

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

Meeting of the Ethics Committee for Research on Human Subjects of MGM Institute of Health Sciences, Navi Mumbai was held on 29th November, 2022 at 10.00 am through dual mode.

The following members had participated in the meeting:

1. Dr. Alaka Deshpande: Chairperson
2. Dr. Prakash P Doke: Clinician Member
3. Dr. Shirish Joshi: Medical Scientist
4. Dr. Savita Shahani: Medical Scientist
5. Dr. Ipseeta Ray: Scientific Member
6. Dr. Raman P Yadav: Scientific Member
7. Dr. Sheela Hosamani: Legal Expert
8. Mr. J. C. Sharma: Social Scientist
9. Mr. Satej Daniel Dhiwar: Lay Person
10. Dr. Prakash N Khandelwal: Member Secretary

Following members intimated their inability to attend the meeting

1. Dr. G.S Narshetty : Clinician Member
2. Dr. Chander P Puri: Scientific Member
3. Dr. Smita Mahale: Scientific Member

Director Research was invited for the meeting

The Secretary welcomed 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 17.08.2022
Minutes of the meeting dated 17.08.2022 were read and confirmed.

II. Research Proposals for Ethical Approval

1. Utility of a Rapid Card Test in the Diagnosis of Coeliac Disease in Symptomatic Children presenting to a Tertiary Care Hospital in Maharashtra, India

Principal Investigator: Dr. Roshni Joshua Patnigere

Guide: Dr. Bageshree Seth

Members Suggested incorporating the following changes in the Research Protocol

- Modify the title
- Submit separate information sheet including parent and children consent
- In consent form; mention the age and relation
- Delete unnecessary investigations

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

2. Spine Care Needs and Perceived Barriers to Accessing and Implementing a Model of Spine Care in Rural Setting of Raigad District, Maharashtra: A Mixed-Method Study

Ph.D. Scholar: Dr. Sona Sarma Kolke

Guide: Dr. Rajani Mullerpatan

Subject: Physiotherapy

Members Suggested incorporating the following changes in the Research Protocol

- Modify the title
- Change the pictures
- Instead of Spine care changes Musculoskeletal
- Remove the drug Coedine from the protocol
- Informed consent and information sheet may be clarified and rewritten
- Check Hindi and Marathi version
- All the villages will be screened and if required then next villages added

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

3. Study of Single Nucleotide Polymorphisms of Adiponectin and Leptin Genes and Their Association With in Gestational Diabetes Mellitus

Ph.D. Scholar: Ms. Arti Moholkar

Guide: Dr. Dhananjay Bhale

Co-guide: Dr. Shubhangi Mande

Subject: Medical Biochemistry

Members Suggested incorporating the following changes in the Research Protocol

- Modify objectives and inclusion criteria
- Confirm pre-existing Diabetes Mellitus
- Add sample size Formula
- Modify Information sheet and consent form

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

4. A Study of Pattern of Chronic Kidney Disease of Unknown Etiology (CKDU) In Marathwada Region in a Rural Agricultural Community

Ph.D. Scholar: Dr. Vajed Mogal

Guide: Dr. Kshitija Gadekar

Subject: Nephrology

Members Suggested incorporating the following changes in the Research Protocol

- Modify Informed consent form and their versions
- Put references in inclusion criteria
- Mention history of consumption of Ayurvedic and Herbal drugs

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

5. A Study of Trend, Estimation and Determinants of Nutritional Status Among Children Below Age 5 Years in India: Analysis of Key Nutrition Indicators Based on Four National Family Health Survey (NFHS) During 1998 -2021

Ph.D. Scholar: Mr. Santosh Saruk

Guide: Dr. Rajesh Dase

Subject: Community Medicine

Members Suggested incorporating the following changes in the Research Protocol

- Mention major determinants step wise
- Mention spatial and geographical determinants

Members suggested to think on the study design and resubmit

6. Antibiotic Profile, Biofilm Formation and Biofilm Associated Genes Detection in Stenotrophomonas Maltophilia

Ph.D. Scholar: Mr. Kamlesh Kule

Guide: Dr. Manjushree Mulay

Subject: Medical Microbiology

Members Suggested incorporating the following changes in the Research Protocol

- Check the formula for sample size in consultation with Statistician
- Mention inclusion criteria from patients
- Make analysis separately
- Consent to be taken from institutions

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

7. Application of Artificial Neural Network for Early Prediction of Diabetes.

Ph.D. Scholar: Mr. Jagdish Powar

Guide: Dr. Rajesh Dase

Co-guide: Dr. Deepak Bhosle

Subject: Biostatistics

Research Protocol is approved.

