



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:20.08.2014

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Member Secretary:

Dr. Pramod Kumar Garg
Clinician

Dr. Rajesh Malhotra,
Professor,
Department of Orthopaedics,
AIIMS, New Delhi.

Ref. No.: *IEC/NP-11/14-02-2014,RP-21/2014*

Sub: "Total Hip replacement for Arthritis following Tuberculosis of Hip" Ref. No.:
IEC/NP-11/14.02.2014

Dear Dr. Malhotra,

This is with reference to your letter dated 16.07.2014 regarding your above mentioned project, clarifying the queries raised by the Ethics Committee on 14.02.2014. The clarifications have been reviewed and documents are "Approved from ethical angle prospectively w.e.f. 20th August 2014"

The study is valid for the entire period of the conduct of study according to this protocol under the responsibility of **Dr. Rajesh Malhotra**, 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.
- IEC should be informed about all SAE's occurring in the study.
- The study progress report should be made available for the IEC review on every 6 months.
- 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,


(Dr. Pramod Garg)
Member Secretary Ethics Committee