



INSTITUTE ETHICS COMMITTEE
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
Room No 102, 1st Floor Old O.T. Block,
ANSARI NAGAR, NEW DELHI 110029
Tel.No.4579 (Internal), 26594579 (Direct)

Date: 12.04.2016

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Basic Scientist

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Social Scientist

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Dr. S.K. Kabra
Clinician

Dr. Nikhil Tandon
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Dr. V.K. Bansal
Clinician

Dr. Pramod Kumar Garg
Clinician

Member Secretary:

Dr. Sameer Bakhshi
Clinician

Dr. Yashdeep Gupta

Assistant Professor

Deptt. of Endocrinology, Metabolism & Diabetes
AIIMS, New Delhi.

Ref. No. IEC-144/04.03.2016, RP-3/ 2016

Sub: To evaluate the distribution of glucose tolerance and risk factors predisposing to abnormal glucose tolerance in spouse of high risk pregnant women (gestational diabetes mellitus/ overweight/obese/pre-existing diabetes): A case-control study.

Dear Dr. Gupta,

This is with reference to your letter regarding your above mentioned project, clarifying the queries raised by the Ethics Committee on 04.03.2016. The clarifications have been reviewed and documents are **"Approved from ethical angle prospectively w.e.f. 12th April 2016"**

- The study is valid for the entire period of the conduct of study according to this protocol under the responsibility of **Dr. Yashdeep Gupta**, Principal Investigator. It is confirmed that the Ethics Committee of AIIMS is composed of and functions as per ICH GCP and other applications regulatory guidelines.
- No significant changes to the research protocol should be made and implemented without prior consent of the IEC and any charges/derivations from the protocol which increase the risk for the subjects should be submitted to the IEC and approved prior to implementation.
- 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.

With best regards,
Your sincerely,

Sameer Bakhshi

(Dr. Sameer Bakhshi)
Member Secretary Ethics Committee



INSTITUTE ETHICS COMMITTEE FOR POST GRADUATE RESEARCH
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI 110029
Room No 102, 1st Floor Old O.T. Block,
Tel No 4579 (Internal), 26594579 (Direct)

Dated: 26.02.2016

Ethics Committee for Post Graduate Research for Clinical Science

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Director of Fortis Hospital

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(Clinician)

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Deptt. of Pharmacology,
AIIMS (Basic Medical Scientist)

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Member Secretary
Dr. Sanjeev Sinha
Prof. Deptt. of Medicine, AIIMS
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Dr. Kalpana Luthra
Professor
Deptt. of Biochemistry, AIIMS

Dr. Alpesh Goyal
D.M. Student
Endocrinology, Metabolism
& Diabetes,
AIIMS, New Delhi

Ref. No. ECPG/177/27.01.2016, RT-4/24.02.2016

Through Guide: Dr. Nikhil Tandon,

Sub: To study the distribution of glucose tolerance among women with previous history of Gestational Diabetes Mellitus and their spouses.

Dear Dr. Goyal,

This has reference to your above mentioned protocol. The protocol was discussed in the Ethics Committee for Post Graduate research (Clinical Science) meeting held on 24.02.2016 at 3:00 P.M. in the Ethics Committee room, AIIMS, and the following members of the ethics committee for post graduate research attended the meeting.

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|--|--------------------|
| 1. Dr. S.N. Dwivedi, Professor, Deptt. of Biostatistics, AIIMS- | Acting Chairperson |
| 2. Dr. Pradeep Venkatesh, Professor, Deptt. of Ophthalmology, AIIMS- | Member |
| 3. Dr. Tulika Seth, Adl. Professor Deptt. of Haematology, AIIMS - | Special invitee |
| 4. Dr. Vimi Rewari, Prof. Deptt. of Anesthesiology, AIIMS - | Member |
| 5. Dr. S.K. Kabra, Professor, Deptt. of Paediatrics, AIIMS - | Member |
| 6. Dr. Ambuj Roy, Addl. Prof, Deptt. of Cardiology, AIIMS - | Member |
| 7. Dr. Maneesh Singhal, Addl. Prof., Deptt. of Surgery (JPNATC) - | Member |
| 8. Dr. Neerja Bhatla, Professor, Deptt. of Obst & Gynae, AIIMS- | Member |
| 9. Dr. B. Pandian, Advocate, Legal Person, AIIMS- | Member |
| 10. Dr. Sanjeev Sinha, Professor, Deptt. of Medicine, AIIMS- | Member-Secretary |

The protocol has been approved from ethical angle w.e.f. 24.02.2016 subject to the following conditions:

- The approval is valid for the period of the conduct of study according to this protocol under the responsibility Dr. Alpesh Goyal.
- No significant changes to the research protocol should be made and implemented without prior consent of the IEC and any changes/deviations from the protocol which increase the risk for the subjects should be submitted to the IEC and approved by it prior to implementation.
- 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.
- No significant changes to the research protocol should be made and implemented without prior consent of the IEC and any changes/deviations from the protocol which increase the risk for the subjects should be submitted to the IEC and approved by it prior to implementation.
- IEC should be informed about all SAE's occurring in the study as per DCGI guidelines.
- The study progress report should be made available to the IEC for review every 6 months.

With best regards,

Yours truly,

Sanjeev Sinha

Dr. Sanjeev Sinha
Member-Secretary

Ethics Committee for Post Graduate Research

Prof. Anand Kumar
Prof. Deptt. of Rep. Biology
AIIMS

Dr. B.K. Das
Prof. Deptt. of Microbiology
AIIMS

Dr. A. Shariff
Professor of Anaesth
AIIMS

Dr. S.N. Dwivedi
Prof. Deptt. of Biostatistics
AIIMS

Dr. Pradeep Venkatesh
Professor, RPE
AIIMS

Dr. T. Velpandian
Professor, Deptt. of
Ocular Pharmacology

Dr. D.N. Sharma
Addl. Prof. Deptt. of
Radiobiology, AIIMS

Member Secretary
Dr. Sanjeev Sinha
Prof. Deptt. of
Medicine