

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 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

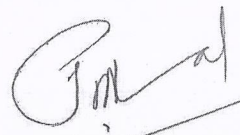
Comments: Committee suggested to provided appropriate changes incorporation of inclusion and exclusion criteria.

Decision: Research Protocol was approved for the study.

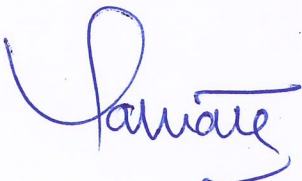
IV. Any other matter with the permission of Chair:

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


21/12/2024

Director

Research & Development
MGM Institute of Health Sciences
Kamothe, Navi Mumbai-410209, India

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



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MGM Educational Campus, Sector 1, Kamothe, Navi Mumbai-410209, India

Tel : 022-27432471/27432994; Website : www.mgmuhs.com

Minutes of the Meeting of Ethics Committee for Research on Human Subjects (ET/08/2023)

Meeting of the Ethics Committee for Research on Human Subjects of MGM Institute of Health Sciences, Navi Mumbai was held on **26 September, 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. 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

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 18.08.2023
Minutes of the meeting dated 18.08.2023 were read and confirmed.

II. Research Proposals for Ethical Approval

1. Molecular Detection of New Delhi Metallo β Lactamase (*bla_{NDM-1}*) Gene From Multi Drug Resistant Enterobacteriaceae Isolated From Patients Admitted to a Tertiary Care Hospital

Ph.D. Scholar: Aishwarya Warang

Guide: Dr. Sharvari A. Samant

Subject: Microbiology

Campus: Navi Mumbai

Suggestions:

- Committee asked to find out number of carbapenem drug resistance cases in past one year or six months at the ICU patient at MGM hospital to justify the sample size in the proposed study.
- Corrections in the consent form is required in all language. Use "Informed Voluntary Consent word" in the consent form
- Include one Clinician in the study as Co-Guide
- Provide clinical Proforma & Biosafety disclosure
- Submit the Revised protocol.

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

2. Dysbiosis in Gut Microbiome of TB Patients and Effect of Antitubercular Drugs on Gut Microbiota Using Genetic Analysis Dysbiosis Test

Ph.D. Scholar: Debapriya Chakraborty

Guide: Dr. Samir Pachpute

Subject: Microbiology

Campus: Navi Mumbai

Suggestions:

- Corrections in the consent form is required in all language. Use "Informed Voluntary Consent word" in the consent form
- Provide clinical Proforma & Biosafety disclosure
- Include one Clinician in the study as Co-Guide
- Submit the Revised protocol.

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

3. Unraveling the Gut Microbiome: A Genetic Analysis Dysbiosis Test for Identification and Characterization of Gut Microbiota in Inflammatory Bowel Disease Patients

Ph.D. Scholar: Sohini Sujit Mitra

Guide: Dr. Samir Pachpute

Subject: Microbiology

Campus: Navi Mumbai

Suggestions:

- Revise the tile
- Corrections in the consent form is required in all language. Use “Informed Voluntary Consent word” in the consent form
- Provide clinical Proforma & Biosafety disclosure

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

4. Effect of Targeted Nursing Interventions on Maternal and Neonatal Outcomes Among Pregnant Women With Gestational Diabetes Mellitus Attending Tertiary Care Maternity Hospital

Ph.D. Scholar: Mrs. Maria Preethi Mathew

Guide: Dr. Prabha K. Dasila

Subject: Nursing

Campus: Navi Mumbai

Suggestions: Nil

Research Protocol is approved.

