objectives (omit inclusion criteria)
- In methodology , justify sample size , recruitment of apparent healthy participants in Control arm and add liver function test
- In case record form mention the details of platelet indices and liver function test methodology , sample size justification needs to be added
- Participant information sheet , mention in detailed the study procedure / test

The proposal was tentatively approved by the IEC

2 Title: Case report - Aoroarteritis a rare pulmonary – renal disease

Investigators: Dr. Tanvee Karande, Guide: Dr. Aditya Nayak, Department of General Medicine

IEC suggestions: The case report was reviewed

The case report was approved by the IEC

3 Title: Improved Oxygenation In Critically Ill Covid 19 Patients With Hypoxemic Respiratory Failure By Placing A Surgical Mask Atop HFNC

Investigators: Dr Aadila Coatwala, Guide: Dr. Mayank Dhir, Department of Emergency Medicine

IEC comments: The proposal was tentatively approved by the IEC subject to the following:

- Administrative permission from Hospital Director/MS to be obtained
- Specify the duration of the records to be accessed for retrospective analysis

The proposal was tentatively approved by the IEC

The meeting ended with thanks to the chair. Date of next meeting to be decided

~~Member Secretary~~

~~Dr. Pradeep Jadhav~~

31/03/22

Convener

(Dr Ipseeta Ray)

Chairperson

Dr . Pramila Yadav



**Mahatma Gandhi Mission's
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Registration number - EC/NEW/INST/2021/2255

Ethics Committee relating to Biomedical and Health Research with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research (DHR)

In pursuance of the circular on the subject dated: **23.3.2022**, the Institutional Ethics Committee (IEC) of MGM Medical College, Kamothe assembled for video conference based meeting on 21st MAY 2022 **at 11 AM via google meet platform** at the following link <https://meet.google.com/cqw-sosr-sdo>

The following functionaries attended the meeting

Sr. No.	Name	Designation of member in Ethics Committee
1	Dr. Pramila Yadav	Chairman
2	Dr. Padmaja Kanchi	Member /Co-Chairperson
3	Dr. Pradeep Jadhav	Member Secretary
4	Dr. Ipseeta Ray	Basic Medical Scientist
5	Dr. Jaishree Ghanekar	Member - Clinician
6	Mrs. Amruta Sachin Dhavale	Lay Person
7	Mrs. Rupali Gujar	Social Scientist
8	Dr. Sheela Hosamani	Legal Expert

Minutes of the previous IEC meeting held on 31/03/2022 were confirmed unanimously

Minutes of IEC meeting held on 21/05/2022

- Following research protocols were reviewed by the committee

1 Title: Does intra-operative fluoroscopy significantly improve component position in a primary total hip arthroplasty? Our experience in a tertiary care hospital

Investigators: Dr. Laksh Agrawal, Guide: Dr. Alfven Vieira, Department of Orthopedics

IEC comments: The proposal was tentatively approved by the IEC subject to the following:

- To submit case record form
- methodology , sample size justification needs to be added

The proposal was approved by the IEC

2 Title: Magnitude and determinants of low birth weight babies in an urban tertiary care level hospital, Raigad District

Investigators: Ms. Manali Sarkar (MBBS Student), Guide: Dr. Sunila Sanjeev, Department of Community Medicine

IEC comments: The proposal was tentatively approved by the IEC subject to the following:

- Study duration to be kept at least 6 months to meet the sample size requirement
- Questionnaire validation needs to be mentioned and if adapted from earlier studies then the references of the research articles to mentioned for the questionnaire.
- Modify the questionnaire as per the associated factors to be identified, also provide option for drugs/supplementation from private sources apart from government agencies and omit capturing of sensitive information of the participants (eg. Caste)

The proposal was approved by the IEC

3 Title: The immunomodulatory effect of aqueous extract of Simarouba glauca with respect to CD8+T cell exhaustion markers in breast cancer

Investigators: Dr. Arpita Singh, Guide: Dr. Ujwala Maheshwari, Department of Pathology

IEC comments: The proposal was tentatively approved by the IEC subject to the following:

- Sample size justification needs to be mentioned as the sample size is small (10 participants)
- Details of standardized plant extract to be mentioned in protocol
- Participant information sheet to mention the name of the test and the charges of the test and also that the test will be done free for the patients and the expenses will be borne by the investigator
- Information regarding application to funding agency and if funding is not granted , the expenses will be borne by the investigators to be mentioned in protocol.

The proposal was approved by the IEC

4 Title: Psychological effects of the COVID-19 pandemic on the medical students

Investigators: Dr Tanvee Karande (Intern), Guide: Dr. Z.G.Badade, Department of Biochemistry

IEC comments: The proposal was tentatively approved by the IEC subject to the following:

- Submit questionnaire to iec
- Add references from which the questionnaire was created in the methodology in the questionnaire section
- To make Online provision of consent form in google form
- Typo error of past tense in sentences to be rectified

The proposal was tentatively approved by the IEC

5 Title: Case report -The traumatic Iris Sunset

Investigators: Dr. Aesha Hastak, Guide: Dr. Reshma Ramakrishnan, Department of Ophthalmology

IEC comments and suggestions: The case study was reviewed and granted clearance

The proposal was approved by the IEC

6 Title: Comparative study between diclofenac suppository and combined oral diclofenac with local anaesthetic agent in pain management in acute fissure-in-ano in out patient department care

Investigators: Dr. Samit Doshi, Guide: Dr. Ali Reza, Department of General Surgery

IEC comments:

- The study design was not clear whether prospective or retrospective
- The investigator had already conducted , collected and analyzed the data before taking appropriate permissions and approvals
- Research misconduct was noted

The proposal was NOT APPROVED by the IEC

7 Title: Attitude among adult Indian populace who have received both vaccination doses on receiving COVID-19 booster dose

Investigators: Ms. Manali Sarkar (MBBS Student), Guide: Dr. Sunila Sanjeev, Department of Community Medicine

IEC comments: The proposal was tentatively approved by the IEC subject to the following:

- Add informed consent in online form

- Submit consent and study questionnaire form

The proposal was approved by the IEC

Pradeep Jadhav
23/5/22
Member Secretary
Dr. Pradeep Jadhav
Secretary
Institutional Ethics
Committee (IEC)
M.G.M. MEDICAL COLLEGE & HOSPITAL
NAVI MUMBAI

J. Ray
23/5/22
Convener
Dr. Jyoti Ray
Convener
Institutional Ethics
Committee (IEC)
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NAVI MUMBAI

P. Yadav
Chairperson
Dr. Pramila Yadav
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E-mail: mgmethics@gmail.com
Registration number - EC/NEW/INST/2021/2255

In pursuance of the circular on the subject dated: **15/7/2022**, the Institutional Ethics Committee (IEC) of MGM Medical College, Kamothe assembled for videoconference based meeting on **21th July 2022**, from **10 AM**, **virtually** via google meet. at the following link
Google Meet link: <https://meet.google.com/fot-vcvf-fde>

The following functionaries attended the meeting

Sr. No.	Name	Designation of member in Ethics Committee
1	Dr. Pramila Yadav	Chairman
2	Dr. Padmaja Kanchi	Member /Co-Chairperson
3	Dr. D. Bhusare	Member- Clinician
4	Dr. Pradeep Jadhav	Member Secretary
5	Dr. Ipseeta Ray	Basic Medical Scientist
6	Dr. R.S. Inamdar	Basic Medical Scientist
7	Dr. Jaishree Ghanekar	Member - Clinician
8	Mrs. Amruta Sachin Dhavale	Lay Person
9	Mrs. Rupali Gujar	Social Scientist
10	Dr. Sheela Hosamani	Legal Expert

Minutes of the previous IEC meeting held on 21/5/2022 were confirmed unanimously

Minutes of IEC meeting held on 21/07/2022

Staff / PG/UG Student Projects

1 Title: Thymoma as a neck swelling – A surgical dilemma

Investigators: Dr. Shifa Kalokhe, Guide: Dr. Lisha Suraj, Department of General Surgery

IEC comments and suggestions:

- The investigators had obtained informed consent from the patient for case report/study

The case report/ study proposal was approved by the IEC

2 Title: NICE guidelines in management of head trauma patient: An audit in a tertiary care hospital

Investigators: Dr. Shifa Kalokhe, Guide: Dr. Neeraj Patni , Department of General Surgery

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Case record form not prepared, to submit the case record form as per the study protocol to capture the data

The research proposal was approved by the IEC

3 Title: Unpleasant surprises – A case series

Investigators: Dr. Shifa Kalokhe, Guide: Dr. Lisha Suraj, Department of General Surgery

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Title is broad and vague does not reflect the presentation of the case series. Title modify to be specific for the rare presentation depending upon the cases

The case report/ study proposal was approved by the IEC

4 Title: Study of correlation between serum amylase and serum lipase level with percentage of necrosis on CECT in acute necrotizing pancreatitis

Investigators: Dr. Shifa Kalokhe, Guide: Dr. Neeraj Patni , Department of General Surgery

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- The study is an Retrospective study, Administrative permission to be obtained
- Sample size – to add duration of one year (retrospective assessment period) in which all cases fulfilling the inclusion and exclusion criteria will be included
- Case record form not prepared, to submit the case record form as per the study protocol to capture the data

The research proposal was approved by the IEC

5 Title: Comparative study between warm sitz bath and warm sitz shower bath in conservative management of acute fissure in ano

Investigators: Dr. Samit Doshi, Guide: Dr. Ali Reza, Department of General Surgery

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Sample size justification
- Add both gender in inclusion criteria
- Add compliance status to assess the compliance of the patient to the interventions
- Add time points in Case record form along with compliance

The research proposal was approved by the IEC

6 Title: Prevalence of stress, Anxiety and depression among healthcare workers working in COVID

Investigators: Dr. Riddhee Talele, Guide: Dr. Rakesh Ghildiyal, Department of Psychiatry

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Specify in the inclusion criteria - Specify healthcare workers- (residents, intern) and healthcare workers who had or are working in covid -19 care
- Permission for the use of copyrighted scales / questionnaire to be obtained (if case of copyrighted scales used)

The research proposal was approved by the IEC

7 Title: Case presentation: A rare case of shared delusional parasitosis

Investigators: Dr. Riddhee Talele, Guide: Dr. Rakesh Ghildiyal, Department of Psychiatry

IEC comments and suggestions:

- The investigators had obtained informed consent from the patient for case report/study

The case report/ study proposal was approved by the IEC

8 Title: Telemental health screening and post Covid OPD psychiatric care amongst covid-19 recovered patients

Investigators: Dr. Anshu Verma, Guide: Dr. Darpan Kaur, Department of Psychiatry

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Title to be modified to reflect the study aim and to be specific
- Objectives to be modified as per the study aim
- Administrative permission to be obtained for retrospective data access
- Method – parameters to be evaluated and analysed to be mentioned in detail
- Implication of the study to be mentioned in the study protocol

The research proposal was approved by the IEC

9 Title: To compare the efficacy of infusion injection propofol and injection dexmedetomidine in maintain hemodynamic stability during intracranial aneurismal clipping

Investigators: Dr. Rahvee Gala, Guide: Dr. Jessy Vennel, Department of Anaesthesiology

