



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

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

Meeting of the ECRHS of MGM Institute of Health Sciences, Navi Mumbai was held on **1st December 2017 at 10.00 am** at 3rd Floor, Conference Hall. The following members had participated in the meeting.

1. Dr Alaka Deshpande	:	Chairperson
2. Dr. Chander P Puri	:	Member
3. Dr. J C Sharma	:	Member
4. Dr. Prakash P Doke	:	Member
5. Dr. Abhijit De	:	Member
6. Dr. Shirish Joshi	:	Member
7. Shri E A Patil	:	Member
8. Dr A Bandivdekar	:	Member
9. Dr Savita Shahani	:	Member Secretary
10. Dr. G S Narshetty	:	Member

Dr. Alaka Deshpande Chaired the meeting.

Title : Biomechanical exploration of Suryanamaskar for scientific application in low back pain

Principal Investigator : Dr. Rajani Mullerpatan
Co-Investigator : Dr. Omkar S N, IISc. Bangalore

Members made the following suggestions :

- Protocol to be rewritten incorporating the following suggestions given by the members
- Age group for inclusion criteria to be changed to 18-40yrs
- Mention details of evaluation of functional outcome measures
- Specify how yoga practice will be standardized for enrolled participants so as to maintained uniformity in frequency and duration of yoga practice
- Make exclusion criteria more specific

- Patient information sheet must mention that all these Asanas will be supervised by trained yoga expert and they are not reported to produce any untoward effect
- Revised protocol may be submitted for ECRHS consideration

Title : Comparison of newly developed prosthetic designs against conventional prosthesis in unilateral below/above knee amputation patients

Principal Investigator : Dr. Rajani Mullerpatan
 Co-Investigator's : Dr. Sujatha Srinivasan, IIT Madras and
 Dr. Rupesh Ghyar, IIT Bombay

Members made the following comments :

- Patient of above knee amputation may only be considered to keep uniformity in evaluation , accordingly the title of protocol also require to be changed and evaluation criteria will be restricted to hip kinematics parameter
- Patient with traumatic amputation may only be considered to maintain uniformity in participant selection
- Principal Investigator was asked to confirm if manufacturer of developed prosthetic have taken any permission from regulatory authority for conducting clinical study.

Title : Biomechanical exploration of Yoga for scientific application in Healthcare

Principal Investigator : Dr. Rajani Mullerpatan
 Co-Principal Investigator's : Dr. Omkar S N, IISc Bangalore and
 Mr. Girish, Yoga Expert

Members made the following comments:

- Identification of criteria for selecting healthy volunteer
- Study design may be changed to make a comparative trial to compare healthy volunteers not practicing yoga with those practicing yoga regularly
- Age of participants may be changed to 18-40 years
- Group should have uniformity in yoga practice in terms of frequency and duration of practice
- ECRHS should mention that these Asanas are not reported to cause any adverse effect in healthy volunteer
- Identify the physician to be included in as co-investigator
- Participants should not pay for any of the investigations performed for the study
- Revised protocol incorporating the suggestions may be submitted to ECRHS.

Title : Gait analysis using i-Sens wearable system and 3D motion analysis

Principal Investigator : Dr. Rajani Mullerpatan
Co-Principal Investigator's : Dr. Sujatha Srinivasan, IIT Madras
Mr. Gunjanbhai Patel, IIT Madras

Members made the following comments :

- To keep age group for participants between 18-40 years to avoid variation in data
- Protocol was approved subject to incorporating the changes as suggested

Title : Biomechanical exploration of sports in healthy and specially abled people

Principal Investigator : Dr. Rajani Mullerpatan
Co-Investigator : Dr. Pravin Gaikwad

Members were made the following suggestions :

- Keep inclusion criteria more specific to avoid variation
- Age group for inclusion may be between 18-40years
- Exercise may be standardized to estimate energy consumption
- Protocol to be revised incorporating changes suggested by ECRHS members and submitted to ECRHS

Title : Biomechanical analysis of Indian classical dance forms

Principal Investigator : Dr. Rajani Mullerpatan
Co-Investigator : Dr. Juhi Bharnuke (PT)

Members were made the following suggestions :

- Only one Indian classical dance may be studied initially including all the mudras of that dance
- May study all parameters of energy consumption for each posture and than for full dance form
- Protocol may be resubmitted incorporating changes

Title : Health related physical fitness in children, adolescents and adults

Principal Investigator : Dr. Rajani Mullerpatan
Co-Investigator's : Dr. Mitesh Thakkar and
Dr. Bhageeshri Seth, MGM Hospital, Kamothe.