5. Ocular Morbidity Profile and Ocular Care Service Barriers Among School Going Children in Rural and Tribal Areas of Maharashtra

Ph.D. Scholar: Rohit I Gupta

Guide: Dr. Varshav Gore

Subject: Optometry

Campus: Navi Mumbai

Suggestions:

Corrections in the consent form is required in all language. Use “Informed Voluntary Consent word” in the consent form

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

6. Assessment of Psychological and Biochemical Parameters: Effect of Heartfulness Yoga and Meditation in Mental Health

Ph.D. Scholar: Mr. Subodh Rahate

Guide: Dr. Mansee Thakur

Co-guide: Dr. Shubhangi Dere

Co-guide: Dr. Veronique Nicolai

Subject: Medical Biotechnology

Campus: Navi Mumbai

Suggestions:

Corrections in the consent form is required in all language. Use “Informed Voluntary Consent word” in the consent form

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

7. Molecular and Cellular Assessment Using Heartfulness Meditation and Yoga as a Preventive Intervention in Hypertension

Ph.D. Scholar: Ms. Pooja Singh

Guide: Dr. Mansee Thakur

Co-guide: Dr. Mitesh Thakkar

Co-guide: Dr. Veronique Nicolai

Subject: Medical Biotechnology

Campus: Navi Mumbai

Suggestions:

Corrections in the consent form is required in all language. Use "Informed Voluntary Consent word" in the consent form

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

8. Identifying Molecular Target-Based Colon Cancer Specific Drugs and Natural Flavonoids for Therapeutic Intervention of Human Colorectal Cancer

Ph.D. Scholar: Aafrin Mohd. Jafar Ansari

Guide: Dr. Chandramani Pathak

Co-guide: Dr. Mansee Thakur

Subject: Medical Biotechnology

Campus: Navi Mumbai

Suggestions: Nil

Research Protocol is approved.

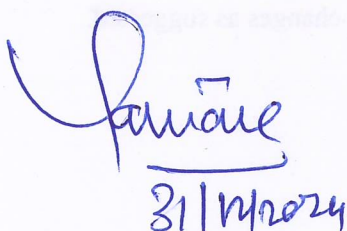
IV. Any other matter with the permission of Chair:

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.



Dr. P.N. Khandelwal
Member Secretary



31/11/2024

Director

Research & Development
MGM Institute of Health Sciences
Kamothe, Navi Mumbai-410209, India

Chairman/Member Secretary
Ethics Committee For Research on Human Subjects
MGM Institute of Health Sciences
3 rd Floor, Sector-1, Kamothe,
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Minutes of the Meeting of Ethics Committee for Research on Human Subjects (ET/09/2023)

Meeting of the Ethics Committee for Research on Human Subjects of MGM Institute of Health Sciences, Navi Mumbai was held on **10th October, 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. 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. Dr. Prakash N Khandelwal: Member Secretary
9. 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. Mr. J. C. Sharma: Social Scientist
5. Mr. Satej Daniel Dhiwar: Lay Person

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 26.09.2023
Minutes of the meeting dated 26.09.2023 were read by member secretary of ECRH and minutes of the meeting was confirmed.

II. Research Proposals for Ethical Approval

1. Development of Comprehensive Nutrition Intervention Package for Prevention and Control of Anaemia Among Adolescent Girls

Ph.D. Scholar: Chethana C

Guide: Dr. Priyanka Parekh

Subject: Clinical Nutrition

Campus: Navi Mumbai

Suggestions:

- Committee suggested to change the title
- Corrections in the consent form is required in all language. Use “Informed Voluntary Consent word” in the consent form
- Change the Contact information in the Consent form as
Name of the PI:
Research & Development Cell
MGM Institute of Health Sciences, Navi Mumbai
Phone No. 022- 27432471/27432994 Email: ecrhs@mgmuhs.com

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

2. Association of Mid-Day Meal Consumption with Nutritional Status, and Micronutrient Deficiencies among Mid-Day Meal Beneficiaries

Ph.D. Scholar: Rashmi Kulkarni

Guide: Dr. Priyanka Parekh

Subject: Clinical Nutrition

Campus: Navi Mumbai

Suggestions:

