

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: 03.03.2015

Chairman

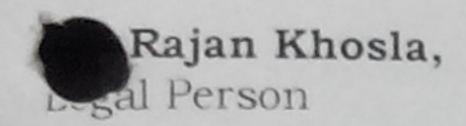
Dr. T.P. Singh, Basic Scientist

Members:

Dr. A.K. Aggarwal, Clinician

Dr. Rama V. Baru Social Scientist

Dr. D.R. Saini, Principal, Lay Person



Dr. Sunesh Kumar Clinician

Dr. Ramanjit Sihota Clinician

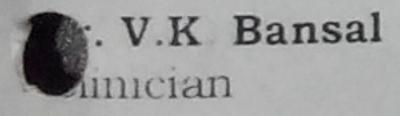
Dr. Peush Sahni, Clinician

Dr. S.K. Kabra Clinician

Dr. Nikhil Tandon Clinician

Dr. S.K. Maulik, Basic Scientist

Dr. R.M. Pandey
Biostatistician



Dr. Sameer Bakhshi Clinician

Member Secretary:

Dr. Pramod Kumar Garg Clinician Dr. Shalimar,
Assistant Professor,
Department of Gastroenterology,
AIIMS, New Delhi-110029.

Ref. No.: IEC/NP-458/12.12.2014, RP-22/2015
Sub: "Long term outcomes of Hepatic Venous Outflow Tract Obstruction: An Ambispective study" Ref. No.: IEC/NP-458/12.12.2014

Dear Dr. Shalimar,

This is with reference to your letter dated 11.02.2015 regarding your above mentioned project, clarifying the queries raised by the Ethics Committee on 12.12.2014. The clarifications have been reviewed and documents are "Approved from ethical angle prospectively w.e.f. 3rd March 2015"

The study is valid for the entire period of the conduct of study according to this protocol under the responsibility of **Dr. Shalimar**, 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,



Member Secretary Ethics Committee