Project was withdrawn by the Principal Investigator

Title : Distal femur reconstruction with rotating versus fixed hinged megaprosthesis: An objective study using gait analysis and comparative data from normal population

Principal Investigator : Dr Manish Agarwal
Consultant, Surgical & Orthopaedic Oncology
P D Hinduja Hospital & MRC, Mumbai

Co-Investigator's : Prof. B Ravi, IIT Bombay,
Dr. Rajani Mullerpatan and Dr. Manit Gundavda

Members were made the following suggestions :

- Study should be only to compare between 2 treatment modalities, omit comparison to normal population data.
- Analysis should be compare no inferiority of modified treatment to conventional treatment
- Ethical clearance documents from institution performing surgery to be submitted
- Protocol to be modified incorporating the suggestions given by ECRHS members and resubmitted.

Title : Study of variation in human gait on treadmill, even and uneven planes for the development of Exoskeleton

Principal Investigator : Dr. P K Rajendrakumar
Professor, Department of Mechanical Engineering
NIT Calicut

Co-Investigator : Dr. Rajani Mullerpatan

Members were made the following suggestions :

- ECG, heart rate and blood pressure may be monitored as physiological response to various groups
- To assess the mentioned physiological responses a physician may be included as co-investigator
- Primary and secondary objectives of study should be well defined
- Patient information sheet should define the objective of study and other relevant information
- Revised protocol may be submitted to ECRHS for consideration

Title : Biomechanical analysis and energy expenditure of traditional, chair and wall suryanamaskar

Principal Investigator : Dr. Apurv Shimpi
Prof. & Head, Department of Community Physiotherapy
Sancheti College of Physiotherapy, Pune
Co-Investigator : Dr. Rajani Mullerpatan

Members were made the following suggestions :

- Exclusion criteria for study should be more specific
- Kinematics and kinetic data for upper limb also should be obtained
- All participants should be evaluated after practicing various asanas for at least 6 weeks
- Self evaluation of participants may be done using validated quaternary
- Revised protocol may be submitted to ECRHS for consideration


(Member Secretary)



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

Meeting of the ECRHS of MGM Institute of Health Sciences, Navi Mumbai was held on 27th December 2017 at 10.00 am at 3rd Floor, Conference Hall. The following members had participated in the meeting.

1. Dr Alaka Deshpande	:	Chairperson
2. Dr. Chander P Puri	:	Member
3. Dr. J C Sharma	:	Member
4. Dr. Prakash P Doke	:	Member
5. Dr. Abhijit De	:	Member
6. Dr. Shirish Joshi	:	Member
7. Dr A Bandivdekar	:	Member
8. Dr Savita Shahani	:	Member Secretary
9. Dr. G S Narshetty	:	Member

Dr. Alaka Deshpande Chaired the meeting.

Title : Study, evaluate and analysis of MGM TB Detector System

Principal Investigator : Dr. P V Potdar

Co-Investigator's : Dr. Mansee Thakur

Members made the following comments:

- The project was discussed in detail. The consensus was that project is not written with proper microbiological or clinical criteria.
- Aims and Objectives are vague and lack both clinical and microbiological perspective.
- The design of the study has many flaws. Each member has given various inputs to improve the design.
- PI claimed that it uses micro-nano technology however when asked to elaborate the PI admitted that it does not use micro-nano technology.

- The PI did not give any details of the detector system and later said that it was developed by another agency. The PI did not provide NOC or MOU from the agency which has developed the detection system.
- TB programme has started Gene-Xpert exam at large number of centres which can be used to detect MTB in any biological sample. This system is only for detection of MTB in sputum so the claim that it can be used for early detection at a cheaper cost at rural set up seems untenable. The cheapest detection is sputum microscopy which is available in all rural health set up.
- The project does not elaborate how it is superior to GeneXpert and how feasible it is for use in a rural set up.
- The patient information sheet and consent form also needs lot of revision.
- The committee unanimously concluded that the project should be revised and rewritten with proper microbiological and clinical inputs.
- Revised project along with a copy of NOC from the developing agency should be re-submitted for ethical consideration.

