



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 November, 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. Smita Mahale | : | Member |
| 5. Dr. Shirish Joshi | : | Member |
| 6. Dr. Ipseeta Mohanty | : | Member |
| 7. Shri. J C Sharma | : | Member |
| 8. Dr. Sheela Hosmani | : | Member |
| 9. Mr. Satej Daniel Dhiwar | : | Member |
| 10. Dr. Savita Shahani | : | Member |
| 11. Dr. Prakash Khandelwal | : | Member Secretary |

Following members intimated their inability to attend the meeting

- | | | |
|-------------------|---|--------|
| Dr. G S Narshetty | : | Member |
| Dr. Raman P Yadav | : | Member |

Following Co-guides were present during the meeting:

Dr. Prashant Mukkanavar, Professor, SDM College of Physiotherapy, Dharward.

Dr. Sandeep Rai, Professor, Department of Medicine, MGM Medical College, Navi Mumbai.

Dr. Alaka Deshpande chaired the meeting.

I. Minutes of the meeting dated 30.09.2021 were read and confirmed.

II. The following PhD Research Protocols were discussed:

1. Title: Effect of Moringa Oleifera supplementation on Clinical Parameters and T Cell associated cytokine levels following non-surgical therapy in subjects with periodontitis: A randomized controlled study

PhD Student : Dr. Vinit Kini
PhD Guide : Dr. Ipseeta Ray
Subject : Pharmacology

- Specify the Manufacturer and product brand of the Moringa oleifera tablets to be used in the study and obtain the information from the manufacturer regarding dietary supplement status of Moringa oleifera.
- Consider the use of placebo in the control group of the study.
- Provide a copy of the consumption compliance diary that would be maintained by the participant during the study period.
- Specify a compliance level / percentage for the Test group to determine whether the participants have been regular with taking the Moringa oleifera dietary supplement so as to have been deemed regular/ compliant with consumption.
- Consider adding hemogram, renal function and liver function tests for safety monitoring at baseline and evaluation points.
- Consent Form to be added

Research Protocol was approved, subject to the submission of the modifications as mentioned above.

2. Title: The Effect of pain science education on pain, disability, Kinesiophobia, catastrophization and quality of life in chronic low back pain subjects - A mixed method study

PhD Student : Dr. Rinkle Hotwani
PhD Guide : Dr. Waqar Naqvi
Subject : Physiotherapy

- No Objection certificate or consent has to be taken from orthopaedic department for recruiting chronic low back pain patients.
- Segregated analysis of chronic low back pain patients who on analgesics, NSAIDs or topical ointment and record keeping of same.
- In depth interview needs to be mentioned under qualitative study design.

- Collaboration with MGM Human Movement Science Lab, Navi Mumbai and MoU to be signed for Multicentre Study.

Research Protocol was approved, subject to the submission of the modifications as mentioned above.

3. Title : Association of PNPLA3 gene polymorphism in Type 2 diabetes Mellitus patients with and without non-alcoholic fatty liver Disease

PhD Student : Ms. Preeti Padvi
 PhD Guide : Dr. Kavita More
 Subject : Medical Biochemistry

- Modify the inclusion and exclusion criteria
- To include step wise procedure of the PCR-RFLP

Research Protocol was approved, subject to the submission of the modifications as mentioned above.

4. Title: Evaluation of Nurse Practitioner in Critical Care Programme: An exploratory Multicentre Study

PhD Student : Ms. Ferganzia
 PhD Guide : Dr. Ponchitra R
 Subject : Nursing

As discussed in the SAC meeting a co-guide should be included from Management College and details to be submitted to Research Secretariat.

There was no ethical issue in the Protocol. Research Protocol was approved.

5. Title: Impact of parent empowerment programme on optimal health of children with Thalassemia and Psychosocial well being of parents

PhD Student : Ms. Anna Hima
 PhD Guide : Dr. Ponchitra R
 Subject : Nursing

- Prevention aspect of Thalassemia should be included in the Parent empowerment programme

- Inclusion criteria should be modified- '**Children who are undergoing Blood transfusion every 3-4 weeks**' need to be added in the inclusion criteria
- To add **Thalassemia major** instead of **Thalassemia** in the protocol
- Study can be done in two or more settings
- Co guide need to be there for clinical topics. So I need to have a Co guide as my topic is thalassemia.