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Changes made prior to IEC meeting need to be resubmitted - Resubmit revised protocol
- Case record form not prepared, to submit the case record form as per the study protocol to capture the data
- Mention the drug dosage in the protocol
- Mention adverse drug reaction reporting in protocol in detail as well in the Case record form

The research proposal was approved by the IEC

10 Title: Prediction of post operative nausea and vomiting using APFEL score

Investigators: Dr. Ananya Garg; Dr. Jessy Vennel, Department of Anaesthesiology

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Sample size justification to be mentioned
- Diagnostic parameters like Sensitivity specificity to be added in assessment

The research proposal was approved by the IEC

11 Title: Childhood – onset systemic lupus erythematosus : A case report

Investigators: Dr. Tanya Pandey, Guide: Dr. Meghana Phiske, Department of Dermatology

IEC comments and suggestions:

- The investigators had obtained informed consent from the patient for case report/study
- Pathology department should be acknowledged in case of using histo pathology findings

The case report/ study proposal was approved by the IEC

12 Title: Unilateral linear capillaritis: a rare subtype of pigmented purpuric dermatoses

Investigators: Dr. Tanya Pandey, Guide: Dr. Meghana Phiske, Department of Dermatology

IEC comments and suggestions:

- The investigators had obtained informed consent from the patient for case report/study
- Pathology department should be acknowledged in case of using histo pathology findings

The case report/ study proposal was approved by the IEC

13 Title: Interesting case of disseminated extra genital lichen sclerosis et atrophicus

Investigators: Dr. Surina Nair, Guide: Dr. Meghana Phiske, Department of Dermatology

IEC comments and suggestions:

- The investigators had obtained informed consent from the patient/LAR for case report/study

- Pathology department should be acknowledged in case of using histo pathology findings

The case report/ study proposal was approved by the IEC

14 Title: Case report : rare case of ecthyma secondary to varicella

Investigators: Dr. Aishwarya Kalathil, Guide: Dr. Meghana Phiske, Department of Dermatology

IEC comments and suggestions:

- The investigators had obtained informed consent from the patient/LAR for case report/study
- Pathology department should be acknowledged in case of using histo pathology sections/findings

The case report/ study proposal was approved by the IEC

15 Title: Interesting case of extragenital lichen sclerosus et atrophicus

Investigators: Dr. Aishwarya Kalathil, Guide: Dr. Meghana Phiske, Department of Dermatology

IEC comments and suggestions:

- The investigators had obtained informed consent from the patient/LAR for case report/study
- Pathology department should be acknowledged in case of using histo pathology sections/findings

The case report/ study proposal was approved by the IEC

16 Title: Balloon kyphoplasty versus percutaneous vertebroplasty for osteoporotic vertebral body compression fractures: Clinical and radiological outcomes

Investigators: Dr. Vasu Jindal, Guide: Dr. Sarabjeet Singh Kohli, Department of Orthopaedics

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Sample size justification
- Remove double blind

- In case record form, the assessment timepoints and parameters/ scoring to be mentioned. Also the list of anticipated complications to be mentioned in Case record form to record the data
- Permission for the use of any copyrighted scale to be obtained

The research proposal was approved by the IEC

17 Title: Solitary osteochondroma of the scapula in a young male : A case report

Investigators: Dr. Vasu Jindal, Guide: Dr. Anil Khandekar , Department of Orthopaedics

IEC comments and suggestions:

- The investigators had obtained informed consent from the patient/LAR for case report/study

The case report/ study proposal was approved by the IEC

18 Title: Functional outcome of simultaneous anterior cruciate ligament reconstruction and high tibial osteotomy for patients with medial compartment osteoarthritis

Investigators: Dr. Dhruv Shah, Guide: Dr. Nilesh Vishwakarma, Department of Orthopaedics

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- patient information sheet and Case record form not prepared, to submit the case record form as per the study protocol to capture the data
- To mention the exact Study duration in the protocol
- Sample size justification to be mentioned
- Permission for the use of any copyrighted scale to be obtained

The research proposal was approved by the IEC

19 Title: Dermatomyositis – A case report and review of literature

Investigators: Dr. Ravi Patil, Guide: Dr. Mitesh Thakkar, Department of General Medicine

IEC comments and suggestions:

- The investigators had obtained informed consent from the patient/LAR for case report/study
- Pathology and Dermatology department should be acknowledged in case of using histo pathology sections/findings from pathology and dermatology opinion/ findings

The case report/ study proposal was approved by the IEC

20 Title: Scrub typhus with multiorgan dysfunction syndrome

Investigators: Dr. Ravi Patil, Guide: Dr. Babita Ghodke , Department of General Medicine

IEC comments and suggestions:

- The investigators had obtained informed consent from the patient/LAR for case report/study

The case report/ study proposal was approved by the IEC

21 Title: Assessment of Health profile in terms of physical and psychosocial health status of people attending the gym

Investigators: Ms. Ritika Thadani, Guide: Dr. Madhavi Mankar, Department of Community Medicine

IEC comments and suggestions:

Investigator and Guide were absent for the meeting

The research proposal will be placed in next IEC meeting for review.

22 Title: Laparoscopic excision of cystic adenomyosis – A case report

Investigators: Dr. Shweta Bhatia, Guide: Dr. Abhishek Mangeshkar, Department of Obstetrics and gynecology

IEC comments and suggestions:

- The investigators had obtained informed consent from the patient/LAR for case report/study

The case report/ study proposal was approved by the IEC

23 Title: A retrospective study of umbilical artery S/D ratio assessment on color Doppler for monitoring of fetal well being in patients with intrauterine growth retardation and its correlation with perinatal outcomes

Investigator: Dr. Suwarna Mane, Department of Obstetrics and gynecology

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Administrative permission to be obtained for retrospective data access
- Consent or participant information sheet not required for retrospective secondary analysis in this study

The research proposal was approved by the IEC

ICMR STS 2022

24 Title: Association between water consumption/urinary practices and incidence of urinary tract infections in working women and female college students in Navi Mumbai

Investigator: Ms. Maryah Kondkari (MBBS Student), Guide: Dr. Santosh Gawali, Department of Biochemistry

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Administrative permission to be obtained for retrospective data access
- Consent or participant information sheet not required for retrospective secondary analysis in this study

The research proposal was approved by the IEC

ICMR STS 2022

25 Title: Assessing risk factors for obstructive sleep apnea (OSA) in hypertensive patients

Investigator: Mr. Krutik Jain (MBBS Student), Guide: Dr. Rita Khadkikar, Department of Physiology

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Administrative permission to be obtained for retrospective data access
- Consent or participant information sheet not required for retrospective secondary analysis in this study

The research proposal was approved by the IEC

ICMR STS 2022

26 Title: Screening for mental health in Covid-19 survivors: healthcare workers versus Non healthcare workers

Investigator: Kashish Makhija (MBBS Student), Guide: Dr. Yashoda Kattimani, Department of Physiology

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Administrative permission to be obtained for retrospective data access
- Consent or participant information sheet not required for retrospective secondary analysis in this study

The research proposal was approved by the IEC

27 Title: Effectiveness of counseling on reduction in sero prevalence of patients attending tertiary care hospital in and around Navi Mumbai

Investigator: Ms. S. Jayalakshmi Guide: Dr. Harapriya Kar, Department of Microbiology

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Study aim and objectives needs to be refined .
- Title to be modified and the methodology design – retrospective as well.
- Suggested title CHANGE - Analysis of HIV –seroprevalence amongst patients attending tertiary care hospital: A 8 yer retrospective study
- Resubmit the revised protocol as per the concept of the study

The research proposal was kept on hold and will be placed in next meeting


28 Title: Study of factors that affect quality of life in elderly living in oldage home

Investigator: Dr. Sheryl Gudi, Department of Geriatric


IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Sample size justification to be mentioned
- Participant information sheet in local languages to be submitted
- Study performa not prepared, need to be prepared and to be submitted
- Adopt case control

The research proposal was approved by the IEC



Member Secretary
Dr. Pradeep Jadhav



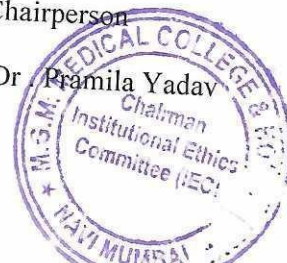

Convener

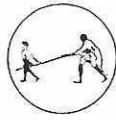
Dr Ipseeta Ray




Chairperson

Dr. Pramila Yadav





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MGM Medical College Institutional Ethics Committee, Navi Mumbai (MGMMC-IEC)
E-mail: mgmethics@gmail.com
Registration number - EC/NEW/INST/2021/2255

In pursuance of the circular on the subject dated: **23-7-2022**, the Institutional Ethics Committee (IEC) of MGM Medical College, Kamothe assembled for videoconference based meeting on **27th July 2022 (Wednesday) virtually at 10.30 AM via google meet.** at the following link Google Meet link: <https://meet.google.com/sey-fonw-aqn>

The following functionaries attended the meeting

Sr. No.	Name	Designation of member in Ethics Committee
1	Dr. Pramila Yadav	Chairman
2	Dr. D. Bhusare	Member- Clinician
3	Dr. Pradeep Jadhav	Member Secretary
4	Dr. Ipseeta Ray	Basic Medical Scientist
5	Dr. Santosh Gawali	Basic Medical Scientist
6	Dr. Jaishree Ghanekar	Member - Clinician
7	Mrs. Amruta Sachin Dhavale	Lay Person
8	Mrs. Rupali Gujar	Social Scientist
9	Dr. Sheela Hosamani	Legal Expert

Minutes of the previous IEC meeting held on 21/07/2022 were confirmed unanimously

Minutes of IEC meeting held on 27/07/2022

MD/ MS thesis protocols

MD/ MS Dissertation Protocols reviewed

Department of Dermatology

1 Title: Study of dermoscopy of neonatal skin

Investigators: Dr. Mundada Shriya Girish, Guide: Dr. Shylaja Someshwar, Department of Dermatology

IEC comments and suggestions:

- In participant information sheet, the contact detailed of the investigators to be added at the end
- Parenteral consent to be included, as the study is conducted in neonates

2 Title: Study of clinical and dermoscopic findings of seborrheic keratosis and its variants

Investigators: Dr. Kannattukunnel Ranjita Sunny, Guide: Dr. Dr. Meghana Phiske, Department of Dermatology

IEC comments and suggestions:

- Participant information sheet is not in standard format , to resubmit the participant information sheet as per the standard format with detailed information

3 Title: Comparative study of the clinical efficacy of intra lesional vitamin D3 and intra lesional BCG for the treatment of common warts

Investigators: Dr.Gaurab Acharjee, Guide: Dr. Shylaja Someshwar, Department of Dermatology

IEC comments and suggestions:

- To include efficacy in objective
- Sample size justification with calculations to be included
- To record adverse drug reactions (ADR) and conduct causality assessment of the ADR
- To include assessment time-points in case record form

Department of Family Medicine

4 Title: Study of Menstrual disorders in patients with deranged thyroid profile

Investigators: Dr. Patil Rushikesh Jayant, Guide: Dr. Rakesh Thamke, Department of Family Medicine

IEC comments and suggestions:

- Refine objective and methodology to remove the counselling intervention
- In methodology, to refine the inclusion criteria as per the study objectives and remove “intervention study” word and mention as “observational descriptive study”
- In participant information sheet, the study details and contact details of the investigators to be added.