- Committee suggested to change the title and include “School Children”
- Include the Socio-economic status of the children in the study
- Provide nutrient description of mid-day meal provided by the school.
- Include the parameter for Measurement of micronutrients, if possible.
- Corrections in the consent form is required in all language. Use “Informed Voluntary Consent word” in the consent form
- Change the Contact information in the Consent form as
Name of the PI:
Research & Development Cell
MGM Institute of Health Sciences, Navi Mumbai
Phone No. 022- 27432471/27432994 Email: ecrhs@mgmuhs.com

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

3. Genetic Evaluation of Ventricular Septal Defect in Children of Paediatric Age

Ph.D. Scholar: Dr. Anjali Sabnis
Guide: Dr. Mansee Thakur
Co-guide: Dr. Snehal Kulkarni
Co-guide: Dr. Radha Joshi
Co-guide: Dr. V. Babu Rao
Subject: Medical Genetics
Campus: Navi Mumbai

Suggestion:

Corrections in the consent form is required in all language. Use "Informed Voluntary Consent word" in the consent form

- Change the Contact information in the Consent form as
Name of the PI:
Research & Development Cell
MGM Institute of Health Sciences, Navi Mumbai
Phone No. 022- 27432471/27432994 Email: ecrhs@mgmuhs.com

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

4. Assessment of Quality of Life (QOL) In Trans-Tibial Amputees Through Prosthetic Service: A Comprehensive Study of Supports Provided by Different Rehabilitation Centre/ Hospitals Across Mumbai

Ph.D. Scholar: Mrs. Deepshika Raut
Guide: Dr. Prasad Waingankar
Subject: Hospital Administration
Campus: Navi Mumbai

Suggestions:

- Change the consent form and use appropriate word "Informed Voluntary Consent for the study.....for the research purpose".
- Change the Contact information in the Consent form as
Name of the PI:
Research & Development Cell
MGM Institute of Health Sciences, Navi Mumbai
Phone No. 022- 27432471/27432994 Email: ecrhs@mgmuhs.com

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

5. Effect of Select Rare Diseases on Individual and Social Security Services in a Tertiary Care Hospital, Raigad District, Maharashtra

Ph.D. Scholar: Sangeeta D. Choundhary
Guide: Dr. Prasad Waingankar
Subject: Hospital Administration
Campus: Navi Mumbai

Suggestions:

- Committee suggested to change the title
- Consider rare disease in India
- Provide rationale for selection of the disease.
- Corrections in the consent form is required in all language. Use “Informed Voluntary Consent word” in the consent form
- Change the Contact information in the Consent form as
Name of the PI:
Research & Development Cell
MGM Institute of Health Sciences, Navi Mumbai
Phone No. 022- 27432471/27432994 Email: ecrhs@mgmuhs.com

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

6. A Situational Analysis of NATIONAL Programme for Prevention and Control of Non-Communicable Diseases (NP-NCD) In Raigad District, Maharashtra

Ph.D. Scholar: Dr. Noopur Kulkarni

Guide: Dr. Prasad Waingankar

Subject: Community Medicine

Campus: Navi Mumbai

Suggestions:

- Change the consent form and use appropriate word “Informed Voluntary Consent for the study.....for the research purpose”.
- Change the Contact information in the Consent form as
Name of the PI:
Research & Development Cell
MGM Institute of Health Sciences, Navi Mumbai
Phone No. 022- 27432471/27432994 Email: ecrhs@mgmuhs.com

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

7. Comprehensive Risk Factor Analysis and Effect of Novel Postural Correction Intervention on Physical Function in Dentists with Spine Pain- A Mixed Method Study

Ph.D. Scholar: Ms. Victoria David Kuttan

Guide: Dr. Bela Agarwal

Co-guide: Dr. Rajani Mullerpatam

Subject: Physiotherapy

Campus: Navi Mumbai

Suggestions:

