



MGM INSTITUTE OF HEALTH SCIENCES

(Deemed University u/s 3 of UGC Act, 1956)

Accredited Grade A by NAAC

Minutes of the Meeting of Ethics Committee for Research on Human Subjects (ECRHS)

Meeting of the Ethics Committee for Research on Human Subjects of MGM Institute of Health Sciences, Navi Mumbai was held on 24th March, 2021 at 10.00 am through virtual platform.

The following members had participated in the meeting:

- | | | |
|------------------------|---|------------------|
| 1. Dr. Alaka Deshpande | : | Chairperson |
| 2. Dr. Prakash P Doke | : | Member |
| 3. Dr. Chander P Puri | : | Member |
| 4. Dr. Shirish Joshi | : | Member |
| 5. Dr. Raman P Yadav | : | Member |
| 6. Shri. J C Sharma | : | Member |
| 7. Dr. Karuna Ramraje | : | Member |
| 8. Shri E A Patil | : | Member |
| 9. Dr. Savita Shahani | : | Member Secretary |

Dr. Alaka Deshpande chaired the meeting

The following members had informed their inability to attend the meeting:

- | | | |
|----------------------|---|--------|
| 1. Dr. Abhijit De | : | Member |
| 2. Dr. Ipseeta Ray | : | Member |
| 3. Dr. Smita Mahale | : | Member |
| 4. Dr. G S Narshetty | : | Member |

Title : Clinical evaluation of quantum dot powered IP-10 antibody based kit for diagnosis and differentiation of latent TC infection from active pulmonary tuberculosis

Principal Investigator : Dr. Pradip Potdar, Prof. & Head, Department of Respiratory Medicine, MGM Medical College & Hospital, Kamothe, Navi Mumbai.

Dr. Pradip Potdar

Dr. Potdar explained principles of working of technology.

- Members suggested modification in study title to **“Quantum Dot based detection kit for the identification and differentiation between Latent TB infection from active Pulmonary Tuberculosis”**
- It was advised to diagnose latent TB via IGRA instead of Montoux test. Please mention that Montoux test will be only added in clinical profile it will not be for diagnostic purpose.
- Members suggested that proper safety precautions should be taken while disposal and handling of biological fluid.
- It was decided to grant ethical approval for pilot study subject to incorporation of changes as suggested. After reviewing the results of pilot study decision can be taken for next phase of study.

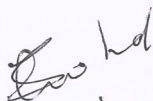
Title : Effectiveness of “Pregnancy Tele Yoga Module” on stress, anxiety or depression during COVID - 19 Pandemic; a prospective, multi- centre, open-label single-arm exploratory study.

Co-Investigator: Dr. Shubhangi S. Dere, Asst. Prof., Department of Psychiatry, MGM Medical College & Hospital, Navi Mumbai.

Members suggested that PI of the Multi Centre Trial should first get the Ethics Committee approval from NIMHANS, Bangalore and based on changes suggested by NIMHANS, Bangalore Ethics Committee, modification of protocol may be required. The Members of the MGMIHS Ethics Committee suggested the following changes which may communicated to PI for incorporation while getting approval from NIMHANS, Bangalore Ethics Committee:

- To start tele yoga in second trimester, as stress is more during this period
- Safety of tele yoga to be assured in late pregnancy
- Approval to be taken from treating gynaecologist for participation of women for tele yoga
- Patient information sheet to be modified indicating clearly risk involved in participation
- It was suggested to send the feedback of this to PI while submitting revised project.

Title : Comparative analysis of growth factor secretion profile between CD146+ and CD146- cell population of endometrium cancer cell line Ishikawa using multiplex bead array cytometry and effect of traconazole on the same.



Principal Investigator: Dr. Mansee Thakur, In-charge Director, MGM School of Biomedical Sciences, Kamothe, Navi Mumbai.

Members suggested that, as there is no ethical issue in the study as it is only a lab work waiver may be granted from Ethics Committee review. However, the project may be reviewed by appropriate Scientific Committee.

Title : Effect of Allicin on CD44+ Cancer Stem Cells from Oral Cancer Cell Line AW13516

Principal Investigator: Dr. Himanshu R Gupta, Assistant Professor, Dept. of Medical Biotechnology, MGMSBS, Kamothe, Navi Mumbai.

Members suggested that, as there is no ethical issue in the study as it is only a lab work waiver may be granted from Ethics Committee review. However, the project may be reviewed by appropriate Scientific Committee.

Title : Education and facility based opportunistic screening for diabetes mellitus: Effect on knowledge, attitude and compliance to screening among adults attending Primary Health Centers at Aurangabad.

PhD Scholar: Mr. Sandeep Thombare, (PhD Nursing)

Project required major revision. It was advised to the candidate to resubmit the project after incorporating changes as suggested by the Chairperson of the Ethics Committee:

He was instructed by the Chairperson of the Ethics Committee to first discuss with his PhD Guide in person and suggestions from a Medical Specialist to take up the PhD Research Project Protocol. You were instructed by the Chairperson of the Ethics Committee to read the details regarding Diabetes and have knowledge of the subject before doing PhD Research in the related subject.

