File No. - EC/NEW/INST/2021/2006



Government of India Ministry of Health & Family Welfare Department of Health Research

2nd Floor, IRCS Building, New Delhi - 110001 Dated: 14-Feb-2022

Provisional Certificate

Subject: Provisional registration of the Ethics Committee relating to Biomedical and Health Research with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research (DHR).

In exercise of the powers conferred by sub-rule (3) of rule 17 of the New Drugs and Clinical Trials Rules, 2019, the designated authority in the Department of Health Research, Ministry of Health & Family Welfare, hereby provisionally registers and permits the following Ethics Committee to perform the duties of ethics committee as specified in Chapter–IV of the New Drugs and Clinical Trials Rules, 2019.

Name:

Institutional Ethics Committee, Venus Institute of Physiotherapy

Address:

Venus Institute of Physiotherapy, At Post- Bhoyan Rathod, Near ONGC

WSS,, Gandhinagar, Gandhinagar, Gujarat - 382420

Contact No:

9784631151,9512343333

Fax:

-NA-

- 2. The Ethics Committee shall observe all the conditions as stipulated in Chapter-IV of the aforesaid Rules, i.e., New Drugs and Clinical Trials Rules, 2019 and the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, specified by the Indian Council of Medical Research (ICMR).
- 3. The designated authority shall scrutinize the documents and information furnished with the application by the Ethics Committee for the issue of final registration certificate.
- 4. The above provisional registration shall be valid for a maximum period of two years from the date of its issue or till grant of final registration or rejection of provisional registration, whichever is earlier.

ANU Digitally signed by ANU NAGAR NAGAR 16:22:44 +05'30' (Anu Nagar)
Joint Secretary
Department of Health Research
Designated Authority



INSTITUTIONAL ETHICS COMMITTEE

VENUS INSTITUTE OF PHYSIOTHERAPY

ANNEXURE - 1

Date:14/06/2021

Ref: VIP/2021/474

To,

The Drug Controller General (India)

Directorate General of Health Services

FDA Bhavan, Kotla Road, New Delhi – 110002.

Subject: An Application for Registration of Institutional Ethics Committee

Ref: Guidelines under appendix VIII, Schedule Y

Dear Sir,

Greetings from Venus Institute of Physiotherapy (Swarrnim Startup and Innovation University), Gandhinagar,

In context to follow national norms for ethics and to facilitate the quality of research in physiotherapy and rehabilitation science, we are forwarding the application for registration of institutional ethics committee,

Venus Institute of Physiotherapy for your kind consideration.

| Sr. | Name | Qualification with Specialization | Current Organization | Designation/Role of the member in the ethics committee | |
|-----|----------------------|---|---|--|--|
| 1. | Dr. Yagna Shukla | PhD Physiotherapy | Physiotherapy I/C Principal, Government Spine Institute and Physiotherapy College | | |
| 2 | Dr. Arvind Kumar | PhD Physiotherapy, MPT(Orthopaedics) | Principal & Professor, Venus Institute of Physiotherapy, Swarrnim Startup & Innovation University | Member Secretary | |
| 3 | Dr. Vinay J. Solanki | MD (Anaesthesiology) | Consultant, K.D. Hospital Ahmedabad | Clinician | |
| 4 | Dr. Vinay Darji | PhD (Pharma) | Associate Professor, Aarihant School of Pharmacy and Bioresearch Institute | Basic Medical Scientist | |
| 5 | Dr. Tanvi Vyas | MPT – Musculoskeletal Conditions | Assistant Professor, Venus Institute of Physiotherapy, Swarrnim Startup & Innovation University | Member | |
| 6 | Mr. Idrish Bengali | LLB | Idrish Bengali & Associates Lawer at Gujarat High Court | Legal Adviser | |
| 7 | Dr. Hitesh V. Patel | PhD Psychology | Consultant Psychologist, Ehsaas Counseling & Psychotherapy Clinic, Ahmedabad | Social scientist | |
| 8 | Mr. Mitesh Patel | 12 th pass | Social worker | Lay Person from Community | |

We appreciate your kind suggestions and advices.

Yours sincerely,

Member Secretary, Institutional Ethics Committee

Venus Institute of Physiotherapy

Member Secretary

Encl: Necessary Documents as per checklist

Institutional Ethics Committee WARRING STARTUP & INNOVATION UNIVERSIME, HIREN KADIKAR Venus Institute of Physiotherapy, 23 43333 | Info@swarrnim.edu.in | www.swarrnim.edu.in Gandhingon Past Bi Gyar Raindia Nr. ONGC WSS, Opp. IFFCO Adalaj - Kalol Hightay, Gandhin

Gujarat -382420

Academic Director Health Sclence Department



INSTITUTIONAL ETHICS COMMITTEE

VENUS INSTITUTE OF PHYSIOTHERAPY

Review Report from Ethics Committee, Venus Institute of Physiotherapy, Swarrnim Startup and Innovation University

Ref no: VIP/2022/FC/101

Date: 25/02/2022

To Ms Bansiben Savaliya

MPT in Orthopedics,

Venus Institute of Physiotherapy,

Swarrnim Startup and Innovation University

Dear Ms. Bansiben Savaliya

Subject: Review Report from Ethics Committee Venus Institute of Physiotherapy, Swarrnim Startup and Innovation University