- Use appropriate terminology muscular skeletal pain in the spine
- Corrections in the consent form is required in all language. Use “Informed Voluntary Consent word” in the consent form.
- Change the Contact information in the Consent form as
Name of the PI:
Research & Development Cell

Ph.D. Scholar: Dr. Sana Gaffoor Khan
Guide: Dr. G.A. Shroff
Subject: Anatomy
Campus: Aurangabad

Suggestions:

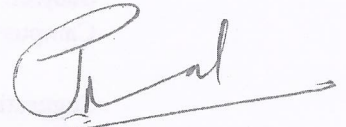
- Change the title with addition spontaneous aborted fetuse
- Provide nutritional parameter details of mother in the protocol
- Revise the consent form
- Corrections in the consent form is required in all language. Use "Informed Voluntary Consent word" in the consent form
- Change the Contact information in the Consent form as
Name of the PI:
Research & Development Cell
MGM Institute of Health Sciences, Navi Mumbai
Phone No. 022- 27432471/27432994 Email: ecrhs@mgmuhs.com

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

IV. Any other matter with the permission of Chair:

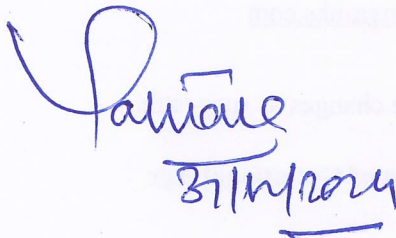
The committee directed that any modifications suggested by the committee must be incorporated and the revised protocol to be submitted and presented before the Ethics Committee for final approval.

Meeting ended with thanks to the Chair.



Dr. P.N. Khandelwal
Member Secretary

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



31/11/2024

Director
Research & Development
MGM Institute of Health Sciences
Kamothe, Navi Mumbai-410209, India

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

8. Study on the Short Term (12 Weeks) And Long Term (52 Weeks) Of Physiotherapy Intervention on Musculoskeletal Pain, Physical Function and Health Related Quality of Life of Bharatanatyam Dancers

Ph.D. Scholar: Ms. Akhila Natesan

Guide: Dr. Rajani Mullerpatam

Subject: Physiotherapy

Campus: Navi Mumbai

Suggestions:

- Sample size should be statistically appropriate.
- Corrections in the consent form is required in all language. Use "Informed Voluntary Consent word" in the consent form
- Change the Contact information in the Consent form as
Name of the PI:
Research & Development Cell
MGM Institute of Health Sciences, Navi Mumbai
Phone No. 022- 27432471/27432994 Email: ecrhs@mgmuhs.com

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

9. Morphometrical Study and Histogenesis of Human Fetal Spleen at Different Gestational Age

Ph.D. Scholar: Dr. Smita Shinde

Guide: Dr. G.A. Shroff

Subject: Anatomy

Campus: Aurangabad

Suggestions:

- Change the tile with addition spontaneous aborted fetuse
- Revise the consent form & corrections in the consent form is required in all language. Use "Informed Voluntary Consent word" in the consent form
- Change the Contact information in the Consent form as
Name of the PI:
Research & Development Cell
MGM Institute of Health Sciences, Navi Mumbai
Phone No. 022- 27432471/27432994 Email: ecrhs@mgmuhs.com

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

10. Morphometry of Human Fetal Long Bones for Estimation of Gestational Age



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Sector -1, Kamothe, Navi Mumbai – 410 209

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Minutes of the Meeting of Ethics Committee for Research on Human Subjects (ECRHS) held on 01.06.2024

The Meeting of the Ethics Committee for Research on Human Subjects was held on 01st June 2024 at 10.00 am at the IQAC Hall, 3rd Floor, MGM Institute of Health Sciences, Navi Mumbai.

