



# MGM INSTITUTE OF HEALTH SCIENCES

(Deemed University u/s 3 of UGC Act, 1956)

Accredited Grade A by NAAC

Minutes of Ethics Committee for Research on Human Subjects held on 11<sup>th</sup> September 2015 at 11.00 am at MGMIHS, Conference Hall, and 3rd Floor.

Following members had participated in the meeting.

Dr. Alaka Deshpande	Chairperson
Dr. Savita Sahani	Member Secretary
Dr. J C Sharma	Member
Dr. Prakash Doke	Member
Dr. Shirish Joshi	Member
Dr. Raman P Yadav	Member
Dr. Ipseeta Ray	Member
Shri L V Patil	Member
Shri E A Patil	Member

Dr. Alaka Deshpande had chaired the meeting. The following projects were reviewed and recommendations made:

1. Project entitled "A Randomized Double-Blind, Placebo-Controlled, Comparative, Prospective, Multicentre Trial to Access Efficacy and Safety of Apremilast Tablets in Subjects with Moderate to Severe Plaque Psoriasis who are candidates for Phototherapy or Systemic Therapy". Investigator from MGMIHS : Dr. Hemangi Jerajani, Head Department of Dermatology.

The above project was not discussed as per letter received from Principal Investigator, mentioning that the submitted protocol was expected to have major revision and revised protocol will be submitted once it was available.

2. Project entitled "Evaluation of Safety and Efficacy of Hydroxychloroquine Sulfate as an Adjunct to Diet and Exercise to Improve Glycemic Control in Type 2 Diabetes Patients Uncontrolled on Sulfonylurea and

Metformin Combination". Investigator from MGMIHS: Dr. Vandana Dandekar, Assistant Professor, Department of Medicine.

The above mentioned project was discussed at length. The members were concerned about late ocular toxicity of hydroxychloroquine as the drug may remain in body for longer duration after discontinuation of treatment. The committee recommended to follow up the cases for ocular toxicity for 12 months after discontinuation of therapy. Project has approved by the Ethics Committee subject to approval of use of hydroxychloroquine sulfate to improve glycemic control in Type 2 diabetes patients by Drug Controller General of India.

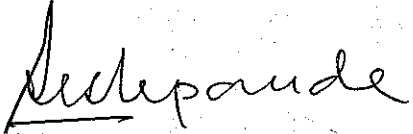
3. Protocol entitled "Impact of Radiations from Cell Phone Towers and Cell Phone Use on Health of Pregnant Women, Neonates and Infants: A Multidisciplinary Collaborative Effort". Principle Investigator: Dr. Maninder Singh Setia, Epidemiologist:

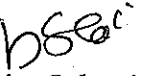
The above mentioned project was discussed in detail and was approved by the Ethics Committee.

4. Project entitled "Non-Invasive TB Triage & Patients Mapping Platform Using Breath Via Low-Cost Titanium Dioxide Nanotube Sensor". Investigator from MGMIHS: Dr. Samir Pachpute, Assistant Professor, Department of Microbiology.

The project was discussed in detail. It is a simple non-invasive breath test to be validated for screening of pulmonary tuberculosis. The study does not interfere in the National protocol of TB diagnosis or management. The statistical details and translation of consent form in regional languages may be subsequently submitted.

The project was approved by the Ethics Committee.

  
Dr. Alaka Deshpande, MD, MAMS, FIMSA, FICP  
Chairperson  
Hon. Professor of Medicine  
Grant Medical College & Sir JJ Group of Hospitals  
Mumbai

  
Dr. Savita Sahani, MD  
Member Secretary  
Professor  
Department of Pharmacology  
MGM Medical College and  
Hospital, Navi Mumbai



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**Minutes of the Ethical Committee for Research on Human Subjects**

Meeting of the Ethical Committee for Research on Human Subjects of MGM Institute of Health Sciences, Navi Mumbai was held on 23<sup>rd</sup> December 2015 in the Conference Hall. The following functionaries had participated in the meeting:

- |                       |               |
|-----------------------|---------------|
| 1. Dr Alaka Deshpande | : Chairperson |
| 2. Dr Chander P Puri  |               |
| 3. Dr Ipseeta Ray     |               |
| 4. Dr J C Sharma      |               |
| 5. Dr Raman P Yadav   |               |
| 6. Shri L V Patil     |               |
| 7. Shri E A Patil     |               |

- 1] Title: A multicenter observational study to describe the complications, cost impact and impact on the quality of life of Herpes Zoster in Indian population.

**Principal Investigator : Dr. Hemangi Jerajani**

**Comments & Recommendations:**

Budget details, including overhead charges sanctioned for the Institute needs to be specified.