5 Title: A comparative study of Prevalence of polycystic ovarian syndrome and its phenotypes in urban and rural population

Investigators: Dr. Nishank Kashyap, Guide: Dr. Rakesh Thamke, Department of Family Medicine

IEC comments and suggestions:

- Refine objective and methodology to remove the counselling intervention
- In participant information sheet, the study details and contact details of the investigators to be added.
- Operation definition of urban and rural to be included in methodology as well to remove the counselling intervention

Department of General Medicine

6. Title: A comparative study of investigations and clinical features of ischemic stroke in non-diabetic and diabetic patients

Investigators: Dr. Dhukka Arshad Abdulmajid, Guide: Dr. Amrit Kejriwal, Department of General Medicine

IEC comments and suggestions:

- Title to be modified- to include study outcome, to make it specific,
- Suggested revised title- A comparative study of clinical profile of ischemic stroke in non-diabetic and diabetic patients
- Sample size not clearly mentioned , uniformity in sample size to be maintained through-out the protocol (50 or 60 per group)
- To incorporate the revised title in the protocol as well in consent and participant information sheet

7. Title: To Study the Association of Carotid Artery Intima Media Thickness with Coronary Artery Disease

Investigators: Dr. Mahesh Babu Cherukuri, Guide: Dr. Sandeep Rai, Department of General Medicine

IEC comments and suggestions:

- In methodology, separate inclusion criteria for cases and control to be included
- In participant information sheet to be submitted along with local language translations.
- Also to include in the participant information sheet that the cost of investigation and radiological scan will not be borne by participants in healthy control. The cost for cost of investigation and radiological scan in healthy control will be borne by investigators

8. Title: Prevalence And Predictors of Diabetes Distress Among Adults with Type 2 Diabetes Mellitus

Investigators: Dr. Niteshkumar M Bhati, Guide: Dr. Sandeep Rai, Department of General Medicine

IEC comments and suggestions:

- Title to be modified- to include study outcome, to make it specific for Sahaja yoga intervention,
- Suggested revised title- Study of diabetes distress and impact of *Sahaja yoga intervention* in patients with type 2 diabetes mellitus

- Methodology to be modified as per the refined objectives
- Sample size to be justified for the *Sahaja yoga intervention*
- To incorporate the revised title in the protocol as well in consent and participant information sheet
- In participant information sheet, the details of *Sahaja yoga intervention and schedule to be mentioned.*

9. Title Evaluation Of Serum Ferritin as A Prognostic Marker in Acute Ischemic Stroke

Investigators: Dr. Farooqui Shareq Ahmed Gous Mohiuddin, Guide: Dr. Jaishree Ghanekar, Department of General Medicine

IEC comments and suggestions:

- Methodology – to include diagnostics parameters like sensitivity , specificity and accuracy in analysis

10. Title: Prospective observational study to predict the success of USG guided supraclavicular block with traditional methods versus using perfusion index

Investigators: Dr. Mayuri Hariharan, Guide: Dr. Olvyna D'souza, Department of Anaesthesiology

IEC comments and suggestions:

- Student and guide to confirm the above title as approved by scientific committee and submit revise title to ethics committee
- Assessment scales scoring to be included in Case record form

11. Title: Study of comparison between epidural versus intravenous Dexmedetomidine (general anaesthesia) on perioperative haemodynamics in laparoscopic surgeries

Investigators: Dr. Deshmukh Priyanka Pravin , Guide: Dr. Jessy Vennel, Department of Anaesthesiology

IEC comments and suggestions:

- Guide to confirm that the protocol title is not repeated in the last 5 years in any research conducted in the Anesthesia department.
- To include in case record form, the list of complications and recording adverse drug reactions

12. Title: A study comparison of the modified Mallampati grading in supine and upright position in predicting difficult laryngoscopy and intubation

Investigators: Dr. Meetali Prasad, Guide: Dr. Olvyna D'souza , Department of Anaesthesiology

IEC comments and suggestions:

No modifications suggested

13. Title: To study and compare the effects of N-Acetyl cysteine on the levels of oxidative stress markers in patients undergoing coronary artery bypass surgery

Investigators: Dr. Patil Tejas Sandesh, Guide: Dr. Vishwas Sathe, Department of Anaesthesiology

IEC comments and suggestions:

- Suggested to keep single blinded study instead of double blinded.
- In-case of double blinded, the allocation, coding and decoding and the process to be mentioned in Protocol and details regarding use of placebo to be mentioned.

14. Title: To study the comparison between analgesic effect of ultrasound guided bilateral erector spinae block and intravenous analgesia in coronary bypass surgery

Investigators: Dr. More Shraddha Sharadkumar , Guide: Dr. Vishwas Sathe , Department of Anaesthesiology

IEC comments and suggestions:

No modifications suggested

15. Title: Study of Comparison between 3.5 ml bupivacaine heavy and 3.5 ml ropivacaine heavy for subarachnoid block in lower limb surgeries in geriatric population

Investigators: Dr. Aiman Fatima Pervez , Guide: Dr. Vishwas Sathe, Department of Anaesthesiology

IEC comments and suggestions:

- Title to be modified- remove volume information (3.5 ml), concentration maybe added and also to replace the word from "population" to "patients".
- Suggested revised title- Study of comparison between 0.1% Bupivacaine heavy and 0.1% Ropivacaine heavy for subarachnoid block in lower limb surgeries in geriatric patients
- In participant information sheet, the study details and contact details of the investigators to be added.

- To incorporate the revised title in the protocol as well in consent and participant information sheet

16. Title: To study comparison of 0.125% Bupivacaine with Inj Dexmedetomidine and inj Clonidine respectively for postoperative epidural analgesia in patients undergoing lower limb orthopaedic surgeries

Investigators: Dr. Shah Rutvi Hetalkumar, Guide: Dr. Archana Har, Department of Anaesthesiology

IEC comments and suggestions:

- Title to be modified- remove the word “respectively” from title
- Suggested revised title To study comparison of 0.125% Bupivacaine with Inj Dexmedetomidine and inj Clonidine for postoperative epidural analgesia in patients undergoing lower limb orthopaedic surgeries
- To incorporate the revised title in the protocol as well in consent and participant information sheet
-

17. Title: A Study comparison of 0.1% Levobupivacaine versus 0.1% Ropivacaine with Nalbuphine in labour analgesia

Investigators: Dr. Agrawal Arooshi Virendhra Kumar Madhu , Guide: Dr. Archana Har , Department of Anaesthesiology

IEC comments and suggestions

- In Participant information sheet, add study details especially the outcomes to be measured in “what does the study involve”

18. Title: A study of comparison between intrathecal hyperbaric 0.5% Levobupivacaine with Fentanyl and hyperbaric 0.5% Bupivacaine with Fentanyl in infra umbilical surgeries

Investigators: Dr. Megha Kunjam , Guide: Dr. Deepika Sathe, Department of Anaesthesiology


- Complication checklist to be added in Case record form

19. Title: To study the comparison of two different doses of Clonidine added to Bupivacaine in brachial plexus block


Investigators: Dr. Bansiben Yogeshkumar Tank, Guide: Dr. Jessy Vennel, Department of Anaesthesiology

IEC comments and suggestions:

- In Participant information sheet, add study details especially the outcomes to be measured in “what does the study involve”
- Complication checklist to be added in Case record form


Member Secretary
Dr. Pradeep Jadhav


Convener
Dr. Ipseeta Ray


Chairperson
Dr. Pramila Yadav





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MGM Medical College Institutional Ethics Committee, Navi Mumbai (MGMMC-IEC)
E-mail: mgmethics@gmail.com
Registration number - EC/NEW/INST/2021/2255

In pursuance of the circular on the subject dated: **22/7/2022**, the Institutional Ethics Committee (IEC) of MGM Medical College, Kamothe assembled for videoconference based meeting on **28th July 2022 (Thursday)** virtually at **10.30 AM** via **google meet**.

Google Meet link: <https://meet.google.com/gxr-gqje-zxf>

The following functionaries attended the meeting

Sr. No.	Name	Designation of member in Ethics Committee
1	Dr. Pramila Yadav	Chairman
2	Dr. D. Bhusare	Member- Clinician
3	Dr. Pradeep Jadhav	Member Secretary
4	Dr. Ipseeta Ray	Basic Medical Scientist
5	Dr. Santosh Gawali	Basic Medical Scientist
6	Dr. Jaishree Ghanekar	Member - Clinician
7	Mrs. Amruta Sachin Dhavale	Lay Person
8	Mrs. Rupali Gujar	Social Scientist
9	Dr. Sheela Hosamani	Legal Expert

Minutes of the previous IEC meeting held on 27/7/2022 were confirmed unanimously

Minutes of IEC meeting held on 28/07/2022

MD/ MS thesis protocols

MD/ MS Dissertation Protocols reviewed

Department of Pathology

1 Title: Diagnostic utility of fluorescent microscopy in detecting mycobacterium leprae in tissue sections: Comparison with Fite-Faraco Staining

Investigators: Dr. Ishita Agrawal, Guide: Dr. Manisha Tambekar, Department of Pathology

IEC comments and suggestions:

- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)
- Sample size calculation and justification to be added

2 Title: Study Utility Of Epithelial Membrane Antigen (Ema) And Calretinin (Cal) In Cell Block Preparations In Pleural And Peritoneal Effusion Cytology

Investigators: Dr.Soni Aesha Nileshkumar, Guide: Dr. Manisha Tambekar, Department of Pathology

IEC comments and suggestions:

- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)
- Sample size calculation and justification to be added
-

3 Title: Study the corelation Anti Nuclear Antibody By Immunoflourescence assay in cases of consecutive two or more Pregnancy Loss

Investigators: Dr.Patel Mayuri Kirtibhai, Guide: Dr. Shilpi Sahu, Department of Pathology

IEC comments and suggestions:

- Title change suggested
- Sample size calculation and justification to be added
- To incorporate the revised title in the protocol as well in consent and participant information sheet

4 Title: Study Of Circulating Tumor Cells Filtered from The Cancer Patients Blood Using Multicolor Flowcytometry

Investigators: Dr. Vaishali Giri Goswami, Guide: Dr. Ujwala Maheshwari, Department of Pathology

IEC comments and suggestions:

- Inclusion criteria modify, specifying the type of cancers to be included
- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)
- Cost of investigations won't be borne patients to be mentioned in study protocol and Participant information sheet. Investigators to bear the cost of the blood marker testing.

5 Title: A prospective study of Immunohistochemical Expression of Cox-2 (Cyclooxygenase-2) in Breast Cancer

Investigators: Dr. Muppadi Mamta Krishna, Guide: Dr. Ujwala Maheshwari, Department of Pathology

IEC comments and suggestions:

- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)
- Sample size calculation and justification to be added
- Case record form is incomplete , study related parameters to be added
- Administrative permission from MGM CBD hospital to be obtained.
- Cost of investigations won't be borne patients to be mentioned in study protocol and Participant information sheet. Investigators to bear the cost of the COX testing.