Title : Active TB case finding in persons infected with HIV having low CD4 count (<200) by screening with symptom screen & investigations

Principal Investigator : Dr. P V Potdar

Co-Investigator's : Dr. Alka Patnaik
 Dr. C D Kulkarni
 Dr. Harapriya Kar
 Dr. Prem Maurya

- Intends to study Tuberculosis in new HIV patients with CD4 <200. PI appeared oblivious to Government of India's ART programme. At present 3 drug ART is started to all seropositive patients, immediately after detection irrespective of CD4 counts. Therefore it is not feasible to get 400 new HIV-TB cases with CD4 <200.
- Secondly the PI will be conducting the study at various ART centres however their consent was not taken. In fact if study material is to be used from various Institutions the approval from respective IECs will also be required.
- It was suggested to modify the project as an observational study and collect data on MDR TB in HIV cases, their presentation, relation to serostatus, response to treatment etc. This study can be done at various DOT plus centres. Accordingly the project should be resubmitted.

Title : Biomechanical analysis and energy expenditure of traditional Chair and wall suryanamaskar

Principal Investigator : Dr. Apurv Shimpi

Co-Investigator : Dr. Rajani Mullerpatan

Protocol was approved unanimously

Title : Biomechanical exploration of Suryanamaskar for scientific application in low back pain

Principal Investigator : Dr. Rajani Mullerpatan

Co-Investigator's : Dr. Omkar S N, IISc., Bangalore
Mr. Girish

Protocol was approved unanimously

Title : Biomechanical exploration of Bharatanatyam dance postures

Principal Investigator : Dr. Juhi Bharnuke

Co-Investigator's : Dr. Rajani Mullerpatan

Protocol was approved unanimously.

Title : Distal femur reconstruction with rotating versus fixed hinged megaprosthesis: An objective study using gait analysis and comparative data from normal population

Principal Investigator : Dr. Manish Agarwal

Co-Investigator's : Dr. Rajani Mullerpatan
Prof. B Ravi
Dr. Manit Gundavda


Protocol was approved subject to submitting permission from Ethics Committee of PD Hinduja Hospital.

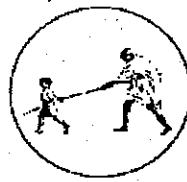
Title : Comparison of newly developed prosthetic designs against conventional prosthesis in unilateral below/above knee amputation patients.

Principal Investigator : Dr. Rajani Mullerpatan

Co-Investigator : Dr. Sujatha Srinivasan, IIT Madras

Protocol was approved unanimously.


Dr. Savita Sahani
(Member Secretary)



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

Meeting of the ECRHS of MGM Institute of Health Sciences, Navi Mumbai was held on 28th February, 2018 at 10.00 am at 3rd Floor, Conference Hall. The following members had participated in the meeting.

1. Dr Alaka Deshpande	:	Chairperson
2. Dr. Abhijit De	:	Member
3. Dr. Sirish Joshi	:	Member
4. Dr A Bandivdekar	:	Member
5. Dr Savita Shahani	:	Member Secretary
6. Dr. G S Narshetty	:	Member
7. Shri E A Patil	:	Member
8. Shri L V Patil	:	Member

Dr. Alaka Deshpande Chaired the meeting.

Title : Study, evaluate and analysis of MGM TB Detector System

Principal Investigator : Dr. P V Potdar

Co-Investigator's : Dr. Mansee Thakur

In response to the query raised in earlier meeting of ECRHS dated 27th December 2017. PI clarified that the MGMTB Detector will be used only for the suspected Pulmonary Tuberculosis Cases using patient's sputum only. PI also clarified regarding the use of micro-nanotechnology mentioning that, as a ramification for some procedure this technology was being used during the development of TB Detector.

- Members suggested only to take Pulmonary Tuberculosis cases, which may be smear negative but diagnosed radiologically/smear positive cases
- Smear positive and culture negative cases also may be included
- The inclusive criteria will be only fresh diagnosed cases
- To incorporate Patient Information Sheet and Informed Consent form in English and its translation in regional language.

