



Strictly Confidential
Address: Ground Floor, Office of Ethics Committee
West Block, Near MS Office
Max Super Speciality Hospital, Saket
(A Unit of Max Healthcare Institute Limited)
1, Press Enclave Road, Saket, New Delhi-110017

Date: 20th March 2021
Place: New Delhi

Ref.No: TS/MSSH/MHIL/SKT-1/MHEC/CC/20-14

To,
Dr. Sahil Kataria,
DNB Candidate, Department of Critical Care,
Max Super Speciality Hospital, Saket (A Unit of Max Healthcare Institute Limited)
1, Press enclave Road, Saket, New Delhi 110017

SUBJECT: THESIS STUDY TITLE: "Hypoperfusion context in septic shock patients and its effects on outcome –An observational Study".

Dear Dr. Kataria,

In response to the comments recorded in the Max Healthcare Ethics Committee (MHEC) letter dated 5th April 2020, regarding the above mentioned Thesis protocol the following documents had been submitted as closure points by Dr. Sahil Kataria (DNB Candidate):

The following documents were submitted by Dr. Sahil Kataria (DNB Candidate) to the Max Healthcare Ethics Committee for review;

1. Response letter to for the queries raised by Max Healthcare Ethics Committee
2. Revised Protocol
3. Patient Information Sheet & Informed consent form (Hindi)
4. Data collection form

Subject Matter 1:

S.NO.	Documents asked for submission/ Queries	Documents submitted /actions taken
1.	The Institutional Ethics Committee has given following advice to Dr. Sahil Kataria (DNB Candidate) Following are the changes suggested and advised by the IEC: 1. Informed consent document (ICD): Simple words & language both in English & Hindi are required. scientific and technical words are to be replaced 2. Protocol: Please write Updated reference	Dr. Sahil Kataria, (DNB Candidate) has submitted the revised documents with required changes / Closed.

Since all the requirements of the Max Healthcare Ethics Committee have been met the Thesis protocol / documents of the above mentioned study is unconditionally approved.

The MHEC has approved the protocol & documents and has advised that the study is to be conducted in its present form at Max Super Speciality Hospital, Saket (A Unit of Max Healthcare Institute Limited, 1, Press Enclave Road, Saket, New Delhi 110017 with Dr. Sahil Kataria (DNB Candidate) under the Guidance of Dr. Omender Singh (Guide) & Dr. Amit Goel Dr. Deven Juneja & (Co-Guide's).

The MHEC would like to be informed about start of Study, any changes in the protocol and to any of the above mentioned documents and ask to be provided a copy of the final report.

The MHEC has advised a copy of final report of the Thesis Protocol should be submitted, this is required by MHEC before the same is submitted to concern authority/publication.



Max Healthcare Institute Limited
Corp Office: 5th & 6th Floor, Tower-A,
DLF Centre Court, DLF City Phase-V, Sector-42,
Golf Course Road, Gurugram - 122002, Haryana
T: +91-124-620 7777
www.maxhealthcare.in

Max Healthcare Institute Limited
Regd. Office: 401, 4th Floor, Man Excellenza, S. V. Road,
Vile Parle (West), Mumbai, Maharashtra - 400 056
T: +91-22 2610 0461/62
E: secretarial@maxhealthcare.com, investors@maxhealthcare.com
(CIN: U72200MH2001PLC322854)



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The MHEC has advised Dr. Sahil Kataria (DNB Candidate), Dr. Omender Singh (Guide) & Dr. Amit Goel Dr. Deven Juneja & (Co-Guide's) to conduct the thesis study under the definition of Biomedical Health Research in Chapter IV of NDCT Rule 2019 and NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS, ICMR 2017 and applicable amendments.

Please Note: This is to confirm that neither Dr. Sahil Kataria (DNB Candidate) nor Dr. Omender Singh (Guide) & Dr. Amit Goel Dr. Deven Juneja & (Co-Guide's) or any other study staff participating in this thesis study was involved in the voting procedure and decision making of this thesis Study.

Please note that the Institutional Ethics Committee is constituted as per ICH-GCP, New Drugs and Clinical trials Rules, 2019 & ICMR guidelines.

Yours Sincerely,

Signature,
Dr. Kavita Sandhu
Member Secretary
Max Healthcare Ethics Committee

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