6 Title: Study the Utility of Line Immuno Assay (Lia) For the Diagnosis of Rheumatoid Arthritis

Investigators: Dr. Keyuri Bhupendrakumar Purohit, Guide: Dr. Shilpi Sahu, Department of Pathology

IEC comments and suggestions:

- Refine study objectives
- Sample size calculation and justification to be added
- Duration of study in methodology to be corrected
- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)

7 Title: Expression of PTEN in Endometrial Hyperplasia and Endometrial Cancer-A prospective study

Investigators: Dr. Suraj Verma, Guide: Dr. Hoogar M.B., Department of Pathology

IEC comments and suggestions:

- Sample size calculation and justification to be added
- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)

8 Title: Predictive Value of Tubulointerstitial Biomarker (Cystatin C) in Diabetic Nephropathy

Investigators: Dr. Nirali M Upadhyay, Guide: Dr. Shilpi Sahu, Department of Pathology

IEC comments and suggestions:

- Sample size calculation and justification to be added
- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)
- To mention diagnostic parameters sensitivity , specificity and accuracy calculation in methodology

9 Title : A Study on Parameters of Hemostasis and Hypercoagulable State in Pulmonary and Extra Pulmonary Tuberculosis

Investigators: Dr. Ashwinamurthy Kumaravel, Guide: Dr. Priyanka Jadhav, Department of Pathology

IEC comments and suggestions:

- Change the aim as per the study objective
- Modify the inclusion and exclusion criteria to make it specific to study
- Case record form is incomplete , study related parameters to be added
- Sample size calculation and justification to be added
- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)

10 Title : Immunohistochemical Expression of Hbme-1, Ck19 and Galectin-3 in a Spectrum of Thyroid Neoplasms

Investigators: Dr. Archi Arun Chawla, Guide: Dr. Reeta Dhar, Department of Pathology

IEC comments and suggestions:

- Sample size calculation and justification to be added
- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)
- Cost of investigations won't be borne patients to be mentioned in study protocol and Participant information sheet. Investigators to bear the cost of the marker testing.

IHBT Department

11. **Title:** A prospective evaluation of hemotherapy in Emergency department at a tertiary care centre.

Investigators: Dr. Dey Damayanti Radhashyam, **Guide:** Dr. Col. Iqbal Singh, Department of IHBT

IEC comments and suggestions:

- Remove pre and post hb, platelet assessment from methods and case record form – as it is not included in study objectives.
- Sample size calculation and justification to be added
- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)

12. **Title:** Utilization of blood and blood components in decompensated liver diseased patients - A prospective study in a tertiary care hospital in Navi Mumbai, Maharashtra

Investigators: Dr. Prabhakaran P, **Guide:** Dr. Col. Iqbal Singh, Department of IHBT

IEC comments and suggestions:

- Remove objective number 3 on appropriate guidelines
- Sample size calculation and justification to be added
- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)

3. **Title:** A prospective study of utilization of blood and its components in patients of chronic-kidney disease in tertiary care hospital, Navi Mumbai

Investigators: Dr. Sonal Gupta, **Guide:** Dr. Shweta Dhote, Department of IHBT

- Sample size calculation and justification to be added
- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)

Paediatrics Department

14. **Title:** Study of clinical profile and outcome of poisoning in children admitted in a tertiary care hospital

Investigators: Dr. Divyakrit Arora, **Guide:** Dr. Jeetendra Gavhane, Department of Paediatrics

IEC comments and suggestions:

- Inclusion criteria to be modified to include: 1 day or upto 18 years of age and either gender

15. **Title:** To study the clinical spectrum of CBNAAT proven tuberculosis patients in Paediatric age group

Investigators: Dr. Baijal Geetesh Sanjay, **Guide:** Dr. Jeetendra Gavhane, Department of Paediatrics

IEC comments and suggestions:

- No modifications suggested

16. **Title:** Study of Micronutrient deficiencies in Transfusion dependent β -Thalassemia patients.

Investigators: Dr. Bose Ashawari Sandip, **Guide:** Dr. Bageshree Seth, Department of Paediatrics

IEC comments and suggestions:

- Inclusion criteria to be modified to include: either gender
- In case record form , to add the list of laboratory parameters to be recorded

17. **Title:** Study of Comparison of Pediatric Early Warning Score (PEWS) and Pediatric South African Triage Scale (P-SATS) for Triage of Pediatric patients in the Emergency Department.

Investigators: Dr. Salunke Ojas Deepak, **Guide:** Dr. Bageshree Seth, Department of Paediatrics

IEC comments and suggestions:

- Aim to be modified as per the study title
- In case record form , to add the scoring and total score of the participant
-

Orthopaedics Department

18. **Title:** Study on the functional outcome of proximal humerus fractures in elderly patients treated with external fixation.

Investigators: Dr. Gayatri Subodh Mehta, **Guide:** Dr. Sarabjeet Singh Kohli, Department of Orthopaedics

IEC comments and suggestions:

- Specify the age group for the term " elderly" in methodology , as study inclusion mentions patients above 50 years (usually elderly is above 60 or 65 years)
- In case of copyrighted scales in study, permission for use of copyright scales to be obtained

19. **Title:** Comparative analysis study between surgical techniques between long arm double sliding flap and Z - plasty in treatment of finger contractures.

Investigators: Dr. Parth Arun Parasnis, **Guide:** Dr. Ashok Ghodke, Department of Orthopaedics

IEC comments and suggestions:

- The method of allocation to either of the groups should be mentioned in protocol as well in the participation information sheet.
- Update Participant information sheet with details of the study and that participant will be placed in either of the two groups by random method
-

20. **Title:** Study of restoration of original hip biomechanics in hemiarthroplasty.

Investigators: Dr. Bhende Janhavi Harish, **Guide:** Dr. Alfven Vieira, Department of Orthopaedics

IEC comments and suggestions:

- In Case record form, list of complications to be added

- Participant information sheet with details of the study to be prepared and submitted in standard format

21. **Title:** Comparative study of the functional outcome between Hardinge vs Southern Moore's approach for total Hip Arthroplasty.

Investigators: Dr. More Aditya Dinar, **Guide:** Dr. Alfven Vieira, Department of Orthopaedics

IEC comments and suggestions:

- The method of allocation to either of the groups should be mentioned in protocol as well in the participation information sheet.
- Update Participant information sheet with details of the study and that participant will be placed in either of the two groups by random method
- Title of the study to be added in consent form
- In case of copyrighted scales in study, permission for use of copyright scales to be obtained
-

22. **Title:** Comparative study of functional outcome of chevron olecranon osteotomy versus triceps sparing paratricipital approach for distal humerus fracture

Investigators: Dr. Akarsha Ravi, **Guide:** Dr. Alfven Vieira, Department of Orthopaedics

IEC comments and suggestions:

- The method of allocation to either of the groups should be mentioned in protocol as well in the participation information sheet.
- Update Participant information sheet with details of the study and that participant will be placed in either of the two groups by random method
- Title of the study to be added in consent form
- In Case record form, the assessment timepoints and scoring of the scales to be added
- In case of copyrighted scales in study, permission for use of copyright scales to be obtained

~~Member Secretary~~

Dr. Pradeep Jadhav



Convener

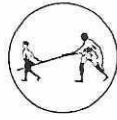
Dr Ipseeta Ray



Chairperson

Dr. Pramila Yadav





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MGM Medical College Institutional Ethics Committee, Navi Mumbai (MGMMC-IEC)
E-mail: mgmethics@gmail.com
Registration number - EC/NEW/INST/2021/2255

In pursuance of the circular on the subject dated: **22/7/2022**, the Institutional Ethics Committee (IEC) of MGM Medical College, Kamothe assembled for videoconference based meeting on **29th July 2022 (Friday)** virtually at **10.30 AM** via **google meet**.

Google Meet link: <https://meet.google.com/mtv-rxkj-agi>

The following functionaries attended the meeting

Sr. No.	Name	Designation of member in Ethics Committee
1	Dr. Pramila Yadav	Chairman
2	Dr. D. Bhusare	Member- Clinician
3	Dr. Pradeep Jadhav	Member Secretary
4	Dr. Ipseeta Ray	Basic Medical Scientist
5	Dr. Santosh Gawali	Basic Medical Scientist
6	Dr. Jaishree Ghanekar	Member - Clinician
7	Mrs. Amruta Sachin Dhavale	Lay Person
8	Mrs. Rupali Gujar	Social Scientist
9	Dr. Sheela Hosamani	Legal Expert

Minutes of the previous IEC meeting held on 28/7/2022 were confirmed unanimously

Minutes of IEC meeting held on 29/07/2022

MD/ MS thesis protocols

MD/ MS Dissertation Protocols reviewed

Department of Radio-diagnosis

1 Title: Study Ultrasonographic measurement of Transcerebellar diameter with its application in determining gestational age and IUGR

Investigators: Dr. Srivastava Suyash Sanjay, Guide: Dr. Priti Kapoor, Department of Radio-Diagnosis

IEC comments and suggestions:

- Sample size calculation and justification to be added
- Case record form missing in protocol, to prepare and submit
- Participant information sheet with details of the study to be prepared and submitted in standard format
- Add study title in case record form/ performa

2 Title: study role of multidetector computed tomography in evaluation of acute abdomen due to gastrointestinal tract related causes

Investigators: Dr. Jamale Namrata Pramod, Guide: Dr. Ashutosh Chitnis, Department of Radio-Diagnosis

IEC comments and suggestions:

- Participant information sheet with details of the study to be prepared and submitted in standard format
- Add study title in consent form
- Add study title in case record form/ Performa

3 Title: Study Role of computed tomography in evaluation of oral cavity lesion

Investigators: Dr. Sneha Jagdish Nain, Guide: Dr. Abhay Gursale, Department of Radio-Diagnosis

IEC comments and suggestions:

- Sample size calculation and justification to be added
- In Case record form, list of risk factors and assessment parameters to be added

- Participant information sheet with details of the study to be prepared and submitted in standard format

4 Title: To study role of cerebroplacental ratio in fetal growth restriction

Investigators: Dr. Balaji S, Guide: Dr. Priti Kapoor, Department of Radio-Diagnosis

IEC comments and suggestions:

- Participant information sheet with details of the study to be prepared and submitted in standard format
- Add study title in consent form
- Add study title in case record form/ Performa

5 Title: Study of role of Magnetic resonance imaging in evaluation of central nervous system infections

Investigators: Dr. Limaye Varun Uday Rashna, Guide: Dr. Sonali Mhaske Kadam, Department of Radio-Diagnosis

IEC comments and suggestions:

- Sample size calculation and justification to be added
- Refine inclusion with types of CNS conditions. Remove sero-positive from inclusion
- In Case record form, add title of study and list of CNS infections
- Participant information sheet with details of the study to be prepared and submitted in standard format
- Add study title in consent form

6 Title: To study and compare measurement of lower uterine segment thickness in normal pregnancy with previous LSCS pregnancy

Investigators: Dr. Bhangdiya Vinay Omprakash, Guide: Dr. Priti Kapoor, Department of Radio-Diagnosis

IEC comments and suggestions:

- Participant information sheet with details of the study to be prepared and submitted in standard format

7 Title: To study Role of multidetector computed tomography in evaluation of grading of liver injuries

Investigators: Dr. Rumao Rhea Robert, Guide: Dr. Ashutosh Chitnis, Department of Radio-Diagnosis

