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Dr. Madhura Bhide,
DNB Candidate, Dept of Critical Care,
Max Super Speciality Hospital, Saket (A unit of Max Healthcare Institute Limited),
1, Press Enclave Road, Saket, New Delhi, 110017

SUB: Thesis Study Title: "A Study of bedside ultrasonography of optic nerve sheath diameter for detection of raised intracranial pressure in nontraumatic neurocritically ill patients in a tertiary hospital"

Dear Dr. Bhide,

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

The following documents were submitted by Dr. Madhura Bhide (DNB Candidate) to the MHEC for review:

1. Response letter to for the queries raised by Institutional Ethics Committee
2. Revised Protocol of the Thesis
3. Patient Information Sheet & Informed consent form (English & Hindi)

Subject Matter 1:

S.NO.	Documents asked for submission/ Queries	Documents submitted/ actions taken
1.	The MHEC has given following advice to Dr. Madhura Bhide (DNB Candidate) Following are the changes suggested and advised by the MHEC: 1. Informed consent document (ICD): a. Simple word & language both in English and Hindi is required scientific and technical words are to be replaced	Dr. Madhura Bhide (DNB Candidate) has submitted the revised documents with required changes / Closed

Since all the requirements of the MHEC have been met the Thesis protocol / documents of the above mentioned study is unconditionally approved

The IEC 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. Madhura Bhide (DNB Candidate) under the guidance of Dr. Deven Juneja (Guide), Dr. Omender Singh & Dr. Amit Goel (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 IEC before the same is submitted to concern authority/publication.

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Max Healthcare Ethics Committee

Address: Ground Floor, Office of Ethics Committee, West Block, Near MS Office
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1, Press Enclave Road, Saket, New Delhi-110017

The MHEC has advised Dr. Madhura Bhide (DNB candidate), Dr Deven Juneja (Guide), Dr Omender Singh & Dr Amit Goel (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. Madhura Bhide (DNB Candidate) nor Dr Deven Juneja (Guide), Dr Omender Singh & Dr Amit Goel (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

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 September 2021

Place: New Delhi

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