8. Study of Association of PTPN22 Gene Polymorphism in Subjects with Vitiligo

Ph.D. Scholar: Ms. Apurva Patil

Guide: Dr. Parineeta Samant,

Co-guide: Dr. Shylaja Someshwar

Subject: Medical Biochemistry

Members Suggested incorporating the following changes in the Research Protocol

- Modify participation and information sheet
- Add ascend form along with the consent for witness
- Modify objectives
- Modify Translation Sheet

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

9. Student- Centric Collaborative Method of Teaching-Learning for Bachelor of Physiotherapy (BPT) Graduates

Ph.D. Scholar: Dr. Mamta Shetty

Guide: Dr. Mrunal Pimparkar

Co-guide: Dr. Rajani Mullerpatan

Subject: Health Profession Education

Members Suggested incorporating the following changes in the Research Protocol

- Correct informed consent form

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

10. Study of T Cell Immunomodulation and Stress Biomarkers in Subjects Enrolled for Heartfulness Meditation Program

Ph.D. Scholar: Ms. Sanjana T. Philip

Guide: Dr. Mansee Thakur

Co-guide: Dr. Nishant Vyas

Subject: Medical Biotechnology

Members Suggested incorporating the following changes in the Research Protocol

- Put a slide of Heartfulness of Medical Technique of meditation with content and advantages
- In Phase 2 Intervention, Mention the time schedule
- Modify consent form
- Mention Blood sugar and Nor-adrenaline levels

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

11. Pharmacogenetic and related factors affecting Glycemic Control and application for developing Glycemic Prediction tool for Personalized Counselling in Type 2 Diabetes Mellitus

Ph.D. Scholar: Shouvik Ganguly

Guide: Dr. Ipseeta Ray

Co-guide: Dr. Sandeep Rai

Subject: Medical Pharmacology

Research Protocol is approved.

12. **Development and Evaluation of a Competency Based Teaching Module in Physiotherapy Program: A Mixed Method Design**

Ph.D. Scholar: Siddharth Mishra

Guide: Dr. Mrunal Pimparkar

Co-guide: Dr. Vrushali Panhale

Subject: Health Profession Education

Members Suggested incorporating the following changes in the Research Protocol

- Modify objectives
- Sample size: All admitted students, may be mentioned.

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

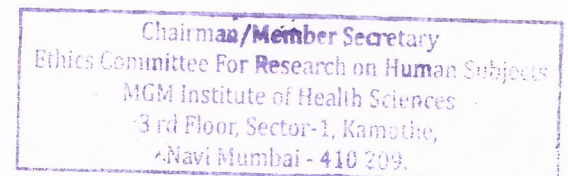
IV. Any other matter with the permission of Chair:

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.



Dr. P.N. Khandelwal
Member Secretary





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Minutes of the Meeting of Ethics Committee for Research on Human Subjects

Meeting of the Ethics Committee for Research on Human Subjects of MGM Institute of Health Sciences, Navi Mumbai was held on 28th March, 2023 at 10.00 am through dual mode.

The following members had participated in the meeting:

1. Dr. Alaka Deshpande: Chairperson
2. Dr. Shirish Joshi: Medical Scientist
3. Dr. Savita Shahani: Medical Scientist
4. Dr. Ipseeta Ray: Scientific Member
5. Dr. Raman P Yadav: Scientific Member
6. Dr. Sheela Hosamani: Legal Expert
7. Mr. J. C. Sharma: Social Scientist
8. Mr. Satej Daniel Dhiwar: Lay Person
9. Dr. Prakash N Khandelwal: Member Secretary

Following members intimated their inability to attend the meeting

1. Dr. G.S Narshetty : Clinician Member
2. Dr. Chander P Puri: Scientific Member
3. Dr. Smita Mahale: Scientific Member
4. Dr. Prakash P Doke: Clinician Member

Director Research was invited for the meeting

The Secretary of ECRHS welcomed all members to the Ethics Committee Meeting and invited Dr. Alaka Deshpande to chair the section and granted the permission to start with meeting.