Ref: Research entitled "EFFECTS OF RESISTANCE AND AGILITY TRAINING ON FALL RISK IN PATIENTS WITH OSTEOPOROSIS – A COMPARATIVE EXPERIMENTAL STUDY"

This has reference to your request letter dated "20/02/2022" for review and ethical approval of above referred research work. We understand that above study is proposed to be carried out by you. Ms. Bansiben Savaliya. MPT Scholar. Venus Institute of Physiotherapy, Swarrnim Startup and Innovation University. Site of Study: Outdoor patient department, Venus Institute of Physiotherapy, Gandhinagar

The protocol of clinical study has been reviewed on 25/02/2022 by following members of Ethical Committee (EC):

| S r. No. | Name | Qualification with Specialization | Current Organization | Designation/Role of the member in the ethics committee | Status Present/Absent |
|----------------|-------------------------|--|--|--|--------------------------|
| 1. | Dr. Yagna Shukla | PhD Physiotherapy | I/C Principal, Government Spine Institute and Physiotherapy College | Chairperson | Present |
| 2 | Dr. Arvind Kumar | PhD Physiotherapy, MPT(Orthopaedi cs) | Principal & Professor, Venus Institute of Physiotherapy, Swarrnim Startup & Innovation University | Member Secretary | Present |
| 3 | Dr. Vinay J. Solanki | MD (Anaesthesiology | Consultant, K.D. Hospital Ahmedabad | Clinician | Present |
| 4 | Dr. Vinay Darji | PhD (Pharma) | Associate Professor, Aarihant School of Pharmacy and Bioresearch Institute | Basic Medical Scientist | Present |
| 5 | Dr. Tanvi Vyas | MPT – Musculoskeletal Conditions | Assistant Professor, Venus Institute of Physiotherapy, Swarrnim Startup & Innovation University | Member | Present |
| 6 | Mr. Idrish Bengali | LLB | Idrish Bengali & Associates Lawer at Gujarat High Court | Legal Adviser | Present |
| 7 | Dr. Hitesh V. Patel | PhD Psychology | Consultant Psychologist, Ehsaas Counseling & Psychotherapy Clinic, Ahmedabad | Social scientist | Present |
| 8 | Mr. Mitesh Patel | 12th pass | Social worker | Lay Person from Community | Present |

SWARRNIM STARTUP & INNOVATION UNIVERSITY



INSTITUTIONAL ETHICS COMMITTEE

VENUS INSTITUTE OF PHYSIOTHERAPY

Total 8 members of committee and one subject expert, who reviewed the application, gave favourable opinion on the protocol. There were no areas of concern relating to the rights, safety, dignity, justice issues and wellbeing of trial subjects. In context to votes from members of IEC, Venus Institute of Physiotherapy, Swarmim Startup and Innovation University who participated in the meeting was recorded and lack of any conflict of interest in the research. Therefore, this committee is pleased to grant approval to the conduct of reviewed research project, subject to the following conditions.

- That no subject would be admitted to the trial before necessary regulatory approvals, if required, are
 obtained, and other necessary documents, as applicable such as, assessment Performa, inform consent
 are submitted to this committee That the study will be conducted in full compliance to good practice
 guidelines and applicable regulatory requirements,
- The IFC. Venus Institute of Physiotherapy, Swarrnim Startup and Innovation University shall do a
 continuing review of the progress of the trial, for which you will provide periodic updates on the
 progress of the same, as a part of your responsibility,
- The IFC- Venus Institute of Physiotherapy, Swarrnim Startup and Innovation University shall provide, according to the applicable regulatory requirements, expedited review of approval/favorable opinion on the minor change(s) in the trial protocol during the course of its conduct, if required.
- That no deviation from, or changes in, the protocol will be initiated without prior written IEC- Venus
 Institute of Physiotherapy, Swarrnim Startup and Innovation University approval favorable opinion on
 an appropriate amendment, except when necessary to eliminate immediate hazards to the subjects or
 when the change(s) involve(s) only logistical or administrative aspects of the trial
- That the investigator would promptly report to the IEC- Venus Institute of Physiotherapy, Swarrnim Startup and Innovation University: (a) deviations from, or changes, in the protocol to eliminate immediate hazards to the trial subjects, (b) changes increasing the risk to subjects and/or significantly affecting the conduct of the trial/c) all adverse events including, serious & unexpected within 24 hours of occurrence followed by a detailed report with due analysis of causal relationship of the event with the clinical study in 14 days of occurrence, and (d) new information that may adversely affect the safety of the subjects or the conduct of the trial.
- Investigator should avoid sharing data with owners of industry where subjects are working.
- Investigator should register with CIRI as soon as he she receives the Ethical Clearance.

Your Sincerely VENUS INSTITUTE OF
Member Secretary, YSIOTHERAPHY

Institutional Ethics Committee, Venus Institute of Physiotherapy,

Swarrnim Startup and Innovation University, Gandhinagar

SWARRNIM STARTUP & INNOVATION UNIVERSITY