Title : Maternal colonization of group B streptococcus in preterm deliveries, preeclampsia and still birth

PhD Scholar : Mr. Abhishek Singh, PhD Microbiology (Batch 2017)

During the meeting of Scientific Advisory Committee of MGMIHS on July, 2019 the members suggested "confirmation and explanation for unexpected results which were observed. Based on further characterization of organisms title of project may require modification".



Based on the recommendations of the SAC and study result, PhD student put-forth revised PhD Title before the Ethics Committee for approval.

Old Title : "Maternal colonization of group B streptococcus in preterm deliveries, preeclampsia and still birth"

New Title: "To study the maternal colonization of group B streptococcus and enterococcus and their association with preterm deliveries and preeclampsia".

Since there is no changes in Objectives and Methodology in the earlier approved Research Project, the revised title is approved by the Ethics Committee.

Meeting ended with vote of thanks.

H. G. G. G.

Member Secretary

Chairman/Member Secretary
Ethics Committee For Research on Human-Subjects
MGM Institute of Health Sciences
3 rd Floor, Sector-1, Kamothe,
Navi Mumbai - 410 209.

Sanjiv



MGM INSTITUTE OF HEALTH SCIENCES
(Deemed University u/s 3 of UGC Act, 1956)
Accredited Grade A by NAAC

**Minutes of the Meeting of Ethics Committee for Research on Human Subjects
(ECRHS)**

Meeting of the Ethics Committee for Research on Human Subjects of MGM Institute of Health Sciences, Navi Mumbai was held on 2nd June, 2021 at 11.00 am through virtual platform.

The following members had participated in the meeting:

- | | | |
|------------------------|---|------------------|
| 1. Dr. Alaka Deshpande | : | Chairperson |
| 2. Dr. Prakash P Doke | : | Member |
| 3. Dr. Chander P Puri | : | Member |
| 4. Dr. Shirish Joshi | : | Member |
| 5. Dr. Raman P Yadav | : | Member |
| 6. Shri. J C Sharma | : | Member |
| 7. Dr. Karuna Ramraje | : | Member |
| 8. Shri E A Patil | : | Member |
| 9. Dr. Savita Shahani | : | Member Secretary |

Dr. Alaka Deshpande chaired the meeting

The following members had informed their inability to attend the meeting:

- | | | |
|----------------------|---|--------|
| 1. Dr. Abhijit De | : | Member |
| 2. Dr. Ipseeta Ray | : | Member |
| 3. Dr. G S Narshetty | : | Member |

Title : Evaluation of incidence and detection of head and neck fungal Infections in patients with and without type 2 diabetes mellitus Diagnosed with COVID - 19: A combined retrospective and Prospective cohort study.

Signature

Principal Investigator : Dr. Ujjwala Maheshwari, Professor, Department of Pathology
MGM Medical College & Hospital, Kamothe, Navi Mumbai.

Co-Principal Investigator : Dr. Srivalli Natarajan, Professor & Head, Department of Oral
and Maxillofacial Surgery, MGM Dental College & Hospital, Kamothe, Navi Mumbai.

Members suggested to change the title to make it more specific for mucormycosis, as
diabetic and non-diabetic both population is included therefore it need not appear in
title

- Study should have Principal Investigator, Co-Principal Investigator and Co-
Investigators. One of the ENT surgeon may also be included in the study.
- Introduction may be modified to make it more specific why this study is
conducted.
- Modify ROL where investigator's own may also be included.
- Change Inclusion criteria to include;
 - i. Participants above 18 years
 - ii. COVID -19 cases confirmed by antigen/RTPCR
- Exclusion criteria may be modified as suggested
- Structural interview may be specified along with the core team involved in this
activity
- Clinical examination should include ocular examination also
- More details should be included regarding oxygen therapy and steroid therapy
- Revised protocol may be submitted.
- Revised protocol may be circulated and reviewed by IEC members and their
comments may be obtained.

Title : Facility based opportunistic screening and education for diabetes mellitus: Effect
on knowledge, attitude and compliance to screening among adults age > 30 years
attending Primary Health Centers in Ahmednagar district, Maharashtra.

Principal Investigator : Mr. Sandeep Thombare, (Nursing, PhD Scholar)

Project was rejected as it was not modified as per suggestions given in last Ethics
Committee meeting. Study requires major revision as suggested earlier. Modified
protocol may be submitted

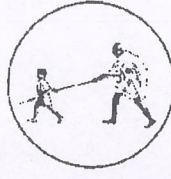
Meeting ended with vote of thanks.

h. s. s. s.

Member Secretary

h. s. s. s.

Chairman/Member Secretary
Ethics Committee For Research on Human Subjects
MGM Institute of Health Sciences
3 rd Floor, Sector-1, Kamothe,
Navi Mumbai - 410 209.