The Protocol was approved by Ethics Committee, subject to clarifications.

- 2] Title: Study of the neuronal and glial changes in olfactory pathway with age.

PhD Student	: Dr. Monali Sonawane
Guide	: Dr. Aruna Mukherjee
Subject	: Anatomy

**Comments & Recommendations**

- a. The title does not specify the source of the specimen. Appropriate modifications in the title needs to be undertaken.

- b. It is desirable to obtain consent from the family for the use of cadavers for the present study in writing, wherever feasible.
- c. It is suggested that, MOU between MGMIHS and NIMHANS should be developed before both the institutions begin collaborating on the PhD research activities.

The research proposal was approved by the Ethics committee, subject to incorporation of suggested changes.

3] Title: Age related changes in human hypothalamus.

PhD Student	: Dr. Pravin Rathod
Guide	: Dr. Aruna Mukherjee
Subject	: Anatomy

#### Comments & Recommendations

- a. The sample size should be increased to obtain meaningful data.
- b. Appropriate modification in the title needs to be undertaken as the present title does not specify the source of the specimen.
- c. It is desirable to obtain consent from the family for use of cadavers for the present study in writing wherever feasible.
- d. It is suggested that, MOU between MGMIHS and NIMHANS should be developed before both the institutions begin collaborating on the PhD research activities.

The proposal was approved by the Ethics Committee, subject to the incorporation of the suggested changes.

4] Title: An epidemiological assessment of brucellosis and associated risk factors in South Nagpur, Maharashtra.

PhD Student	: Dr. Satish Ghuegy
Guide	: Dr. Maninder Setia
Subject	: Community Medicine

#### Comments & Recommendations

- a. The sample size needs to be recalculated as the present sample size seems to be too small for an epidemiological study.
- b. CRF Form, Patient Information sheet and the Educational Intervention module should be submitted to the Ethics Committee for final approval.

The proposal was approved by the Ethics Committee, subject to modifications and incorporation of suggested changes..



- 5] Title: To study the utility of novel breath-based point-of-care titanium dioxide nanotube sensor device for the screening and diagnosis of pulmonary tuberculosis.

PhD Student : Dr. Samir Pachpute  
Guide : Dr. A D Urhekar  
Subject : Microbiology

#### Comments & Recommendations

- Mycobacterial Culture/PCR should be used as gold standard for microbiological diagnosis in pulmonary tuberculosis in suspected cases where sputum has to be induced
- The accessories such as plastic bags that would be discarded needs to be disposed off according to the Standard Guidelines

The proposal was approved by the Ethics Committee, subject to modifications and incorporation of the suggested changes.

- 6] Title: To study association between obesity, type-2 diabetes and obstructive sleep apnea disease.

PhD Student : Vijay Kumar Shah  
Guide : Dr. Z.G. Badade  
Subject : Biochemistry

#### Comments & Recommendations

- Title and study objectives do not match. The title needs to be modified appropriately.
- Study group III (Life style change /dietary intervention without CPAP) committed in the study protocol is not ethically permissible. CPAP therapy cannot be withheld in individuals with sleep apnea as it is medically indicated (Known to be beneficial) in such cases
- CRF Form and Patient Information sheet should be submitted to the Ethics Committee for final approval

The proposal was approved by the Ethics subject to modification and incorporation of suggested changes.

- 7] Title: Impact of parent -child education package on psychosocial adjustment and academic performance among teen agers with internet addiction disorder in selected schools of Mumbai/Navi Mumbai.

PhD Student : Farjana Begam  
Guide : Dr. PrabhaDasila  
Subject : Nursing

## Comments & Recommendations

- a. Study Title is too long. Needs to be abbreviated and simplified.
- b. Questionnaire for the study needs to be modified in the Indian context

The proposal was approved by the Ethics Committee, subject to the incorporation of the suggested changes and modification of the title.

- 8] Title: Utility of D-dimer as a potential biomarker for assessing the severity and response to treatment in acute and chronic urticaria


Principal Investigator : Dr. Shaurya Rohatgi  
Co-Investigator : Dr. Hemangi Jerajani

The Project was approved by the Ethics Committee.

- 9] The protocol entitled "Phase IV Clinical trial with Hydroxychloroquine sulfate 400 mg in Type 2 diabetes" submitted by Dr Vandana Dandekar was tentatively approved by the Ethics Committee meeting held on 11<sup>th</sup> September 2015, subject to DCGI approval. After going through the communication of DCGI vide their letter No. CT NOC No: CT/SND/66/2015 dated 8.12.15, permitting the Phase IV trial, the study was approved by the Ethics Committee.

The meeting ended with thanks to the chair.

Agenda and date of next Meeting to be decided.

  
For Member Secretary  
29/12/15