Research Protocol was approved, subject to the submission of the modifications as mentioned above.

6. Title : Utilization of Government Welfare Schemes and their association with quality of life among senior citizen of Konkan Division: Cross Sectional Study

PhD Student : Ms. Vandana Kumbhar
 PhD Guide : Dr. Ponchitra R
 Subject : Nursing

- Categorize the government welfare schemes as per the type of schemes applicable to various group, like schemes applicable for below poverty line senior citizens , Tribal community, etc.
- To conduct Community education or awareness programme regarding social welfare schemes for senior citizen.
- Permission from District health officer for data collection need to taken and related documents has to be submitted to Research Secretariat.

Research Protocol was approved, subject to the submission of the modifications as mentioned above.

IV) Any other matter with the permission of Chair:

- It was suggested that, in the Multicentre study, there should be a MoU with the Collaborating Institute.
- Nursing Students should have co-guide from concerned department with whom the Research is being carried out.
- All Clinical Trials/Clinical Studies should be registered with CTRI and number should be quoted in next presentation and submit the hard copy to Research Secretariat.
- It was suggested that, the investigator should submit the modified Version of Research Protocol within 1 week with Version No.

Meeting ended with thanks to the Chair.

Member Secretary

Dr. Prakash Khandelwal



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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 1st March, 2022 at 10.00 am through virtual platform.

The following members had participated in the meeting:

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|---------------------------|---|------------------|
| 1. Dr. Alaka Deshpande | : | Chairperson |
| 2. Dr. Prakash P Doke | : | Member |
| 3. Dr. Chander P Puri | : | Member |
| 4. Dr. Smita Mahale | : | Member |
| 5. Dr. Raman P Yadav | : | Member |
| 6. Shri. J C Sharma | : | Member |
| 7. Dr. Sheela Hosamani | : | Member |
| 8. Dr. Savita Shahani | : | Member |
| 9. Dr. Prakash Khandelwal | : | Member Secretary |

Following members intimated their inability to attend the meeting

- | | | |
|-------------------------|---|--------|
| Dr. G S Narshetty | : | Member |
| Dr. Ipseeta Mohanty | : | Member |
| Dr. Shirish Joshi | : | Member |
| Mr. Satej Daniel Dhiwar | : | Member |

Dr. Alaka Deshpande chaired the meeting.

I. Minutes of the meeting dated 30.11.2021 were read and confirmed

II. The following Research Protocols were discussed:

1. **Title: The study of GSTTI, GSTM1 and PON2 gene polymorphism and its relation with oxidative stress markers in polycystic ovary syndrome**

- | | | |
|-------------|---|----------------------|
| PhD Student | : | Ms. Mridula Mishra |
| PhD Guide | : | Dr. Parineeta Samant |
| Subject | : | Biochemistry |

More information required in Consent Form and Patient Information Sheet
Modify Inclusion criteria by changing the word Non-obese instead of Lean
The word Ovarian Morphology should be replaced with Pelvic Sonography
Study design word Prospective should be removed
Rotterdam criteria should be mentioned
Research Protocol is approved subject to incorporation of changes as suggested.

- Title:** Clinical Evaluation of quality of life and effectiveness parameters with 3D printed mechano myogram (MMG) & based prosthesis with ViroTactile Feedback.
A pilot study Orthotics

Principal Investigator : **Dr. Uttara Deshmukh**
HoD, Prosthetics & Orthotics

MoU to be signed between Bionic Hope Pvt. Ltd., and MGM University Department of Prosthetics & Orthotics, before starting the study.

Research Protocol is approved.

- Title :** Study of molecular and Karyotyping abnormalities in infertility cases and sperm motility enhancement using anti-oxidants

Principal Investigator : **Dr. Shilpi Sahu**
Professor & Head, Dept. of Pathology, MGMMCNM

Consent Form and Patient Information Sheet to be submitted to Research Secretariat
In Male Infertility Control sample to be taken

Investigate the partner for Sexual Dysfunction before enrollment.