IEC comments and suggestions:

- Participant information sheet with details of the study to be prepared and submitted in standard format

8 Title: Study of high-resolution computed tomography chest in the evaluation of pulmonary edema

Investigators: Dr. Anadhi Joshi, Guide: Dr. Abhay Gursale, Department of Radio-Diagnosis

IEC comments and suggestions:

- Sample size calculation and justification to be added
- Participant information sheet with details of the study to be prepared and submitted in standard format
- Add list of risk factors in Case record form

Department of Community Medicine

9 Title: Epidemiological study of prevalence of Hypertension and factors associated in age group of 30 - 79 years in tribal population in Panvel taluka of Raigad district of Maharashtra, India

Investigators: Dr. Mayank Purohit, Guide: Dr. Prasad Waingankar, Department of Community Medicine

Investigator was absent, due to Covid -19 infection

Department of Obstetrics and gynecology

10 Title: Study the role of second trimester uterine artery Doppler in Prediction of preeclampsia.

Investigators: Dr. Ridhorkar Rucha Vasudeo, Guide: Dr. Jaishree Narshetty, Department of Obstetrics and gynecology

IEC comments and suggestions:

- Objective 3 is implication of the study- suggested to remove from objectives
-

11 Title: Comparison of Zuspan and pritchard regimen of magnesium sulphate in management of eclampsia.

Investigators: Dr. Sharma Neha Yogendra, Guide: Dr. Sunil Sharma, Department of Obstetrics and gynecology

IEC comments and suggestions:

- Refine objectives remove hypothesis statement
- In Case record form, list of complications to be added
- Refine objectives, remove hypothesis statement objective
- Keep 35 patients in each groups, as total is 70 patients
- Add monitoring timelines in protocol and case record form
- The method of allocation to either of the groups should be mentioned in protocol as well in the participation information sheet.
- Update Participant information sheet with details of the study and that participant will be placed in either of the two groups by random method

12 Title: A comparative study of the effectiveness of oral nifedipine versus intravenous labetalol in controlling hypertension in severe pre- eclampsia.

Investigators: Dr. Shah Maitri Snehal, Guide: Dr. Sabrina Mhapankar, Department of Obstetrics and gynecology

IEC comments and suggestions:

- Refine objectives, specify efficacy and adverse effects of the drugs (remove effectiveness)
- The method of allocation to either of the groups should be mentioned in protocol as well in the participation information sheet.
- Update Participant information sheet with details of the study and that participant will be placed in either of the two groups by random method

13 Title: Comparative study of the fetomaternal outcome in patients with PIH with and without HELLP Syndrome.

Investigators: Dr. Darshika Goyal, Guide: Dr. Sushil Kumar, Department of Obstetrics and gynecology

IEC comments and suggestions:

- Participant information sheet with details of the study and contact details to be prepared and submitted in standard format

14 Title: Study of evaluation of umbilical cord abnormalities with neonatal outcome at a tertiary care hospital.

Investigators: Dr. Patil Sanika Arjun, Guide: Dr. Sabrina Mhapankar, Department of Obstetrics and gynecology

IEC comments and suggestions:

- No modifications suggested

15 Title: study of B-Lynch suture and uterine artery ligation for atonic PPH during LSCS and its comparison with B-Lynch suture alone.

Investigators: Dr. Gabhane Sameeksha Surendra, Guide: Dr. JaishreeNarshetty, Department of Obstetrics and gynecology

IEC comments and suggestions:

- Refine objective, add comparison word in objective since it is a comparative study

16 Title: Comparative study of the feto-maternal outcomes in term pregnancy with meconium stained amniotic fluid and with clear amniotic fluid.

Investigators: Dr. Thakker Yesha, Guide: Dr. Sunil Sharma, Department of Obstetrics and gynecology

IEC comments and suggestions:

- Add separate inclusion criteria for cases and control in methodology

17 Title: A comparative study - Epidural analgesia during labor vs no analgesia: A comparative study.

Investigators: Dr. Adam Aisha Farooq, Guide: Dr. Shaifali Patil, Department of Obstetrics and gynecology

IEC comments and suggestions:

- Title to be modified- to include study outcome and to remove no analgesia wording
- Suggested revised title- A comparative study of Feto-Maternal Outcome with or without epidural analgesia in patients during labour
- To incorporate the revised title in the protocol as well in consent and participant information sheet

18 Title: Study of subclinical hypothyroidism in pregnancy.


Investigators: Dr. Ankita Ashok Goyal, Guide: Dr. ShaifaliPatil, Department of Obstetrics and gynecology

IEC comments and suggestions:


- Title to be modified- to include study outcome, to make it specific,
- Suggested revised title- Study of Feto-Maternal Outcomes in subclinical hypothyroidism during pregnancy
- To incorporate the revised title in the protocol as well in consent and participant information sheet


Member Secretary

Dr. Pradeep Jadhav


Convener

Dr Ipseeta Ray


Chairperson

Dr . Pramila Yadav





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MGM Medical College Institutional Ethics Committee, Navi Mumbai (MGMMC-IEC)
E-mail: mgmethics@gmail.com
Registration number - EC/NEW/INST/2021/2255

In pursuance of the circular on the subject dated: 5/8/2022, the Institutional Ethics Committee (IEC) of MGM Medical College, Kamothe assembled for videoconference based meeting on 10th August 2022 (Wednesday) virtually at 10.30 AM via google meet.

Google Meet link: <https://meet.google.com/xbk-zfow-quz>

The following functionaries attended the meeting

Sr. No.	Name	Designation of member in Ethics Committee
1	Dr. Pramila Yadav	Chairman
2	Dr. Padmaja Kanchi	Member /Co-Chairperson
3	Dr. D. Bhusare	Member- Clinician
4	Dr. Pradeep Jadhav	Member Secretary
5	Dr. Ipseeta Ray	Basic Medical Scientist
6	Dr. Santosh Gawali	Basic Medical Scientist
7	Dr. Jaishree Ghanekar	Member - Clinician
8	Mrs. Amruta Sachin Dhavale	Lay Person
9	Mrs. Rupali Gujar	Social Scientist
10	Dr. Sheela Hosamani	Legal Expert

Minutes of the previous IEC meeting held on 29/7/2022 were confirmed unanimously

Minutes of IEC meeting held on 10/08/2022

MD/ MS thesis protocols

MD/ MS Dissertation Protocols reviewed

1 Title: Study to compare Vit D Levels in Patients with High Vs Low Cardio-Vascular Disease Risk Using Qrisk3 Score

Investigators: Dr. Radha Rohit Deshpande, Guide: Dr. Amrit Kejriwal, Department of General Medicine

IEC comments and suggestions:

- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)
- Consent form- update LAR signature and add study title
- Add vitamin d levels in Case record form to record it

2 Title: Assessment of risk of metabolic syndrome and cardiovascular diseases in people living with HIV

Investigators: Dr. Tanvi Anil Gersappa , Guide: Dr. Mitesh Thakkar , Department of General Medicine

IEC comments and suggestions:

- Aim to refine serp-positive patients
- Methodology not clear ??

To represent again in subsequent IEC after revising the protocol

3Title: Clinical Study Of Renal Artery Stenosis

Investigators: Dr. Ingale Raviraj Arvind , Guide: Dr. Babita Ghodke , Department of General Medicine

IEC comments and suggestions:

- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)
- Consent form- update with LAR signature

- Sample size calculation

4 Title: Comparative Study Of Patients Of Organophosphorous Compound Poisoning Requiring Ventilatory And Non Ventilatory Support

Investigators: Dr. Bargal Rajesh Ramdas , Guide: Dr. Mitesh Thakkar , Department of General Medicine

IEC comments and suggestions:

- Revised the aim and objectives With or without ventilator
- Exclusion criteria- exclude other poisoning and snake bites
- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)
- Consent form- update with LAR signature

5 Title: Study of Correlation between hypertension and vitamin b12 levels

Investigators: Dr. Choudhary Ratan Khetaram , Guide: Dr. Babita Ghodke , Department of General Medicine

IEC comments and suggestions:

- Revise aim and objectives
- Inclusion criteria include patients suffering from hypertension
- Exclusion – patients with co morbidities will be excluded
- Update case record form with study assessment parameters

6 Title: A Clinical Correlation Of Neutrophil/Lymphocyte Ratio In Patient With Acute Ischemic Stroke

Investigators: Dr. Mishra Varun Onkarnath , Guide: Dr. Amrit Kejriwal , Department of General Medicine

IEC comments and suggestions:

- Update case record form with study assessment parameters
- Add the various conditions in exclusion in which NLR is raised or lower
- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)
- Consent form- update with LAR signature and add study title

7 Title: Study of Clinical profile in poisoning

Investigators: Dr. Subhan Sajid Quraishi , Guide: Dr. Babita Ghodke , Department of General Medicine

IEC comments and suggestions:

- Suggested Title change as per the study aim and objectives
- Update case record form with study assessment parameters
- Update consent and participant information sheet as per the new revised title

8 Title: Study of Clinical Profile Of Iron Deficiency Anemia In Subclinical And Overt Hypothyroidism

Investigators: Dr. Kalambe Shashank Ashok , Guide: Dr. Vandana Dandekar , Department of General Medicine

IEC comments and suggestions:

- Consent form- update with LAR signature
- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)

9 Title: Study of profile of arrhythmias in patients presenting with chest pain in Emergency room

Investigators: Dr. Abdul Haris KK , Guide: Dr. Dattatray Bhusare , Department of Emergency Medicine

IEC comments and suggestions:

- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)

10 Title: Study prevalence of hypocalcaemia in polytrauma patients in Emergency department

Investigators: Dr. Amal Joy , Guide: Dr. Dattatray Bhusare , Department of Emergency Medicine

IEC comments and suggestions:

- Inclusion – add patients with polytrauma in inclusion criteria
- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)

- Add study Title in consent and case record form

11 Title: Study the utility of the thrive score in cases of acute ischemic stroke

Investigators: Dr.Ganvir Aditya Gautam , Guide: Dr. Khatija Jumkawala , Department of Emergency Medicine

IEC comments and suggestions:

- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)
- Add Title in case record form
- Consent form- update with LAR signature

12 Title: Comparative study of the outcomes in traumatic brain injury patients with or without skull fracture

Investigators: Dr.Patel Dharmangkumar Kantibhai , Guide: Dr. Khatija Jumkawala , Department of Emergency Medicine

IEC comments and suggestions:

- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)
- Submit case record form
- Sample size keep as 72 with 36 in each group

13 Title: Comparison of lactate enhanced qsofa score with mews score in predicting outcome in patients presenting to Emergency department with sepsis

Investigators: Dr. Rabadiya Milan Jayantilal , Guide: Dr. Sagar Sinha , Department of Emergency Medicine

IEC comments and suggestions:

- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)
- Submit case record form
- Exclude non sepsis patients in exclusion criteria

14 Title: A study profile of patients with thoracic trauma presenting to the traumatology and surgery department

Investigators: DR. S Renish , Guide: Dr. Ashish Jadhav , Department of Traumatology and Surgery

IEC comments and suggestions:

- Consent form- update with LAR signature
- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)

15 Title: Comparative study of P-possum and NISS scoring systems in predicting post operative mortality and morbidity of patients with polytrauma undergoing emergency laparotomy

