Notification of Decision of Ethics Committee

Date: 06-Dec-2022

To

Dr. Vikram Sharma Principal Investigator

Department of Pharmacology ESIC Medical College & Hospital NH-3, NIT, Faridabad- 121001

**Protocol Title:** Impact Of Aetcom Module About Autonomy, Empathy And Equanimity On Ensuing Clinical Practice: Perceptions Of Medical Undergraduates

**Subject:** Review of document of above mentioned study (submission dated 24-Nov-2022) during IEC meeting dated 30-Nov-2022.

Dear Investigator,

We have reviewed the following documents during our IEC meeting:

1. Protocol
2. Google Form
3. CV of Principal Investigator

The Protocol was discussed in the Ethics Committee meeting held on 30-Nov-2022 at 11:00 AM. The following members of the Ethics Committee of ESIC Medical College and Hospital, Faridabad were involved in review and approval process of the Protocol:

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| **Name** | **Qualification** | **Designation** | **Role in Ethics Committee** |
| Dr. Kishore Kumar  Deepak | MBBS, MD (Physiology) | Prof. & Head, Dept. Of Physiology,  AIIMS, Delhi | Chairperson |

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| **Name** | **Qualification** | **Designation** | **Role in Ethics Committee** |
| Dr. Anil Kumar Pandey | MBBS, MD (Physiology) | Prof. & Head, Dept. Of Physiology, ESIC MC&H, Faridabad | Member Secretary (Basic Medical  Scientist) |
| Dr. Pooja Goyal | MBBS, MD (Community  Medicine | Prof. & Head, Dept. Of Community  Medicine, ESIC MC&H, Faridabad | Clinician |
| Dr. Rashmi VirmaniTaneja | MBBS , MD (Anaesthesia) | Associate Prof., Dept. of  Anaesthesia, ESIC MC&H, Faridabad | Clinician |
| Mr. Kanhiya Lal Vasishtha | B.A., LLB | Advocate at District Court,  Faridabad | Legal Expert |
| Sh. BechuGiri | Higher Secondary | General Secretary, Haryana, All  India Trade Union Committee (AITUC) | Lay Person |
| Mrs. Archana Jha | Dip. In Yoga, Double M.A. (Pol.  Sci. and History) | Retired Yoga Teacher | Social Scientist |
| Sh. Satish Kumar | M.A. | Journalist, MazdoorMorcha | Social Scientist |

Neither you nor any of your study team member(s) participated in voting/decision making process during the meeting.

**Review outcome: Approved.**

**Remarks/ Suggestions:**

The Ethics Committee hereby approves the research proposal to be conducted in its presented form only at your site under your guidance. The validity of decision of Ethics Committee will be of 01 year from the date of decision of Ethics Committee.

The Ethics Committee expects to be informed about study related information (new or changed or updated) that may affect safety of subjects and/or conduct of the study.

The Ethics Committee expects to be informed about the progress of the study 6 months basis from date of decision of Ethics Committee and/or case-by-case basis.

Member of the Ethics Committee will have right to monitor study site and conduct of study with or without prior intimation.

**कम´चारीराǛबीमािनगम**

# Institutional Ethics Committee

(ŵमएवंरोज़गारमंTालय, भारतसरकार) **Employees’ State Insurance Corporation** (Ministry of Labour & Employment, Govt. of India)

***CDSCO Registration N .ECR/1539/Inst/HR/2021 DHR Registration No. EC/NEW/INST/2021/1843* ई.एस.आई.सीिचिकTामहािवOालयएवंंअ4ताल** एनएच3, एनआईटी, फरीदाबाद-121001(हįरयाणा)

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EC File No: 134 X/11/13/2022- IEC/114

Information regarding initiation, on-going and completion, Termination of study should be informed.

The Ethics Committee operates in accordance with New Drugs and Clinical Trials Rules, 2019, ICMR Guidelines for Biomedical research on Human Subjects, ICH- GCP guidelines which govern Good Clinical Practices and IEC/IRB operations, WMA Declaration of Helsinki, Brazil, Oct 2013 and 21 CFR part 56 and 21 CFR part 50.

Yours Sincerely,



Dr. Anil Kumar Pandey Member Secretary

IEC ESIC MC&H