- I. To confirm the minutes of the meeting held on 29.11.2022
Minutes of the meeting held on dated 29.11.2022 were confirmed by the committee.

II. Research Proposals for Ethical Approval

1. Screening of Individuals at risk for Peripheral Arterial Disease in lower extremity and influence of supervised exercise training on physical function and lower extremity vascularization

Principal Investigator: Dr. Bhoomika Sawant

Guide: Dr. Rajni Mullerpatan

Subject: Physiotherapy

Suggestions:

1. Define the Peripheral Arterial Disease
2. Use of proper scientific terms in the objectives
3. Involvement of one clinician in the study
4. Age limit 40-80 instead of 45
5. Mention the site of fixing the BP cuff.

Research proposal is approved subject to incorporation of the changes as suggested and submit revised proposal to the Research & development cell.

2. Assessment of various Biomarkers in patients of sepsis admitted in Tertiary care centre before and after Treatment

Ph.D. Scholar: Ms. Dhanshri Patil

Guide: Dr. Dhananjay Bhale

Co-guide: Dr. Pramod Bhale

Subject: Medical Biochemistry

Suggestion:

1. Revise sample size
2. Correct the proposals using proper scientific words with relevant citations.
3. Provide revised consent and patients information sheet

Research proposal is approved subject to incorporation of the changes as suggested and submit revised proposal to the Research & development cell.

3. Development of a Prediction app for sleep quality, Activities of Daily living, and functional outcome in patient with stroke

Ph.D. Scholar: Dr. Gaurav Mhaske

Guide: Dr. Tabish Fahim

Subject: Physiotherapy

Suggestion:

1. Modify the introduction
2. Involve clinician according to expertise
3. Revise the consent form

Research proposal is approved subject to incorporation of the changes as suggested and submit revised proposal to the Research & development cell.

4. **TB Preventive Therapy uptake and status of Program implementation in selected districts of Maharashtra: A Mixed Method study**
Ph.D. Scholar: Dr. Harshad Lande
Guide: Dr. Swati Mahajan
Subject: Community Medicine
Suggestion:
Approved
5. **Eutopic endometrial cell repertoire in women presenting different subtypes of endometriosis and its association with endometrial receptivity**
Principal Investigator: Dr. Geetanjali Sachdeva
Scholar: Ms. Itti Munshi
Collaboration: Dr. Pratima Thamke (MGM)
Subject: Obstetrics and Gynecology
Suggestion:
Approved
6. **Impact of accreditation process in improvement of quality and quality perception of stakeholders in a Tertiary Care Medical college hospital in Raigad district.**
Ph.D. Scholar: Ms. Madhubala Nair
Guide: Dr. Prasad Waingankar
Subject: Hospital Administration
Suggestion:
Mention the correct strength of the bed in the hospital
Obtain the permission for procurement of the data.

Research proposal is approved subject to incorporation of the changes as suggested and submit revised proposal to the Research & development cell.
7. **A process evaluation of culturally appropriate pain science education for Marathi-speaking people with chronic low back pain**
Ph.D. Scholar: Dr. Rinkle Hotwani
Guide: Dr. Tabish Fahim
Subject: Physiotherapy
Suggestion
Describe the causative factor of pain, ex. Low back pain due to muscular, vaginal, TUI infection driven pain.

Approved.

8. **A Study of Trend, Estimation and Determinants of Nutritional Status among Children below age 5 years in India: Analysis of key nutrition indicators based on four National Family Health Survey (NFHS) during 1998=2021.**

Ph.D. Scholar: Mr. Santosh Saruk

Guide: Dr. Rajesh Dase

Subject: Biostatistics

Suggestion:

Incorporate the data from national level state wise in the study

Research proposal is approved subject to incorporation of the changes as suggested and submit revised proposal to the Research & development cell.