The Title should be modified as "Study of molecular and Karyotyping abnormalities in male infertility cases and sperm motility enhancement using anti-oxidants"

Research Protocol is approved subject to incorporation of changes as suggested.

- Title :** Autoreactive CD8+ exhausted T-cells profiling in Diabetes Type-1

Principal Investigator : **Dr. Ujjwala Meheshwari**
Professor, Dept. of Pathology, MGMMC

Consent Form and Patient Information Sheet to be submitted to Research Secretariat

Addition of C peptide between 12 to 18 years age

Mention the age range of samples

Research Project is approved subject to the submission above modification.

5. **Title :** Impact of Pandemic on Child Development: A Longitudinal Study in Rural/ Urban Settings Rationale

Principal Investigator : Dr. Sindhu Thomas
Asst. Professor. MGMNBCON

Since the COVID Pandemic is over and the situation is reviving, it will be difficult to get the baseline data of all the objectives.

The Research Protocol is not approved.

6. **Title :** Screening for early Peripheral Vascular Disease and influence of patient-education with self-care using mobile application based guided tele-rehabilitation

Principal Investigator : Dr. Rajani Mullerpatan
Director, MGMSOP, NM

The study should be restricted to arterial disease only.

Modify the Consent Form

Research Protocol is approved subject to incorporation of changes as suggested.

7. **Title:** Mobile based application for tele-rehabilitation of older adults with primary insomnia.

Principal Investigator : Dr. Rajani Mullerpatan
Director, MGMSOP, NM

Research Protocol is approved.

8. **Title:** Association of circulating microRNAs and Irisin peptide with risk of acute coronary syndrome

Principal Investigator : Dr. Santosh S Gawali
Prof. & Head, Dept. of Biochemistry, MGMMCNM

Research Protocol is approved.

9. **Title:** Study of Amylin, Adiponectin, Inflammatory and Endothelial markers in Diabetes, with and without Cardiovascular Disease

Principal Investigator : Dr. Z G Badade
Prof. Dept. of Biochemistry, MGMMCNM

Research Protocol is approved.

10. Title: Efficacy of Chemoprophylaxis in prevention of active tuberculosis in house hold contacts of DR TB patients in rural population

Principal Investigator : Dr. P V Potdar
Professor & Head, Dept. of Respiratory Medicine

Research Protocol is approved.

IV) Any other matter with the permission of Chair:

- All Clinical Trials/Clinical Studies should be registered with CTRI and number should be quoted in next presentation and submit the hard copy to Research Secretariat.
- It was suggested that, the investigator should submit the modified Version of Research Protocol within 1 week with Version No.

Meeting ended with thanks to the Chair.

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.

Dr. Prakash Khandelwal



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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 21st June, 2022 at 10.00 am through virtual platform.

The following members had participated in the meeting:

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|---------------------------|---|------------------|
| 1. Dr. Alaka Deshpande | : | Chairperson |
| 2. Dr. Prakash P Doke | : | Member |
| 3. Dr. Chander P Puri | : | Member |
| 4. Dr. Smita Mahale | : | Member |
| 5. Dr. Raman P Yadav | : | Member |
| 6. Shri. J C Sharma | : | Member |
| 7. Dr. Sheela Hosamani | : | Member |
| 8. Dr. Savita Shahani | : | Member |
| 9. Dr. Prakash Khandelwal | : | Member Secretary |

Following members intimated their inability to attend the meeting

- | | | |
|-------------------------|---|--------|
| Dr. G S Narshetty | : | Member |
| Dr. Ipseeta Mohanty | : | Member |
| Dr. Shirish Joshi | : | Member |
| Mr. Satej Daniel Dhiwar | : | Member |

Dr. Alaka Deshpande chaired the meeting.