The Research project was approved subject to the incorporation above mentioned changes.

Title : Intensify TB case finding in persons infected with HIV by Symptom screening and using high quality investigations

Principal Investigator : Dr. P V Potdar
Co-Investigator's : Dr. Alka Patnaik
Dr. C D Kulkarni
Dr. Harapriya Kar
Dr. Prem Maurya

- Members suggested to modify the title of the Research Project by deleting the word "Symptom Screening"
- Sample selection should be all newly diagnosed HIV positive cases, excluding the pregnant women
- To incorporate Patient Information Sheet and Informed Consent form in English and its translation in regional language.
- The Research project was approved subject to the incorporation above mentioned changes.

Title : A multicenter, randomized double-blind placebo-controlled Phase 3 study to evaluate the efficacy and safety of Baricitinib. In adult patients with moderate to severe atopic dermatitis

Principal Investigator : Dr. Hemangi Jerajani

Study can only be started after permission of regulatory authorities. If any additional Pharmacokinetic/Pharmacodynamic studies required to be done in participants appropriate permission from regulatory authority must be obtained.
The project was approved unanimously.

Title : A phase 3 multicenter, double-blind study to evaluate the long Term safety and efficacy of baricitinib in adult patients with atopic Dermatitis

Principal Investigator : Dr. Hemangi Jerajani

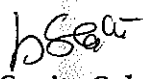
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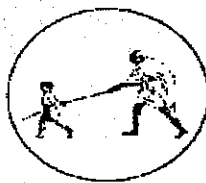
The project was approved unanimously.

Title : 'inj-TR²SERVE': comprehensive program to train, triage and improve services for unintended childhood injuries in India

Principal Investigator : Dr. Maninder S Setia

The project was approved unanimously.


**Dr. Savita Sahani
(Member Secretary)**



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

Meeting of the ECRHS of MGM Institute of Health Sciences, Navi Mumbai was held on 13th March, 2018 at 09.30 am at 3rd Floor, Conference Hall. The following members had participated in the meeting.

1. Dr Alaka Deshpande	:	Chairperson
2. Dr Abhijit De	:	Member
3. Dr Sirish Joshi	:	Member
4. Dr A Bandivdekar	:	Member
5. Dr Savita Shahani	:	Member Secretary
6. Shri E A Patil	:	Member
7. Dr. Ipseeta Ray	:	Member
8. Dr. J C Sharma	:	Member

Title : To study phenotypic characteristics of different types of diabetes in the young and genetic characterization of monogenic diabetes (MODY)

PhD Student	:	Neha V More
Guide	:	Dr. Parineeta Samant
Subject	:	Biochemistry

Candidate was asked to modify the Consent Form and incorporate the Patient Information Sheet and Translation in local languages.

Research project was approved subject to incorporating the changes as suggested.

Title : Associative role of MTHFR, PR & TYMS6bpdel polymorphisms with reference to pre-term delivery

PhD Student	:	Surya Panikar
Guide	:	Dr. Mansee Thakur
Subject	:	Genetics

Candidate was asked to modify the Consent Form and incorporate the Patient Information Sheet and Translation in local languages.

Modify the Proforma mentioning the details of the drug abuse and medical history

Research project was approved subject to incorporating the changes as suggested.

Title : Study of lipoarabinomannan (LAM) as a biomarker for diagnosis of tuberculosis and response to treatment

PhD Student	:	Arth Nath Dube
Guide	:	Dr. A D Urhekar
Subject	:	Microbiology

Candidate was asked to exclude MDR TB cases

Modify the Consent Form and incorporate the Patient Information Sheet and Translation in local languages.

Research project was approved subject to incorporating the changes as suggested.

Title : Evaluation of Microteaching as Teaching - Learning tool for Teachers in Health Sciences

PhD Student	:	Madhavi Mankar
Guide	:	Dr. Siddharth Dubashi
Subject	:	Health Profession Education

Candidate presented the Research Proposal before the committee, members were of opinion that, the project does not involve the ethical clearance as the study doesn't involve any human or animal biological fluid or the patients data.