III. **Clinical Trials for Ethical Approval**

1. **Prospective, Randomized, Multi-centric, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of KSM-66 Ashwagandha (Withania somnifera) in Adults Experiencing High Stress and/or Anxiety**

Principal Investigator: Dr. P. N. Khandelwal

Department: Pharmacology

Suggestion:

Provide the details of KSM-66

Addition of Psychiatrist

Approved

2. **A Prospective, Randomized, Double-Blind, Placebo Controlled Clinical Study to evaluate the effects of KSM-66 Ashwagandha Capsule (300 mg) on skin and hair health in Healthy Men and Women**

Principal Investigator: Dr. Shylaja Someshwar

Department: Dermatology

Suggestion:

Provide the details of KSM-66

Addition of Psychiatrist

Approved

3. **A Prospective, Randomized, Double-Blind, Placebo Controlled Clinical Study to evaluate the Efficacy and Safety of Ashwagandha Lotion in Photo-Aged Healthy Subjects**

Principal Investigator: Dr. Shylaja Someshwar

Department: Dermatology

Suggestion:

If any query arises change the name of contact person
Addition of Psychiatrist

Approved

4. A Prospective, Randomized, Double-Blind, Placebo Controlled Clinical Study to evaluate the Efficacy and Safety of Ashwagandha Serum Application on the Hair Health in Healthy Adults.

Principal Investigator: Dr. Meghna Phiske
Department: Dermatology

Suggestion:

Provide the meaning of Ashwagandha serum
If any query arises change the name of contact person
Correct consent form

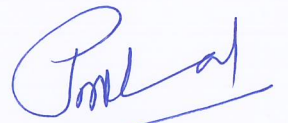
Approved

IV. Any other matter with the permission of Chair:

The projects directed any modification or suggestions by the committee must be incorporated and submit revised proposal/compliance in the clinical trial to the Research & Development cells & secretary of the Ethics Committee for final approval.

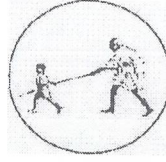
Meeting ended with thanks to the Chair.

- Agenda of the meeting and attendance sheet included for reference.



Dr. P.N. Khandelwal
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.



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Minutes of the Meeting of Ethics Committee for Research on Human Subjects

Meeting of the Ethics Committee for Research on Human Subjects of MGM Institute of Health Sciences, Navi Mumbai was held on 4th July, 2023 at 11.00 am through dual mode.

The following members had participated in the meeting:

1. Dr. Alaka Deshpande: Chairperson
2. Dr. Smita Mahale: Scientific Member
3. Dr. Prakash P Doke: Clinician Member
4. Dr. Shirish Joshi: Medical Scientist
5. Dr. Savita Shahani: Medical Scientist
6. Dr. Ipseeta Ray: Scientific Member
7. Dr. Raman P Yadav: Scientific Member
8. Dr. Sheela Hosamani: Legal Expert
9. Mr. J. C. Sharma: Social Scientist
10. Mr. Satej Daniel Dhiwar: Lay Person
11. Dr. Prakash N Khandelwal: Member Secretary
12. Dr. Chandramani Pathak: Director Research

Following members intimated their inability to attend the meeting

1. Dr. G.S Narshetty : Clinician Member
2. Dr. Chander P Puri: Scientific Member

Director Research was invited for the meeting and welcomed 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 29.03.2023
Minutes of the meeting dated 29.03.2023 were read and confirmed.

Research Proposals for Ethical Approval

1. A phase IV open label multicentre observational study to record the safety of AScVS (Anti Scorpion Venom Serum) administered as a standard treatment for scorpion sting

Principal Investigator: Dr. Vivek S. Natu

Presented by: Dr. Vishwas Sovani

Type of Study: Clinical Trial

Comments

Committee suggested following corrections and asked to submit revised proposal.

- One Co-PI should be from MGM Medical college & Hospital.
- Consent from all the PI, Biodata, Medical Registration number and Biodata.
- Description about the product.
- Clarity in the protocol.
- Revised consent
- Confidentiality of Personal data & maintenance of the case study record
- Remove compensation

Decision:

Research Protocol will be approved further evaluation of subject to incorporation of the changes as suggested by the committee.

2. **Validation of Biochemical Assays: Extraction of DNA and RNA from Clinical Samples**
Principal Investigator: Dr. Chandramani Pathak
Co-Principal Investigator: Dr. Mansee Thakur
Type of Study: Consultancy Project

Comments

Committee suggested following corrections and asked to submit revised proposal.

- Define sample for isolation of mtb. Suggested to isolate the bacteria from scutum.
- Describe inclusion and exclusion criteria for Blood and saliva sample in the protocol
- Describe the tissue may be used as pathological patients or from normal human.
- Define tissue type and one similar type of tissue may used for the study.
- Provide the description of which gold standard kit will be used for validation.

Decision:

Research Protocol will be approved further evaluation of subject to incorporation of the changes as suggested by the committee.

