Institutional Ethics Committee (IEC)
for
Biomedical and Health Research

D. Y. Patil Deemed to be University School of Medicine, Navi-Mumbai
Dept. of Pharmacology, 5th floor, Plot No. 2, Sector-5, Nerul, Navi Mumbai - 400 706
Mail: dypsom.src@dypatil.edu; Phone: 02227702218 Extn. 167
[Registration #: EC/NEW/INST/2019/473 (DHR, MOHFW, Govt. of India)]

IEC Ref. No: DYP/IECBH/2023/082 Date: 20/04/2023

To,

Dr. Sanjiv Kale
Dept. of Psychiatry
D Y Patil Medical College & Hospital
Nerul, Navi Mumbai
Maharashtra, India 400 706
Mail: **sanjiv.kale@dypatil.edu**

Sir/Madam,

The Institutional Ethics Committee for Biomedical and Health research (IECBH) of Dr D Y Patil Medical College & Hospital, Navi Mumbai has reviewed and discussed your application to conduct the study. titled "**Randomised Controlled Trial for Smartphone based Smoking Cessation Program - QuitSure**" on 20/04/2023. Your research involves risk category "Less than minimal risk" as per the 'National Ethical Guidelines for Biomedical & Health Research involving Human Participants, ICMR, 2017' (ICMR_Ethical_Guidelines_2017.pdf), and your project was processed as "Expedited" by the IECBH.

The following documents were reviewed by the IECBH:

Document	*Reviewed*
1. Covering letter of submission	Yes
2. Synopsis of protocol/study/dissertation/thesis	Yes
3. Participant Information Sheet (PIS) in English, Hindi and Marathi	Yes
4. Informed Consent Form (ICF) in English, Hindi and Marathi	Yes
5. Case Record Form (CRF) / Study proforma / Questionnaire(s)	Yes
6. Other	None

The following members of the IEC were present in the full board meeting:

Sr.	*Name*	*Designation, Role in IEC*	*Affiliated to Institute*
1.	Dr. Baishali Bhattacharya	Chairperson, Scientific	No
2.	Dr. Vaishali Thakare	Member secretary, Scientific	Yes
3.	Dr. Deepak Langade	Basic Medical Scientist (Pharmacologist)	Yes
4.	Dr. Rochna Bakshi	Clinician	Yes
5.	Dr. Bhakti Sarang	Clinician	No
6.	Ms. Usha More	Legal Expert	No
7.	Mr. Sharukh Tara	Lay person (Non-scientific)	No
8.	Mr. Rajesh Dhoke	Social Scientist (Non-scientific)	Yes
9.	Dr. Violet Pinto	Basic Medical Scientist	Yes

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None of the study team members including principal investigator were a part of the voting procedure.

DECISION

- The IEC hereby approves the study to be conducted in its presented form subject to:
    1. All clinical studies are recommended to be registered on the "Clinical Trials Registry - India (CTRI)" at "http://ctri.nic.in" before commencement of study subjects (first patient in (FPI).
    2. All applicable mandatory regulatory and other permissions to be obtained prior to commencement of the study.
    3. The study team members should be trained on the protocol & protocol related procedures and the Good Clinical Practices (GCP) Guidelines prior to commencing the study.
    4. Participating subjects should not be put to additional financial burden due to participation in the study.
    5. Monitor all enrolled patients for adverse events (AE) and serious adverse events (SAE).
    6. The study conduct should comply with the provisions of 'New Drugs & Clinical Trial Rules, 2019', and the 'National Ethical Guidelines for Biomedical & Health Research involving Human Participants, ICMR, 2017'.
- The validity of this approval is for the duration of the study period.
- The IEC is required to be informed about the following:
    1. All updates on safety related information.
    2. Any SAE occurring during the study to be communicated within 24 hours of information to the IEC and the sponsor (if applicable).
    3. Progress of the study to be reported annually to the IEC.
    4. Any amendments/changes in the protocol and/or patient information / informed consent document.
    5. To provide a copy of the final report after completion of the study.

Thank you

Thakare

Chairperson / Secretary
Institutional Ethics Committee for Biomedical and Health Research (IECBH)
D Y Patil School of Medicine
Navi Mumbai

Dr. Vaishali Thakare
Member Secretary, IECBH
Mail: dypsom.src@dypatil.edu ; vaishali.thakare@dypatil.edu