I. Minutes of the meeting dated 01.03.2022 were read and confirmed

II. The following Research Protocols were discussed:

- 1. Title:** A clinical evaluation of effectiveness parameters with Gait Analysis Using MASC-KAFO: A Comparative Pilot Study of MASC-KAFO & the conventional Drop-Lock Caliper

Principal Investigator : Dr. Uttara Deshmukh
HoD, Prosthetics & Orthotics

The members suggested PI to show publication in this filed.
Insurance Policy for damage with the patient during the trial to be framed.
MoU should be signed by the competent authority after inclusion of suggestion from the Ethics Committee Members.
Expert from specialized filed will be called during the presentation
Rewrite inclusion criteria in a Scientific way
Permission from the Regulatory Authority should be taken before the trial
Members want the clarification about the study, whether it is a Clinical Study or Phase-I Trial
Revised protocol to be submitted including the suggestions given by Ethics Committee.

2.Title: Project SUCHIT: System for urgent childhood injuries Triage and Treatment

Principal Investigator : Dr. Maninder S Setia
Epidemiologist

Since the mentioned study was presented before the Ethics Committee on 28.02.2018, members asked to submit the letter regarding the status of the study.
The study is involved rural population members suggested to find the feasibility include Government Official DHO in the study as a collaborator.
Research Project is approved subject to incorporating/submitting mentioned suggestions.

3. Title : Epidemiological predictors of metabolic syndrome as a Multi-factorial disease among adult population

PhD Student : Dr. Mahavir Nakel
Guide : Dr. Shobha Salve
Subject : Community Medicine

Members suggested to take NOC from the Dean, Government Medical College, Nanded to pursue PhD at MGMIHS under the guidance of Dr. Shobha Salve, Professor & Head, Department of Community Medicine, MGM Medical College, Aurangabad.
Ethical approval from GMC, Nanded is to be submitted to the Ethics Committee of MGMIHS.
Revised research protocol should be submitted.

III. PhD Research Projects Change of Title as per the suggestions in SAC:

1. **Dr. Rinkle Hotwani, PhD Physiotherapy, Batch 2020-21**

Old Title : The effect of pain science education on pain, disability, Kinesiophobia, catastrophization and quality of life in chronic low back pain subjects - A mixed method study.

New Title: Effect of culturally sensitive content of pain neuroscience education for Marathi speaking patients with chronic low back pain on disability, pain and quality of life A mixed method study.

Members suggested to present the study before Ethics Committee for change in the title. The title of the study is too lengthy to make it short.

2. **Ms. Poonam Desai, PhD Physiotherapy, Batch 2019-20**

Old Title : Level of physical function in elderly in Urban and Rural setting

New Title: An evaluation of the level of physical function among elderly in urban and rural settings and the effect exercise intervention in the elderly in an urban setting.

Members suggested to present the study before Ethics Committee for change in the title.

3. **Ms. Sanjana Philip, PhD Biotechnology, Batch 2019-20**

Old title: Design and development of SiO₂ - QD based non-invasive system for detection of IFN- γ and IP-10 antigen of tuberculosis (TB)

New Title: Design and development of SiO₂ - QD based non-invasive system for detection of IP-10 biomarker of tuberculosis (TB)

Members suggested to present the study before the Ethics Committee for change in the title.

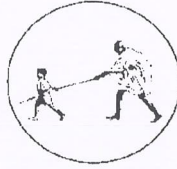
IV. Any other matter with the permission of Chair:

It was decided by the Committee that, once Ethical Approval is given and if any changes in the approved protocol, revised protocol to be submitted and presented before the Ethics Committee.

Meeting ended with thanks to the Chair.

Member Secretary
Prof. & Head Pharmacology
M.G.M. Medical College,
Kamoth. Navi Mumbai-402008

Dr. Prakash Khandelwal



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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 17th August, 2022 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. Smita Mahale : Member
5. Dr. Raman P Yadav : Member
6. Shri. J C Sharma : Member
7. Dr. Sheela Hosamani : Member
8. Dr. Savita Shahani : Member
9. Dr. Ipseeta Mohanty : Member
10. Dr. Shirish Joshi : Member
11. Dr. Prakash Khandelwal : Member Secretary

Following members intimated their inability to attend the meeting

- Dr. G S Narshetty : Member
Mr. Satej Daniel Dhiwar : Member

Director Research was invited for the meeting

The Secretary welcome all members to the Ethics Committee Meeting and invited Dr. Alaka Deshpande to chair the section and took the permission to start with meeting.