The following members had participated in the meeting:

Name of the Members

Dr. Alaka Deshpande	: Chairperson
Dr. Prakash P. Doke	: Clinician Member
Dr. Shirish Joshi	: Medical Scientist
Dr. Savita Shahani	: Medical Scientist
Dr. Smita Mahale	: Scientific Member
Dr. Raman P. Yadav	: Scientific Member
Dr. Sheela S. Hosamani	: Legal Expert
Dr. Jagdish C. Sharma	: Social Scientist
Mr. Satej D. Dhiwar	: Lay Person
Dr. Prakash N. Khandelwal	: Member Secretary
Dr. Chandramani Pathak	: Director (Research & Development)

The following members conveyed their inability to join the meeting:

Dr. G.S. Narshetty	: Clinician Member
Dr. Chander P. Puri	: Scientific Member
Dr. Ipseeta Ray	: Scientific Member

Director Research welcomed the Members, Guides and Students for the meeting and started with the agenda.

Director Research sorted the permission of the Chairperson to begin with the meeting. The agenda of the meeting was taken up.

I. To confirm the previous minutes of the meeting

Minutes of the Meeting of ECRHS held on 10.10.23 were read and confirmed.

II. Research Proposals for Ethical Approval:

1. To study the association of HbA1C titer, Lipid Profile and S Creatinine on severity of sensorineural hearing loss in patients of type II Diabetes Mellitus

Ph.D. Scholar: Dr. Swapnil Gosavi, Navi Mumbai

Guide: Dr. Kalpana Rajiv Kumar

Subject: ENT

Suggestions:

1. Change the introduction as T2DM is metabolic disorder rather than endocrine disorder and describe pathogenesis of diabetes scientifically.
2. Remove ICU patients
3. Remove hospitalized patients
4. Change sampling method as Random sampling
5. Patient information should not be disclosed
6. Provide patient consent form in local language with the help of concern person, don't use google translator.

Remarks: Submit revised proposal within 30 days. Proposal will be approved after subject to incorporation of the changes as suggested.

2. Identifying molecular target-based colon cancer specific drugs and natural flavonoids to unveil its synergistic effect in regulation of cell proliferation of Human colorectal cancer cells

Name of PI: Dr. Chandramani Pathak

Type of Study: Single Center

Name of Sponsor: Lady Tata Memorial Trust

Suggestions:

1. refine the abstract and title. As no human procedure is involved so that exempted from the review.

Remarks: The project is technically approved.

3. Comparison of joint kinematics in healthy adults during walking, running, cycling and Activities of Daily Living (ADLs) using 2D motion capture GaitON system and 3D motion capture system: A Validation study

Name of PI: Dr. Rajani Mullerpatan

Name of Co-Investigator: Dr. Bela Agarwal

Mr. Siddharth Hans

Dr. Gayatri Suresh

Type of Study: Validation Study

Name of Sponsor: Auptimo Technologies LLP

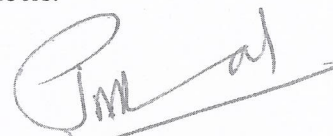
Suggestions:

1. Change as reference standard instead of gold standard.
2. Specify the study is specific to lower limb not for upper limb provide justification.
3. Describe no invasive procedure involve only physical examination will be carried out in the study.
4. No any compensation will be provided to participant as the study is associated with voluntary participation.

Remarks: The project proposal is technically approved subject to incorporation of the changes as suggested. Submit the revised proposal with in 30 days.

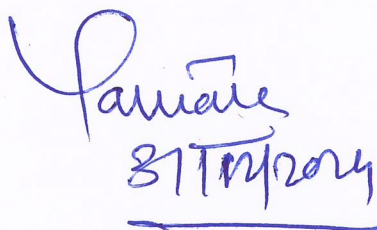
III. Any other matter with the permission of Chair

Meeting ended with vote of thanks to Chairperson and all the Members.



Dr. Prakash N. Khandelwal

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



Director
Research & Development
MGM Institute of Health Sciences
Kamothe, Navi Mumbai-410209, India