MGM INSTITUTE OF HEALTH SCIENCES
(Deemed University u/s 3 of UGC Act, 1956)
Accredited Grade A by NAAC

**Minutes of the Meeting of Ethics Committee for Research on Human Subjects
(ECRHS)**

Meeting of the Ethics Committee for Research on Human Subjects of MGM Institute of Health Sciences, Navi Mumbai was held on 3rd August, 2021 at 11.00 am through virtual platform.

The following members had participated in the meeting:

- | | | |
|------------------------|---|------------------|
| 1. Dr. Alaka Deshpande | : | Chairperson |
| 2. Dr. Prakash P Doke | : | Member |
| 3. Dr. Chander P Puri | : | Member |
| 4. Dr. Shirish Joshi | : | Member |
| 5. Dr. Raman P Yadav | : | Member |
| 6. Dr. Ipseeta Mohanty | : | Member |
| 7. Dr. G S Narshetty | : | Member |
| 8. Shri. J C Sharma | : | Member |
| 9. Dr. Karuna Ramraje | : | Member |
| 10. Shri E A Patil | : | Member |
| 11. Dr. Savita Shahani | : | Member Secretary |

Dr. Alaka Deshpande chaired the meeting

Title : Evaluation of pertussis disease in young infants in India - A hospital based multi-centric study.

Principal Investigator : Dr. Nimain C Mohanty, Professor (Emeritus) Pediatrics

1. Protocol is approved. However, IEC members made some suggestions which may be communicated to PI and if possible may be incorporated in protocol.
2. Apart from hospitalised cases OPD patients may also be enrolled.
3. Centres may conduct RTPCR test in-house to avoid inconvenience in sending sample to Central Lab.

Title : Quality of life assessment of Long COVID - 19

Principal Investigator : Dr. Divyashree S, Consultant, Department of Infectious Diseases, MGM New Bombay Hospital, Vashi

As this is a multi-centric study members advised to convey to PI to incorporate certain changes in protocol.

1. All participants should be enrolled at 6 weeks visit, so that data for all time points may be obtained.
2. Severity of COVID-19 may be as per ICMR guidelines.
3. During follow-up some mechanism may be introduced to assess altered Post-COVID biochemical function.
4. Status of vaccination after COVID infection may be noted, which may help to assess if there is any associated complication after vaccination.
5. Inclusion criteria should be only Laboratory confirmed COVID-19 cases.
6. Whether study is enrolled to CTRI site.

Study may be approved after getting clarification regarding the queries.

Meeting ended with vote of thanks.

Handwritten signature

Member Secretary

Chairman/Member Secretary
Ethics Committee For Research on Human Subjects
MGM Institute of Health Sciences
3rd Floor, Sector-1, Kharadi
Navi Mumbai - 410 204

Handwritten signature



MGM INSTITUTE OF HEALTH SCIENCES
(Deemed University u/s 3 of UGC Act, 1956)
Accredited Grade A by NAAC

**Minutes of the Meeting of Ethics Committee for Research on Human Subjects
(ECRHS)**

Meeting of the Ethics Committee for Research on Human Subjects of MGM Institute of Health Sciences, Navi Mumbai was held on 30th September, 2021 at 11.00 am through virtual platform.

The following members had participated in the meeting:

- | | | |
|----------------------------|---|------------------|
| 1. Dr. Alaka Deshpande | : | Chairperson |
| 2. Dr. Prakash P Doke | : | Member |
| 3. Dr. Chander P Puri | : | Member |
| 4. Dr. Raman P Yadav | : | Member |
| 5. Dr. Ipseeta Mohanty | : | Member |
| 6. Shri. J C Sharma | : | Member |
| 7. Dr. Sheela Hosmani | : | Member |
| 8. Mr. Satej Daniel Dhiwar | : | Member |
| 9. Dr. Savita Shahani | : | Member |
| 10. Dr. Prakash Khandelwal | : | Member Secretary |

Following members intimated their inability to attend the meeting

- | | | |
|-------------------|---|--------|
| Dr. Shirish Joshi | : | Member |
| Dr. Smita Mahale | : | |
| Dr. G S Narshetty | : | Member |

Dr. Alaka Deshpande chaired the meeting

Minutes of the last meeting were read and confirmed

The following protocol was discussed:

Signature

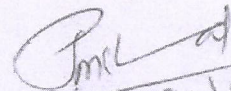
Title: Development of interventions for improving vaccine uptake in tribal and rural population, Maharashtra: A qualitative Study.

Members wanted to know whether all facilities are available at training centre and persons involved in the study are trained for the study.

It was advised to change the title to Raigarh district instead of Maharashtra as study population is only from this district.

Study protocol was approved, however study should be registered with CTRI before enrolling the participants.

Meeting ended with vote of thanks.


30/11/21
Member Secretary

Chairman/Member Secretary
Ethics Committee For Research on Human Subjects
MGM Institute of Health Sciences
3 rd Floor, Sector-1, Kamothe,
Navi Mumbai - 410 209.