Investigators: DR. Abhijit B R, Guide: Dr. Ashish Jadhav , Department of Traumatology and Surgery

IEC comments and suggestions:

- P-possum and NISS scoring to be added in case record form at assessment timepoints

16 Title: Study of clinical profile of patients presenting with Glaucoma to a tertiary health care center

Investigators: Dr. Venya Sharma, Guide: Dr. Varshav Gore, Department of Ophthalmology

IEC comments and suggestions:

The study has excluded children and will be include only Adult patients – change noted

17 Title: Comparative study to determine axial length of eyeball, using USG A scan technique and USG B scan technique in cataract patients

Investigators: DR. Ishan Pasricha , Guide: Dr. Reshma Ramakrishnan , Department of Ophthalmology

IEC comments and suggestions:

Immature cataract USG scan charges to be borne by investigator and not by patient, as it is not indicated. To be also mentioned in Participant information sheet

18 Title: Study of Improvement in patient symptom scores after sinonasal surgery for chronic rhinosinusitis

Investigators: Dr. Iyer Nikita Subramaniam , Guide: Dr. Padma Ramesh , Department of E.N.T

IEC comments and suggestions:

- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)

19 Title: To study the clinical profile, aetiopathology and management in cases of Vertigo

Investigators: Dr.Kabir Sharma , Guide: Dr. Vaishali Sangole , Department of E.N.T

IEC comments and suggestions:

- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)
- Update case record form to capture the Management aspect

20 Title: To study and Evaluate the hearing loss in relation to tympanic membrane perforations

Investigators: Dr. Desai Paavan Kalpen , Guide: Dr. Kalpana Rajivkumar , Department of E.N.T

IEC comments and suggestions:

- Participant information sheet with details of the study to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)

21 Title: To study and compare the effect of using air versus alkalized 2% lignocaine for inflating endotracheal tube cuff on postoperative coughing and sore throat

Investigators: Dr. Subhashree Sahu , Guide: Dr. Olvyna D'souza , Department of Anaesthesiology

IEC comments and suggestions:

- In exclusion criteria- Exclude conditions associated with cough
- Method of allocation to the groups to be mentioned in methodology
- Participant information sheet -add the details of randomization to either of the groups

~~Member Secretary~~

Dr. Pradeep Jadhav



Convener

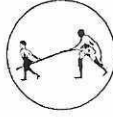
Dr Ipseeta Ray



Chairperson

Dr . Pramila Yadav





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Registration number - EC/NEW/INST/2021/2255

In pursuance of the circular on the subject dated: 5/8/2022, the Institutional Ethics Committee (IEC) of MGM Medical College, Kamothe assembled for videoconference based meeting on 12th August 2022 (Friday) virtually at 10.30 AM via google meet.

Google Meet link: <https://meet.google.com/ori-bsbh-cwq>

The following functionaries attended the meeting

Sr. No.	Name	Designation of member in Ethics Committee
1	Dr. Pramila Yadav	Chairman
2	Dr. D. Bhusare	Member- Clinician
3	Dr. Pradeep Jadhav	Member Secretary
4	Dr. Ipseeta Ray	Basic Medical Scientist
5	Dr. Santosh Gawali	Basic Medical Scientist
6	Dr. Jaishree Ghanekar	Member - Clinician
7	Mrs. Amruta Sachin Dhavale	Lay Person
8	Mrs. Rupali Gujar	Social Scientist
9	Dr. Sheela Hosamani	Legal Expert

Minutes of the previous IEC meeting held on 10/8/2022 were confirmed unanimously

Minutes of IEC meeting held on 12/08/2022

MD/ MS thesis protocols

MD/ MS Dissertation Protocols reviewed

Department of Psychiatry

1. Title: To study Psychiatric comorbidities, sexual functioning, perceived social support, quality of life and coping in patients with locomotor disability.

PG Student: Dr. Shashwat Swaroop Srivastava, M.D. (Psychiatry) Guide: Dr. Rakesh Ghildiyal,

IEC comments and suggestions:

- Randomly select 20 male and 20 female from each batch to maintain uniform ratio for gender assessment

2. Title: To Study Gender differences in eating attitudes, body image issues, social anxiety, and stress anxiety, depression in undergraduate medical students.

PG Student: Dr. Singh Adarsh Dinesh Kumar, M.D. (Psychiatry) Guide: Dr. Rakesh Ghildiyal.

IEC comments and suggestions:

- Sample size calculation with actual numbers to be mentioned
- Update Case record form – study title is missing
- Update participant information sheet- add signature of LAR

Respiratory Medicine

3. Title: Prevalence of latent tuberculosis and active tuberculosis in household contacts of drug resistant pulmonary tuberculosis patients.

PG Student: Dr. Singhi Krupa Sudhir, M.D. (Respiratory Medicine) Guide: Dr. P.V. Potdar

IEC comments and suggestions:

- In Objectives, add the 3 subgroup assessment indices (children, spouse, etc)
- Assent consent and information sheet to be submitted

4. Title: Comparative study of COPD assessment test with bode index in stable COPD patients.

PG Student: Dr. Barve Atharva Rajesh, M.D. (Respiratory Medicine) Guide: Dr. P.V. Potdar

IEC comments and suggestions:

- In Objectives, add correlation assessment statement
- Participant information sheet with details of the study to be prepared and submitted in standard format

5. Title: Study to find prevalence of aeroallergen sensitivity in patients of Bronchial asthma by skin prick test.

PG Student: Dr. Neha Dixit, M.D. (Respiratory Medicine) Guide: Dr. Shreeja Nair

IEC comments and suggestions:

- Participant information sheet with details of the study, risk of allergy testing and safety measures to be prepared and submitted in standard format - English as well in local languages (Hindi & Marathi)
- Assent form and information sheet to be submitted
- Parenteral consent to be added
- Monitoring time points to be mentioned in protocol

PAEDIATRICS

6. Title: To study correlation between clinical jaundice, transcutaneous and total bilirubin levels in neonatal jaundice

PG Student: Dr. Joshi Pooja Rajeev, M.D. (Paediatrics) Guide: Dr. Nitin Kadam

IEC comments and suggestions:

- Objective number 3 to be refined – to add Correlation of the 3 parameters

7. Title: Study of clinical profile and inflammatory markers in children between 2 months and 12 years of age with influenza like illness.

PG Student: DR. NAGARGOJE RAJAT VILAS, M.D. (Paediatrics) Guide: Dr Vijay Kamale

IEC comments and suggestions:

- To add list of Influenza like illness including swine flu in protocol analysis and Case record form

8. Title: Study of Neurodevelopmental outcome in infants of mothers with hypertensive disorders of pregnancy.

PG Student: Dr. Shruti Rajamani, M.D. (Paediatrics) Guide: Dr. Bageshree Seth

IEC comments and suggestions:

- Add in objectives the assessment timepoints; ie Anthropometric assessment at birth, 3 months and 6 months

9. Title: Study of Neurodevelopmental outcome of neonatal seizures.

PG Student: Dr. Khadija Quraish Damohwala, M.D. (Paediatrics) Guide: Dr N Revathi

IEC comments and suggestions:

- No change suggested

10. Title: Study of Cardiopulmonary dysfunction among transfusion dependent thalassemia children.

PG Student Dr. Niharika Singh, M.D. (Paediatrics) Guide: Dr. Vikram Patra

IEC comments and suggestions:

- No change suggested

11. Title: Study of Clinical profile and environmental factors in children with enuresis.

PG Student Dr. Mudit Gupta, M.D. (Paediatrics) Guide: Dr. Vijay Kamale

IEC comments and suggestions:

- Objective number 2 and 3 to be omitted as not specific to the study protocol since it is a cross sectional study.
- List of environmental factors to be added in methodology and case record form

12 Title: Study on the Functional Outcome of Surgically treated Achilles Tendon Rupture

Investigators: Dr. Anuj Samir Parikh , Guide: Dr. Sarabjeet Singh Kohli, Department of Orthopaedics

IEC comments and suggestions:

- case record form update with FADSI score and list of complications
- Permission for scale to be obtained in case of copyrighted scale

13 Title: A comparative study of functional outcomes in patients with anterosuperior rotator cuff tears with Mini open vs Arthroscopic single row repair using two different scoring systems- A midterm comparative system

Investigators: Dr. Raman Singh , Guide: Dr. Rahul Kadam, Department of Orthopaedics

IEC comments and suggestions:

- Remove midterm comparative system from title
- Add pre operative assessment of the two scores
- Refine objective and update Case record form with mention of total scores and list of complications

14 Title: A comparative study of clinical and functional outcome in patients with neck of femur fracture treated by hemiarthroplasty using lateral approach and accessing the hip anterior or posteriorly

Investigators: Dr. Lakhdive Rohan Sudhir , Guide: Dr. Rahul Kadam, Department of Orthopaedics

IEC comments and suggestions:

- Refine the objectives as per the aim
- Sample size justification
- Participant information sheet with details of the study to be prepared and submitted in standard format
- Permission for scale to be obtained in case of copyrighted scale

15 Title: study of functional outcome of distal femur fractures AO type C2/C3 in adults treated with bicolumnar fixation

Investigators: Dr. Singh Kriteya Subhash , Guide: Dr. Sarabjeet Singh Kohli, Department of Orthopaedics

IEC comments and suggestions:

- Case record form update with complications, scoring and timepoints
- Participant information sheet with details of the study to be prepared and submitted in standard format
- Permission for scale to be obtained in case of copyrighted scale

16 Title: study of prevalence of polycystic ovarian disease among MBBS students in tertiary care teaching hospital

Investigators: Dr. Kawade Rucha Vikram , Guide: Dr. Shaifali Patil, Department of Obstetrics and gynecology

IEC comments and suggestions:

- Refine Inclusion criteria – participants only fulfilling the PCOD criteria only will be included
- Also to include in the participant information sheet that the cost of investigation and radiological scan will not be borne by participants. The cost for cost of investigation and radiological scan will be borne by investigators

17 Title: Effectiveness of octreotide in treatment of patients with of Acute Pancreatitis- A prospective study

Investigators: Dr. Kele Vivek Murhari Manisha , Guide: Dr. Lisha Suraj, Department of General Surgery

IEC comments and suggestions:

- Methodology should be in tailed specifying that it is an observation clinical study and does not involve randomization
- Refine the inclusion – will include Moderate n severe case only
- Exclude mild cases
- Efficacy parameters to be analysed in methodology needs to be added in detailed.

