

Date: 3th Dec 2016

Reference no: MICR 660/2016

To,

Dr. Yatin Mehta

Principal Investigator

Medanta – The Medicity,

Sector -38, Gurgaon

Haryana-122001, India

Reference: “A Retrospective Multi-centric Cross Sectional Study to Evaluate Clinical Outcomes Following Extracorporeal Cytokine Adsorption Device (Cytosorb) in patients with Sepsis and Septic Shock”

Subject: Ethics Committee Final approval for the conduct of the above referenced study at Medanta the Medicity.

Dear Sir,

The Medanta Institutional Ethics Committee reviewed and discussed the following documents for the referenced study at the meeting held on **30th Nov 2016**.

List of documents reviewed:

1. Study Protocol version 1.0 dated 21 st October 2016
2. CRF
3. Undertaking by Investigator

The following members of the Ethics Committee were present at the meeting held on the aforementioned date at **3:00 pm** in the Upper ground floor meeting room, Medanta-The Medicity, Gurgaon.

Name of member	Gender	Designation	Role in IEC	Affiliated to Institute
Dr NK Ganguly	Male	Basic Medical Scientist	Chairperson	No
Pastor Alwin Rajan	Male	Theologian	Member	No
Col. Ramphal Gulia	Male	Lay Person	Member	No
Mr. Alishan Naqvee	Male	Legal Expert	Member	No

OHRP Registration no: IRB00007595

DCGI Registration no. ECR/282/Inst/HR/2013

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Dr Sanjay Mittal	Male	Clinician	Member	Yes
Dr. Yatin Mehta	Male	Clinician	Member	Yes
Dr A K Dubey	Male	Member Secretary	Member	Yes

- Dr. Yatin Mehta declared Conflict of interest for the above referenced study and abstained from voting process.

MIEC Decision: Approved

The MIEC has reviewed the submitted documents and approved the same, permitting the conduct of the study at the Medanta site.

Please take a special note of below:

It is to be noted that neither you nor any of your study team members were present during the decision-making procedures of this Institutional Ethics Committee.

I hereby confirm that this Institutional Ethics Committee is organized and operates according to the ICMR and ICH-GCP guidelines and schedule Y requirements.

Please quote the Reference no: **MICR- 660/2016** for any future correspondence regarding this study.

Sincerely,



Dr. A. K. Dubey
Member Secretary
Medanta Institutional Ethics Committee
Medanta - The Medicity
Sector -38, Gurgaon
Haryana-122001, India

Medanta Institutional Ethics Committee
Regn. No. IRB00007595