



Suplaji Pl. mail it to me

**MAULANA AZAD MEDICAL COLLEGE
AND ASSOCIATED HOSPITAL**

G.B.Pant Institute of Postgraduate Medical Education and Research
Hospital, Guru Nanak Eye Centre, Chacha Nehru Bal Chikitsalaya & Janakpuri Super
specialty Hospital) New Delhi - 110 002)

(INSTITUTIONAL ETHICS COMMITTEE)

F.1/IEC/MAMC/(51/5/2015/No 28

Dated : 9/3/16

To,

Dr. Sudha Prasad
Director Professor & HOD
Department of
Maulana Azad Medical College &
Associated Lok Nayak Hospital
New Delhi - 110002

Subject: Grant of Ethics clearance for the Research Project "Impact of behavioral intervention package on the health status of married abused pregnant women attending antenatal clinic of LN hospital, New Delhi: A randomized control trail.

Dear Madam,

With reference to your letter on the subject cited above, we have received your application for revalidation of ethical clearance of above research project in reference to the study you wish to conduct at MAMC.

The Institutional Ethics Committee, MAMC has reviewed and discussed your application to conduct the Research Project entitled "Impact of behavioral intervention package on the health status of married abused pregnant women attending antenatal clinic of LN hospital, New Delhi: A randomized control trail.

At the Institutional Ethics Committee Meeting held on 22/12/2015 the above mentioned documents were examined and & discussed. The clarifications submitted by you on 16/02/16 have been accepted and the committee has decided to approve the study under the referenced protocol.

It is understood that the study is being conducted under your direction at Maulana Azad Medical College & Associated Lok Nayak Hospital, G.B.Pant Institute of Postgraduate Medical Education and Research Hospital and, Guru Nanak Eye Centre, Bahadur Shah Zafar Marg, New Delhi - 02.

- Any Serious Adverse Event that occurs during the conduct of the study at Maulana Azad Medical College & Associated Lok Nayak Hospital, G.B.Pant Institute of Postgraduate Medical Education and Research Hospital and, Guru Nanak Eye Centre, Bahadur Shah Zafar Marg, New Delhi - 110002, should be reported to the Ethics Committee immediately.
- It is also to inform you that the financial transactions of the drug trials and non-government sponsored studies will be routed through MAMC society for promotion of Medical Research only.
- A report of the study should be sent to the Ethics Committee annually
- We approve the trial to be conducted in its presented form. The approval is valid for one year.

Member secretary (IEC)

The Institutional Ethics Committee Maulana Azad Medical College & Associated Lok Nayak, GovindBallab Pant Hospital, Guru Nanak eye Centre, New Delhi-110002 is registered (Registration 'No.ECR/329/Inst/DL/2013) with Drug Controller General of India, Directorate General of Health Services, New Delhi as per the Rule 122D of the Drugs and Cosmetics Rules 1945.

WITH REFERENCE TO NOTIFICATION OF DRUG CONTROLLER GENERAL OF INDIA, (DCGI) DIRECTORATE GENERAL OF HEALTH SERVICES(DHS), NEW DELHI DATED 19/NOV/ 2013 REGARDING AUDIO-VISUAL RECORDING OF THE INFORMED CONSENT PROCESS, IT IS NOW MANDATORY TO TAKE AUDIO -VISUAL CONSENT FROM ALL CLINICAL TRIAL PATIENTS WITH IMMEDIATE EFFECT, IEC, MAMC, NEW DELHI-002 DIRECTS YOU TO PLEASE ADHERE TO THE DCGI GUIDELINES RELATED TO THE NEW CONSENTING PROCESS IN ALL THE ONGOING CLINICAL TRIALS

The following members of the Ethics Committee were present at the meeting held on 22nd December 2015 at 2:00 PM in the Dean's conference room, Maulana Azad Medical College, New Delhi-110002

<u>Name of the Members</u>	<u>Designation & Affiliation</u>
1. Dr. S.N.Sinha	Chairperson, (Chair the meet)
2. Dr. Sabita Mishra	Member Secretary, Professor, Department of Anatomy, MAMC

Members:-

3. Mr. Aniruddha Mayee	Legal Advisor
4. Mr. L.D. Kashyap	Social Worker, Community Medicine, MAMC
5. Dr. M.K.Daga	Dir. Professor, Department of Medicine, MAMAC
6. Dr. Puja Sakhuja	Dir. Professor & HOD Department of Pathology, GBPH
7. Dr. Ritu Arora	Dir. Professor, Deptt. of ophthalmology GNEC
8. Dr. Anup Motha	Dir. Professor & HOD, Department of Paediatric Surgery, CNBC
9. Dr. Shalini Chawla	Professor, Department of Pharmacology, MAMC

(Dr. V.K.Gupta, Director Prof. of P&SM, Dean's representative authorized signatory for Clinical trial agreement)

(It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee)

Yours,



(Dr. Sabita Mishra)
Member Secretary
Institutional Ethics Committee

Date: 21/12/15