DNB – MGM HOSPITAL VASHI

18 Title: Study of Efficacy of multiparametric MRI in prostatic lesion characterization and correlation of Pi-rads with Histopathological studies

Investigators: Dr. Shashikant Morale, Guide: Dr. Neelam Gupta, Department of Radio-diagnosis

IEC comments and suggestions:

- Title change – add the word “diagnostic utility” to be specific
- Suggested to revise the title to- Study of the diagnostic utility of multiparametric MRI in prostatic lesion characterization and correlation of PI-RADS with histopathological studies
- Participant information sheet and consent form to be prepared and submitted in standard format

19 Title: Study of role of computed tomography in the evaluation of acute pancreatitis and its complications

Investigators: Dr. Deepti Mishra, Guide: Dr. Neelam Gupta, Department of Radio-diagnosis

IEC comments and suggestions:

- Title change – add the word “diagnostic utility” to be specific
- Suggested to revise the title to- Study of the diagnostic utility of computed tomography in the evaluation of acute pancreatitis and its complications
- Participant information sheet and consent form to be prepared and submitted in standard format

20 Title: A study of the clinical, biochemical and microbiological profile of sepsis in adults admitted to intensive care unit


Investigators: Dr. Syam Nandajan, Guide: Dr. Uday Jadhav, Department of General Medicine

IEC comments and suggestions:


- No changes suggested


Member Secretary

Dr. Pradeep Jadhav

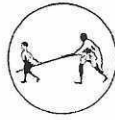

Convener

Dr Ipseeta Ray


Chairperson

Dr . Pramila Yadav





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MGM Medical College Institutional Ethics Committee, Navi Mumbai (MGMMC-IEC)
E-mail: mgmethics@gmail.com
Registration number - EC/NEW/INST/2021/2255

In pursuance of the circular on the subject dated: **17/8/2022**, the Institutional Ethics Committee (IEC) of MGM Medical College, Kamothe assembled for videoconference based meeting on **22nd August 2022 (Monday)** virtually at **10.00 AM** via **google meet**.

Google Meet link: <https://meet.google.com/ygq-tgkv-tib>

The following functionaries attended the meeting

Sr. No.	Name	Designation of member in Ethics Committee
1	Dr. Pramila Yadav	Chairman
2	Dr. D. Bhusare	Member- Clinician
3	Dr. Pradeep Jadhav	Member Secretary
4	Dr. Ipseeta Ray	Basic Medical Scientist
5	Dr. Santosh Gawali	Basic Medical Scientist
6	Dr. Jaishree Ghanekar	Member - Clinician
7	Mrs. Amruta Sachin Dhavale	Lay Person
8	Mrs. Rupali Gujar	Social Scientist
9	Dr. Sheela Hosamani	Legal Expert

Minutes of the previous IEC meeting held on 12/8/2022 were confirmed unanimously

Minutes of IEC meeting held on 22/08/2022

MD/ MS thesis protocols

MD/ MS Dissertation Protocols reviewed

Department of Community Medicine

1 Title: Epidemiological study of prevalence of Hypertension and factors associated in age group of 30 - 79 years in tribal population in Panvel taluka of Raigad district of Maharashtra, India

Investigators: Dr. Mayank Purohit, Guide: Dr. Prasad Waingankar, Department of Community Medicine

IEC comments and suggestions:

- Participant information sheet (PIS) not submitted. To submit PIS -English as well in local languages (Hindi & Marathi)

Department of General Medicine

2 Title: Assessment of risk of metabolic syndrome and cardiovascular diseases in people living with HIV

Investigators: Dr. Tanvi Anil Gersappa, Guide: Dr. Mitesh Thakkar, Department of General Medicine

IEC comments and suggestions:

- Title Modify – people living with HIV is broad- keep it specific
- Refine the objectives
- Add sample size calculation with actual values
- Participant information sheet (PIS)- add contact details of investigator

3 Title: Study of clinical profile and serum chloride levels in patients of heart failure.

Investigators: Dr. Mane Sagar Satish, Guide: Dr. Mitesh Thakkar, Department of General Medicine

IEC comments and suggestions:

- Add sample size calculation with actual values
- Consent form – add LAR signature

- To submit PIS -English as well in local languages (Hindi & Marathi)

Department of Geriatrics

4 Title: To study relationship of cognitive impairment in elderly patients with type 2 diabetes

Investigators: Dr. Belgudri Rushabh Mallappa, Guide: Dr. Bharat Dhareshwar, Department of Geriatrics

IEC comments and suggestions:

- Separate inclusion criteria for cases and control to be added in methods
- Sample size justification to be added
- Participant information sheet with details of the study to be prepared and submitted

Department of Paediatrics

5 Title: Study of screening of children of MDR TB patient contact

Investigators: Dr. Smaran Thakur, Guide: Dr Vijay Kamale, Department of Paediatrics

IEC comments and suggestions:

- Assent information sheet not submitted. to submit assent information sheet

Department of Psychiatry

6 Title: Profile of academic stress, peer bullying, somatic symptoms and school avoidance in children and adolescents with anxiety and depression

Investigators: Dr. Raj Arvind Yalgi, Guide: Dr. Darpan Kaur, Department of Psychiatry

IEC comments and suggestions:

- To submit assent form and information sheet, since the study is conducted in children

Department of Ophthalmology

7 Title: A study of profile of ocular diseases in paediatric age group patients presenting to a tertiary care center

Investigators: Dr. Praveen Kumar Mohan Kumar, Guide Dr. Gayatri Bhonsale, Department of Ophthalmology

IEC comments and suggestions:

- To submit assent form and information sheet, since the study is conducted in children

Department of General Surgery

8 Title: A comparative study of clinical outcome between Desarda's Tissue based repair technique Vs Moloney's Suture based darning technique for treatment of inguinal hernia

Investigators: Dr. Sanjana Sanjay Patil, Guide: Dr. K. Gedam, Department of General Surgery

IEC comments and suggestions:

- Case record form update with complications and assessment timepoints and resubmit
- Participant information sheet with details of the study to be prepared including details of randomization method and resubmit

9 Title: A prospective observational study of traumatic brain injury in pillion rider of motorised two wheeler

Investigators: Dr. Magre Nikhil Laxman, Guide: Dr. G. S. Narshetty, Department of General Surgery

IEC comments and suggestions:

- Case record form update with assessment timepoints (follow-ups) and resubmit
- Consent form – add LAR signature
- Submit assent form, since children are included in the study

10 Title: A comparative study of level of prostate specific antigen in males more than 50 years of age presenting with lower Urinary tract symptoms before and after treatment

Investigators: Dr. Akhil Mudgal, Guide: Dr. G. S. Narshetty, Department of General Surgery

IEC comments and suggestions:

- Suggested to omit age limit from title
- Add sample size calculation with actual values
- Case record form update with prostate specific investigations and parameters as per the study
- To submit Participant information sheet (PIS) of local languages (Hindi & Marathi)

11 Title: Randomised comparative clinical study of securing the vase of appendiceal stump during laparoscopic appendectomy using hem o lok clips and endoloop

Investigators: Dr. Vardan Kumar, Guide: Dr. K. Gedam, Department of General Surgery

IEC comments and suggestions:

- Objective 3 of cost effectiveness to be remodified or omitted
- Add sample size calculation with actual values

- Submit assent form, since children are included in the study

12 Title: to study and Compare the utility of national nosocomial infection surveillance (NNIS) and surgical site infection risk scores (SSIRS) in predicting surgical site infection (SSI) in exploratory Laparotomy

Investigators: Dr. Jatoo Sameer Ahmed Mehboob Ali, Guide: Dr. Ali Reza, Department of General Surgery

IEC comments and suggestions:

- Objectives to be refined
- Case record form not submitted to IEC, to prepare and submit
- Also, Participant information sheet not submitted, to prepare and submit Participant information sheet (PIS) English version and local languages (Hindi & Marathi)

13 Title: Comparison of topical beta blocker timolol v/s saline dressing in chronic ulcer healing

Investigators: Dr. Luv Kushagra, Guide: Dr. Sameer Kadam, Department of General Surgery

IEC comments and suggestions:

- To add in inclusion the range of ulcer dimensions to be included
- Add standard of care (debridement) plus topical beta blocker timolol or saline dressing in the two groups
- To correct the Participant information sheet which is mentioning double blinded study

14 Title: A comparative study of Platelet rich plasma dressing and normal saline dressing in Ulcer healing

Investigators: Dr. Kulkarni Gayatri Milind, Guide: Dr. Lisha Suraj, Department of General Surgery

IEC comments and suggestions:

- Inclusion criteria is broad, to make it specific.add the range of ulcer dimensions and ulcer sites to be included. The two groups should be matched homogenously in terms of ulcer for assessment
- In exclusion criteria, mention conditions which can alter or can confound the ulcer healing
- Randomization method to be mentioned in detail
- Methodology – add the standard procedure for discarding the unused PRP

15 Title: Compare the post operative complication in early laparoscopic cholecystectomy versus delayed laparoscopic cholecystectomy in acute cholecystitis

Investigators: Dr. Twisha Divyesh Shah, Guide: Dr. Sameer Kadam, Department of General Surgery

IEC comments and suggestions:

- Title to be modified, add “post operative outcomes” instead of post operative complications
- Accordingly refine the aim and objectives
- In methodology, method of randomization needs to be added in detail.
- Sample size in methodology and participant information sheet is mismatch (48 or 50). Rectify

16 Title: To study prognostic factors and outcome of patients undergoing Decompressive Craniectomy in traumatic brain injury

Investigators Dr. Patel Nandini Kantilal:, Guide: Dr. Neeraj Patni, Department of General Surgery

IEC comments and suggestions:

- No modifications suggested

17 Title: To study and compare the efficacy of swab vs tissue culture and its application for management of diabetic foot wound

Investigators: Dr. Bhumi Padole, Guide: Dr. Ali Reza, Department of General Surgery

IEC comments and suggestions:

- Title to be modified The study assesses the diagnostic utility of two methods and is not related to efficacy of treatment
- Objectives to be refined
- In methodology, change the randomization of two groups to single group. The included patients will undergo both the methods swab and tissue culture for diagnostic accuracy.

Department of Orthopaedics


18 Title: A comparative study of Functional Outcome in patients with Tricompartamental Osteoarthritis of the knee undergoing Primary Total knee arthroplasty using Midvastus vs medial parapatellar approach

Investigators: Dr. Tangadi Nishant Shankar, Guide: Dr. Rahul Kadam, Department of Orthopaedics


IEC comments and suggestions:

- Sample size justification
- Mention method of randomization

- In methodology, method of randomization and what does the study involve with time points for followup needs to be added in detail.


Member Secretary
Dr. Pradeep Jadhav


Convener
Dr Ipseeta Ray


Chairperson
Dr . Pramila Yadav





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MGM Medical College Institutional Ethics Committee, Navi Mumbai (MGMMC-IEC)
E-mail: mgmethics@gmail.com
Registration number - EC/NEW/INST/2021/2255

In pursuance of the circular on the subject dated: **17/8/2022**, the Institutional Ethics Committee (IEC) of MGM Medical College, Kamothe assembled for videoconference based meeting **27th August 2022 (Saturday) virtually at 10.30 AM** via google meet to review MD/MS Dissertation Protocols.