3. **Effect of Heartfulness Meditation on Physiological and Psychological parameters among adults residing in rural areas of Ahmednagar district of Maharashtra**
Ph.D. Scholar: Mr. Sandeep Thombare
Ph.D. Guide: Dr. Jyoti Chaudhari
Type of Study: Ph.D. Research Project

Comments:

Committee suggested following corrections and asked to submit revised proposal.

Provide description of heartfulness & yoga training & more refine the objective as a comparative study for best outcomes.

Decision:

Research Protocol is approved with subject to incorporation of the changes as suggested by the committee.

IV. Any other matter with the permission of Chair:

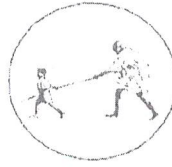
The committee directed that any modifications suggested by the committee must be incorporated and the revised protocol to be submitted and presented before the Ethics Committee for final approval.

Meeting ended with thanks to the Chair.



Dr. P.N. Khandelwal
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.



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Minutes of the Meeting of Ethics Committee for Research on Human Subjects

Meeting of the Ethics Committee for Research on Human Subjects of MGM Institute of Health Sciences, Navi Mumbai was held on 18th August, 2023 at 10.30 am through dual mode.

The following members had participated in the meeting:

1. Dr. Alaka Deshpande: Chairperson
2. Dr. Smita Mahale: Scientific Member
3. Dr. Savita Shahani: Medical Scientist
4. Dr. Ipseeta Ray: Scientific Member
5. Dr. Raman P Yadav: Scientific Member
6. Dr. Sheela Hosamani: Legal Expert
7. Mr. J. C. Sharma: Social Scientist
8. Mr. Satej Daniel Dhiwar: Lay Person
9. Dr. Prakash N Khandelwal: Member Secretary
10. Dr. Chandramani Pathak: Director Research

Following members intimated their inability to attend the meeting

1. Dr. G.S Narshetty : Clinician Member
2. Dr. Chander P Puri: Scientific Member
3. Dr. Prakash P Doke: Clinician Member
4. Dr. Shirish Joshi: Medical Scientist

Director Research was invited for the meeting. The Secretary welcomed 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 04.07.2023
Minutes of the meeting dated 04.07.2023 were read and confirmed.

II. Research Proposals for Ethical Approval

1. A phase IV open label multicentre observational study to record the safety of AScVS (Anti Scorpion Venom Serum) administered as a standard treatment for scorpion sting

Principal Investigator: Dr. Vivek S. Natu

Presented by: Dr. Vishwas Sovani

Type of Study: Clinical Trial

Comments:

The revised proposal was presented by Dr. Vishwas Sovani to the ethics Committee was not satisfactory due to lack of informations (data of clinical trials phase I, II & III) and unsatisfactory response. The proposal aimed to carry out Post Marketing Surveillance-Phase IV study and Dr Sovani claimed that it is not a Clinical trial. The agreement provided by applicant is revealing "Clinical trail agreement" and signed by itself Dr. Sovani in behalf of Authorized signatory. The committee has shown the apprehension for presenting the proposal by Dr. Vishwas Sovani in behalf of Principal Investigators and Co-investigators. The committee was not found this proposal satisfactory for ethical approval.

Decision: Not recommended

2. Validation of Biochemical Assays: Extraction of DNA and RNA from Clinical Samples

Principal Investigator: Dr. Chandramani Pathak

Co-Principal Investigator: Dr. Mansee Thakur

Type of Study: Consultancy Project

Comments: Not applicable

Decision: Revised Research Protocol was approved for the study.

3. Re-configuration of management of osteoporosis in children and adults: a shift in paradigm from treatment to prevention using a novel biotechnology device "Swasthya for Asthi-Tavasya"

Principal Investigator: Dr. Rajani Mullerpatan; **Co-Principal Investigator:** Dr. Triveni Shetty,

Dr. Dayanand Shetty, Dr. Sunil Wagh

Type of Study: DBT EMR Grant

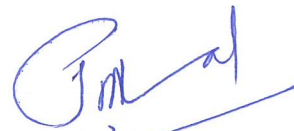
Comments: Committee suggested to provided appropriate changes incorporation of inclusion and exclusion criteria.

Decision: Research Protocol was approved for the study.

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.



Dr. P.N. Khandelwal

Member Secretary