I. To confirm the minutes of the meeting held on 21.06.2022:

Minutes of the meeting dated 21.06.2022 were read and confirmed. There was a suggestion by the members to submit the report of the project which has been approved by the Ethics Committee to know the progress and outcome of the Research. The report of the same is being attached along with minutes of the meeting.

II: Change of title of three PhD Research Proposals:

1. Title: A clinical evaluation of effectiveness parameters with Gait Analysis Using MASC-KAFO: A Comparative Pilot Study of MASC-KAFO & the conventional Drop-Lock Caliper

**Principal Investigator : Dr. Uttara Deshmukh
HoD, Prosthetics & Orthotics**

The change of title was accepted and approved subject to condition had she should submit the MOU between the BETiC, IIT Bombay and Aumeesh Technical Private Limited with information to all members.

2. Title : Epidemiological predictors of metabolic syndrome as a Multi-factorial disease among adult population.

**PhD Student : Dr. Mahavir Nakel
Guide : Dr. Shobha Salve
Subject : Community Medicine**

- The earlier presented on 21st June 2022 was not up to the mark and he was asked to resubmit the proposal and take NOC from the Dean, Govt. Medical College Nanded. He has not taken NOC from his institute to pursue PhD at MGMIHS nor has he taken Ethical approval from the parent Institute.
- In the meeting the presentation of the topic was not related to PhD in Community Medicine therefore the members did not accept the topic and asked him to modify the topic and have a relevant topic for the PhD.
- He was asked to be accompanied by his guide during the presentation.
- Suggested to change the topic with the permission of guide and topic should be relevant to community medicine.
- He was admitted for PhD in 2015 complete 7 years and no progress has been made towards research.

3. Title: Effect of culturally sensitive content of pain neuroscience education for Marathi speaking patients with chronic low back pain on disability, pain and quality of life A mixed method study.

**PhD Student : Dr. RinkleHotwani
Guide : Dr. Rajani Mullerpatan
Subject : Physiotherapy**

She was absent for the meeting.

4. **Revised Title: An evaluation of the level of physical function among elderly in urban and rural settings and the effect of exercise intervention in the elderly in an urban setting.**

The protocol with revised title was presented

PhD Student : Ms. Poonam Desai,
Guide : Dr. Rajani Mullerpatan
Subject : Physiotherapy

Revised title & Research Protocol was approved

5. **Revised Title: Design and development of SiO₂ - QD based non-invasive system for detection of IP-10 biomarker of tuberculosis (TB).**

The protocol with revised title was presented

PhD Student : Ms. Sanjana Philip
Guide : Dr. Raman Yadav
Subject : Biotechnology

Revised title & Research Protocol was approved

III The following Research Protocols were discussed:

1. **Title: Prediction and Management of Diabetic neuropathy in Urban, Rural and Tribal people of Raigad District, Maharashtra: The Foot MaP study.**

Dr. Rajani Mullerpatan : Director
MGM School Physiotherapy, NM

Members suggested incorporating the following changes in Research Protocol.

- Suggested to remove other neuropathies and only diabetic neuropathic neuropathy should be included
- Submit consent form and information sheet
- Incorporate the Compliance of Exercise & its record
- Delete the word Tribal in title
- Revised research protocol to be presented again incorporating the suggestions given by ethical Committee.

2. **Title: Genetic evaluation of congenital malformation in patients of pediatric age group in rural and tribal population of Raigad district.**

Dr. Anjali Sabnis : Professor & Head of Anatomy
MGM Medical College, Navi Mumbai

She was absent for the meeting.

3. Title: Develop & validate mentorship framework for enhancing mentoring competencies among teaching faculty of nursing colleges.

Dr. Prabha K. Dasila : Director
MGM New Bombay College of Nursing, NM

The topic was appreciated and the research protocol was approved.

IV. Any other matter with the permission of Chair:

The committee directed that any modifications suggested by the committee must be incorporated and the revised protocol to be submitted and presented before the Ethics Committee for final approval.

Meeting ended with thanks to the Chair.

Encl: Details of Research Project

Member Secretary

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

Dr. Prakash Khandelwal