

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 20th January 2017 at 11.00 am at 3rd Floor, Conference Hall. The following members had participated in the meeting:

Dr Alaka Deshpande	:	Chairperson
Dr. Chander P Puri	:	Member
Dr. J C Sharma	:	Member
Dr A Bandivdekar	:	Member
Shri. E A Patil	:	Member
Dr Savita Shahani	:	Member Secretary
Dr Raman P Yadav	:	Member

Dr. Alaka Deshpande Chaired the meeting.

Title : Long term monitoring of functional outcome of multilevel orthopedic surgeries in children and adolescents with cerebral palsy

Name of PhD Student	:	Triveni Shetty
Guide	:	Dr. Rajani Mullerpatan
Subject	:	Physiotherapy

The above mentioned Research Project was reviewed by the Members Research and recognition Committee (RRC) at its meeting held on 14th December 2016. RRC had recommended to incorporate the suggestions, and the modified project be thereafter referred to Ethics Committee for approval. Accordingly the members of the Ethics Committee observed the changes which had been incorporated in the revised project and also change in the title.

The Ethical Committee reviewed the ethical aspects of the revised research project and reviewed the following:

Members suggested to use correct terminologies

Members also suggested that in case of control group which included patient without surgical interventions it should be recorded that participant/his/her LAG refused to give consent for surgery inspite of counseling.

Candidate was asked to submit informed consent form with patient information sheet and consent form for children above 10 years.

Candidate was suggested to keep a note of relevant biochemical and radiological reports of participants which may be considered for data analysis.

The Research Project was approved by Ethical Committee subject to approval from SAC.

Title: Isolation of plant derived efflux pump inhibitor and its Drug susceptibility potential in *Plasmodium falciparum*

Name of PhD Student : Chandana Kulkarni
Guide : Dr. Raman P Yadav
Subject : Biotechnology

Study design which was approved by Research and Recognition Committee (RRC) meeting held on 16th December 2016, required Ethical Committee approval for collection of blood from healthy volunteers required for laboratory culture. Approval was granted subject to submission of relevant informed consent documents.

Title: Real world, non-interventional, observational study of Venusia® max cream as moisturizer in psoriasis

Principal Investigator : Dr. H R Jerajani

Recommendations:

1. To modify the study objectives as the submitted study design can't analyze the efficacy of product.
2. Mention the number of centers participating in the proposed multicenter study.
3. Provide information whether the product is registered as cosmetics or a drug and whether any approval from regulatory authorities had been obtained for conducting clinical trial. Provide a copy of letter from DCGI to this effect.
4. Incorporate provision for treatment of adverse events including SAEs for study participants.
5. Make provision for compensation of volunteers for travel and time lost related expenses. The medicine should be provided free to the participating volunteers.

6. Sponsor's agreement and publication policy needs to be reconsidered, allowing the PI to publish work.

✓ Title: Real world, non-interventional, observational study of Hydroxyzine Hydrochloride in chronic pruritus

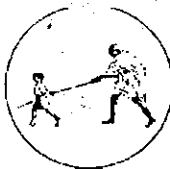
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hsg
(Member Secretary)



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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 **10th May 2017 at 10.30 am** at 3rd Floor, Conference Hall. The following members had participated in the meeting.

Dr Alaka Deshpande	:	Chairperson
Dr. Chander P Puri	:	Member
Dr. J C Sharma	:	Member
Dr. Shirish Joshi	:	Member
Dr A Bandivdekar	:	Member
Dr Savita Shahani	:	Member Secretary
Dr. Ipseeta Ray	:	Member
Dr Raman P Yadav	:	Member
Dr Abhijit De	:	Member

Dr. Alaka Deshpande Chaired the meeting.

Title : Spectrum of tuberculosis infection among children, resistance pattern, drug compliance and treatment outcome to RNTCP anti-TB regimen.

Principal Investigator	:	Dr. Nimain C Mohanty
Co-Investigator	:	Dr. Vijay Kamale

Members made the following comments :

- Project title should include: using anti-TB medication as per RNTCP guidelines
- To observe proper precautions for sputum handling
- Participant should not bear the cost of medication/ investigations
- To maintain uniformity medication may be sourced from a single source.
- Age of the participants should be rewritten as from birth to 15 years of age.
- Informed consent form and its translations are required to be rewritten.
- Assent form to be included for participants above 8 years of age

Project may be approved subject to submission of revised protocol incorporating the changes as advised.

Title: A prospective, randomized, parallel group, single centre study to evaluate efficacy & safety of *Bacillus clausii* (2 Billion Spores per 5 ml) suspension as an add on therapy to standard of care in acute viral diarrhea in children.

Principal Investigator : Dr. Nimain C Mohanty
Co-Investigator : Dr. Vijay Kamale

Project was approved subject to submission of revised consent form in English and translations in local language and translation of information sheet in local language.

Title: Role of nano particles of silicon in autoimmune skin lesions

Principal Investigator : Dr. Ashok Kalyanshetti

Investigator was advised to submit the complete protocol for the study proposal justifying the objective of the study. If there is off label indication for use of drug then proper justification for the indication may be submitted.

Title: A prospective, single blind, randomized, parallel group, single centre study to evaluate efficacy and safety of Pomegranate Seeds as an add-on therapy to standard of care ORS+Zinc Vs ORS+Zinc+Probiotic in managing acute viral diarrhea in children and its mode of action on in-vitro rabbit intestine.

Principal Investigator : Dr. Nimain C Mohanty
Co-Investigator : Dr. Vijay N Kamale
Dr. Vikram Patra
Dr. Ipseeta Ray

Project was approved subject to addition of informed consent form in English and translation in local language as well as assent form for children above 8 years.

Title: Influence of hydrophilic and lipophilic media in continuous and pulsed modes of therapeutic ultrasound in phonophoresis phase II

PhD Student : Sreeraj S R
Guide : Dr. Bharati Bellare
Subject : Physiotherapy

Candidate was advised to analyse results of experimental studies conducted by him and based on experimental data a clinical study may be designed. However members were of opinion that the procedure and the drugs used for the study are routinely

used in practice therefore study may be approved subject to submission of revised project.

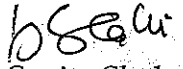
Title: Management of diabetes with education and involvement of the spouse for lifestyle modification

PhD Student : Fernandes Perpetua
Guide : Dr. Prabha Dasila
Subject : Nursing

Candidate was advised to make following changes in study design only type II diabetics may be included who can be divided into :

- i) Newly detected diabetics who are on diet and exercise.
- ii) Diabetics on medical treatment for more than one year
- iii) Results may be analysed in both the groups after intervention for 2 months

Ethical approval may be granted after submission of revised project.


Dr. Savita Shahani
Member Secretary

Received with Thanks
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