Title : Studies on maternal colonization of group B streptococcus and its association with preterm deliveries, preeclampsia & still birth

PhD Student	:	Abhishek Singh
Guide	:	Dr. A D Urhekar
Subject	:	Microbiology

Candidate was asked to modify the Consent Form and incorporate the Patient Information Sheet and Translation in local languages

Research project was approved subject to incorporating the changes as suggested.

Title : Comparative study of microanatomy of fetal cerebrum of normal and eclamptic mothers

PhD Student	:	Muthuchitra R Pandian
Guide	:	Dr. Anjali Sabnis
Subject	:	Anatomy

Candidate was asked to :

To clarify the fate of the foetus after research study is completed

Modify the Consent Form and to incorporate the Patient Information Sheet and Translation in local language

Research project was approved subject to incorporating the changes as suggested and justification.

Title : Comparative effectiveness of different treatments for Chronic Low Back Pain

PhD Student : Sidharth Verma
Guide : Dr. Olvyna D'souza
Subject : Anesthesiology

Candidate was asked to modify the Consent Form and to incorporate the Patient Information Sheet and Translation in local languages.

Research project was approved subject to incorporating the changes as suggested.

Title : Effect of spouse support interventions on knowledge regarding ^{fertility}infertility, stress and quality of life among infertile couples attending selected fertility centers

PhD Student : Sonali Banerjee
Guide : Dr. Mary Mathews
Subject : Nursing

Candidate was asked to Develop the separate information sheet and consent form for both the spouses

Research project was approved subject to incorporating the changes as suggested.

Title : Patients' perceived service quality for Mahatma Jyotiba Phule Jan Arogya Yojna (A study based in Raigad district, Maharashtra)

PhD Student : Rupali Gujar
Guide : Dr K R Salgotra
Subject : Nursing

Candidate was asked to modify the Consent Form and incorporate the Patient Information Sheet and its Translation in local languages.

Research project was approved subject to incorporating the changes as suggested.

Title : Impact of traditional versus brain based learning (BBL) approach on knowledge, clinical performance, motivation and self-esteem among B.Sc. nursing students

PhD Student : Kirti Jamdar
Guide : Dr. Prabha Dasila
Subject : Nursing

Candidate was asked to Incorporate Information sheet

Research project was approved subject to incorporating the changes as suggested.

Title : Effect of structured nursing interventions on self-management behavior and health related quality of life among children with Bronchial Asthma

PhD Student	:	Deepa Awlegoankar
Guide	:	Dr. Mary Mathews
Subject	:	Nursing

Candidate was asked to Incorporate Patient Information sheet separate for child and parents. Also incorporate ascent form for the children above ten years and its translation in local languages

Research project was approved subject to incorporating the changes as suggested.

Title : Develop and evaluate practice model for care givers in crèches

PhD Student	:	Arunima S.
Guide	:	Dr. Mary Mathews
Subject	:	Nursing

Candidate was asked to modify the Consent form and incorporate Information sheet
Research project was approved subject to incorporating the changes as suggested.

Title : Impact of Nurse directed intervention for the management of anemia in pregnancy

PhD Student	:	Geeta Sagnali
Guide	:	Dr. Mary Mathews
Subject	:	Nursing

Candidate was asked to modify the Consent form and incorporate Information sheet
Research project was approved subject to incorporating the changes as suggested.

Title : Effect of nurse led intervention on TNF alpha, cognitive and non-cognitive function of patients receiving chemotherapy for CRC at Tata Memorial Hospital

PhD Student	:	Anita D'souza
Guide	:	Dr. Mary Mathews
Subject	:	Nursing

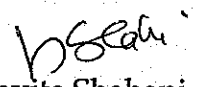
Candidate was asked to incorporate Patient Information sheet and to translate Consent form and Information sheet in local languages.

To take the permission from the authorities from where patients' data will be collected
Research project was approved subject to incorporating the changes as suggested.

Title : Protein mediated synthesis of anti-oxidant calcium nanoparticles and its UV protecting potential

PhD Student	:	Sasmita Barik
Guide	:	Dr. Raman P Yadav
Subject	:	Biotechnology

Candidate forwarded the Research Proposal to the Ethics Committee, Committee members were discussed about the proposal and members were of opinion that, the project does not involve the ethical clearance, as the study doesn't involve any human or animal biological fluid or the patients data.


Dr. Savita Shahani
(Member Secretary)