Google Meet link: <https://meet.google.com/szh-nwjk-ecb>

The following functionaries attended the meeting

Sr. No.	Name	Designation of member in Ethics Committee
1	Dr. Pramila Yadav	Chairman
2	Dr. D. Bhusare	Member- Clinician
3	Dr. Pradeep Jadhav	Member Secretary
4	Dr. Ipseeta Ray	Basic Medical Scientist
5	Dr. Santosh Gawali	Basic Medical Scientist
6	Dr. Jaishree Ghanekar	Member - Clinician
7	Mrs. Amruta Sachin Dhavale	Lay Person
8	Mrs. Rupali Gujar	Social Scientist
9	Dr. Sheela Hosamani	Legal Expert

Minutes of the previous IEC meeting held on 22/8/2022 were confirmed unanimously

Minutes of IEC meeting held on 27/08/2022

MD/ MS thesis protocols

MD/ MS Dissertation Protocols reviewed

1 Title: Study the outcome of pregnancy with low lying placenta diagnosed by ultrasonography between 18-24 weeks

Investigators: Dr. Deshpande Rasika Vivek, Guide: Dr. Sushil Kumar, Department of Obstetrics and gynecology

IEC comments and suggestions:

- Case record form; add study title and details of fetal and maternal outcomes
- Participant information sheet, add LAR signature
-

2 Title: Comparative study of Integrity and scar thickness through sonography and intraoperatively in patients with previous caesarean section

Investigators: Dr. Ayushi Sharma, Guide: Dr. Pratima Thamke, Department of Obstetrics and gynecology

IEC comments and suggestions:

- Case record form; add study title and details of fetal and maternal outcome parameters, Time taken for operation , Assessment Time points and Scar parameters

3 Title: Study of ocular manifestations in patients of road- traffic accidents presenting to a tertiary care centre

Investigators: Dr. Shubhangi Mahesh, Guide: Dr. Varshav Gore, Department of Ophthalmology

IEC comments and suggestions:

- Update Sample size calculations with actual numbers and prevalence value

4 Title: A comparative study of mortality as predicted by revised trauma score, injury severity score and trauma related injury severity score

Investigators: DR. Bhargavi Voorakalli, Guide: Dr. Sameer Kadam, Department of General Surgery

IEC comments and suggestions:

- Language translation of participant information sheet to be submitted
- Case record form – update to record the scoring of the scales
- Remove simple randomization sampling from methods, as all patients presenting will be included

5 Title: Outcome of medial patellofemoral ligament reconstruction in recurrent patellar instability


Investigators: Dr. Mohammad Ibrahim Raza, Guide: Dr. Nilesh Vishwakarma, Department of Orthopaedics

IEC comments and suggestions:


- Objectives to be refined focusing on functional, radiological and complications
- sample size calculation with actual values
- Assent consent form and parenteral consent to be submitted for children above 13 years
- participant information sheet (PIS) is incomplete, resubmit PIS with detailed information pertaining to the study
- Case record form – update with assessment details and time points


Member Secretary

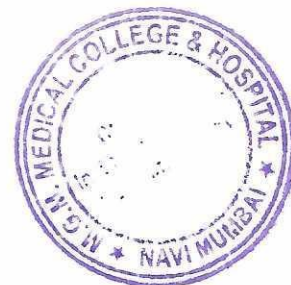
Dr. Pradeep Jadhav


Convener

Dr Ipseeta Ray


Chairperson

Dr . Pramila Yadav





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E-mail: mgmethics@gmail.com

Registration number - EC/NEW/INST/2021/2255

In pursuance of the circular on the subject dated: **06/10/2022**, the Institutional Ethics Committee (IEC) of MGM Medical College, Kamothe assembled for videoconference based meeting on **12th October 2022**, from **10.30 AM**, **virtually** via google meet. at the following link Google Meet link: <https://meet.google.com/yng-onxh-nwa>

Or join via google code: yng-onxh-nwa

The following functionaries attended the meeting

Sr. No.	Name	Designation of member in Ethics Committee
1	Dr. Pramila Yadav	Chairman
2	Dr. D. Bhusare	Member- Clinician
3	Dr. Pradeep Jadhav	Member Secretary
4	Dr. Ipseeta Ray	Basic Medical Scientist
5	Dr. Santosh Gawali	Basic Medical Scientist
6	Dr. Jaishree Ghanekar	Member - Clinician
7	Mrs. Amruta Sachin Dhavale	Lay Person
8	Mrs. Rupali Gujar	Social Scientist
9	Dr. Sheela Hosamani	Legal Expert

Minutes of the previous IEC meeting held on 27/8/2022 were confirmed unanimously

Minutes of IEC meeting held on 12/10/2022

Staff / PG/UG Student Projects

1) Pediatric acute abdomen : A study in a tertiary care centre

Investigators: Dr. Samit Doshi, Guide: Dr. D.B. Bhusare, Department of General Surgery

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Mention sample size justification
- Update CRF with nature of injury, etiology factors.

2) Gastric pH as a prognostic tool for evaluation of perforative peritonitis – a prospective study in a tertiary care centre

Investigators: Dr. Sujhdev Adhikari, Guide: Dr. Narendra Naik, Department of General Surgery

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Mention sample size calculation
- Mention in detail the method of allocation to the groups

3) A comparative study between conventional suturing vs skin glue in elective clean surgery for skin closure

Investigators: Dr. Akshaya Parthiban, Guide: Dr. Lisha Suraj, Department of General Surgery

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Mention sample size justification
- Submit Participant information sheet

4) Fibrocalculous pancreatic diabetes (FCPD) an uncommon presentation of diabetes mellitus

Investigators: Dr. Niharika Sabnis, Guide: Dr. Sandeep Rai, Department of General Medicine

IEC comments and suggestions:

- The case study was reviewed.
- No changes suggested

The proposal was approved by the IEC

5) Comparative study between streptokinase and alteplase as fibrinolytic agents in management of Covid 19 patients with acute pulmonary embolism :A retrospective study

Investigators: Dr. Lakshmi Kode, Guide: Dr. D.B. Bhusare, Department of Emergency Medicine

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Administrative permission to be obtained to access retrospective data
- Update Case record form with the recording parameters

6) Association between insomnia and cognitive decline among the geriatric population of old age homes

Investigators: Dr. Karishma Patil, Guide: Dr. Rita Khakikar, Department of Physiology

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Mention sample size justification
- Permission to be obtained in case of using copyrighted scales
- Include co- investigator from geriatric department , as they are involved in the assessment

7) Profile of child and adolescent consultation liaison psychiatry services at a Covid – 19 designated tertiary medical college and Hospital

Investigators: Dr. Aakash Ponda, Guide: Dr. Darpan Kaur, Department of Psychiatry

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Mention sample size justification
- Administrative permission to be obtained to access retrospective data

8) Comparative study of primary repair with open meshplasty v/s abdominoplasty in a tertiary care hospital in assessing the outcome of incisional hernia

Investigators: Dr. Ashika Mehta, Guide: Dr. Narendra Naik, Department of General Surgery

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Mention sample size justification
- Update participant information sheet with requisite answers to the questions along with language translation
- Update case record form with list of complications and assessment time points

9) Assessing the circadian chronotype and sleep of health professional education students and observing its implications on various domains of health

Investigators: Ms. Sanaya Shah, Guide: Dr. Rita Khakikar, Department of Physiology

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Title modification – add health domain or quality of life domains , omit the implication part
- Permission to be obtained in case of using copyrighted scales/ questionnaire

10) Study of correlation between veress needle and open technique in laparoscopic surgeries – A surgeons preference

Investigators: Dr. Shifa Kalokhe, Guide: Dr. G.S. Narshetty, Department of General Surgery

IEC comments and suggestions: The proposal was tentatively approved by the IEC subject to the following:

- Submit Participant information sheet with language translations

11) A rare case of dapsons poisoning presenting with methemoglobinemia

Investigators: Dr. Lakshmi Kode, Guide: Dr. D.B. Bhusare, Department of Emergency Medicine

IEC comments and suggestions:

- The case study was reviewed.
- Suggested to add causality assessment of the adverse drug reaction

The proposal was approved by the IEC

12) Delayed presentation of infantile hypertrophic pyloric stenosis A diagnostic dilemma

Investigators: Dr. NinadChitnavis, Guide: Dr. Prajakta Vedak, Department General Surgery

IEC comments and suggestions:

- The case study was reviewed.
- No changes suggested

The proposal was approved by the IEC

13) Cryptococcal meningitis in a HIV sero-positive patient – A case study

Investigators: Ms. S. Jayalakshmi, Guide: Dr. Neha Singh, Department Microbiology

IEC comments and suggestions:

- The case study was reviewed.
- No changes suggested

The proposal was approved by the IEC

14) Pelvic fractures – An epidemic on our roads

Investigators: Dr. Vishakha Malhotra, Guide: Dr. D.B. Bhusare, Department Traumatology & Surgery

IEC comments and suggestions:

- Investigator was absent for the meeting

The proposal is kept on hold and will be placed in the next subsequent IEC meeting

15) Case report – Aortic dissection – rare presentation of a rare disease

Investigators: Dr. Nidhi Anam, Guide: Dr. Badal Taori, Department General Medicine

IEC comments and suggestions:

- The case study was reviewed.
- No changes suggested

The proposal was approved by the IEC

16) Protein C deficiency causing recurrent deep vein thrombosis (DVT) in a young male :

Case report

Investigators: Dr. Kubal Sahil, Guide: Dr. Badal Taori, Department General Medicine

IEC comments and suggestions:

- The case study was reviewed.
- No changes suggested

The proposal was approved by the IEC

17) Hemophagocytic lymphohistiocytosis

Investigators: Ms. Revaa Kovil, Guide: Dr. Manjari Shukla, Department General Medicine

The proposal was approved by the IEC

13) Cryptococcal meningitis in a HIV sero-positive patient – A case study

Investigators: Ms. S. Jayalakshmi, Guide: Dr. Neha Singh, Department Microbiology

IEC comments and suggestions:

- The case study was reviewed.
- No changes suggested

The proposal was approved by the IEC

14) Pelvic fractures – An epidemic on our roads

Investigators: Dr. Vishakha Malhotra, Guide: Dr. D.B. Bhusare, Department Traumatology & Surgery

IEC comments and suggestions:

- Investigator was absent for the meeting

The proposal is kept on hold and will be placed in the next subsequent IEC meeting

15) Case report – Aortic dissection – rare presentation of a rare disease

Investigators: Dr. Nidhi Anam, Guide: Dr. Badal Taori, Department General Medicine

IEC comments and suggestions:

- The case study was reviewed.
- No changes suggested

The proposal was approved by the IEC

16) Protein C deficiency causing recurrent deep vein thrombosis (DVT) in a young male :
Case report

Investigators: Dr. Kubal Sahil, Guide: Dr. Badal Taori, Department General Medicine

IEC comments and suggestions:

- The case study was reviewed.
- No changes suggested

The proposal was approved by the IEC

17) Hemophagocytic lymphohistiocytosis

Investigators: Ms. Revaa Kovil, Guide: Dr. Manjari Shukla, Department General Medicine

IEC comments and suggestions:

- The case study was reviewed.
- No changes suggested

The proposal was approved by the IEC

18) A rare case of malakoplakia of urinary bladder

Investigators: Dr Pranav Raja Yadav, Guide: Dr Piyush Singhanian, Department Urology

IEC comments and suggestions:

- The case study was reviewed.
- No changes suggested

The proposal was approved by the IEC

19) Analysis of HIV-seroprevalence amongst patients attending tertiary care hospital : a 8 year retrospective study

Investigators: Ms. S. Jayalakshmi, Guide: Dr. Harapriya Kar, Department Microbiology

IEC comments and suggestions:

- Administrative permission to be obtained as it is retrospective study
- No changes suggested

The proposal was approved by the IEC


Member Secretary

Dr. Pradeep Jadhav




Convener

Dr Ipseeta Ray



Chairperson

Dr . Pramila Yadav