



Institutional Ethics Committee for Human Research
"Protecting Participants, Guiding Researchers"

Communication of Decision of the Institutional Ethics Committee

Ref. No.: TDU/IEC/2021/6

Date: 21/10/2021

Valid till: 20/10/2022

To,
Dr. Ashwini Godbole
Associate Professor,
TDU, Bengaluru

The study protocol submitted by you for expedited review was reviewed by subcommittee of Institutional Ethics Committee of TDU. The details of the protocol are as follows:

Protocol No.: TDU/IEC/12E/2021/PR45: Version: 2; dated: 23/06/2021

Protocol Title: Review of hospital based Ayurvedic Electronic Health Records to gain real world knowledge - A retrospective data analysis

Principal Investigator: Dr. Ashwini Godbole, TDU

The following members of IEC were participated in the review process:

SL No.	Name/Designation/Address
1	Dr. Olinda Timms , Chairman Adjunct Professor, Division of Health and Humanities, St. Johns Research Institute, Bengaluru
2	Dr. Nirmala Murthy , Member Health Management Consultant, Honorary President, Foundation for Research in Health Systems, Bengaluru
3	Dr. Neelambika , Member Clinical Registrar, Senior Consultant, I-AIM Healthcare Centre, Bengaluru
4	Dr. Prakash B. N. , Member Secretary Associate Professor, Trans-Disciplinary University, Bengaluru

IEC members reviewed the following documents:

1	Study protocol	Yes	5	Amendment	NA
2	Participant's information sheet	NA	6	Consent form	NA
3	Investigator's brochure	NA	7	Investigators CV's	Yes
4	Assessment scales	NA	8	Case record form	NA

Issues discussed and reviewed in detail. All the members in subcommittee have **approved** this protocol after certain modifications were made.

The committee approves the study to be conducted in the presented form. The approval is valid for **one year**. The investigator must take re-approval after one year if the study is not initiated. The investigator is requested to submit periodic **progress report** once in **six months** to IEC. IEC expects to be informed about any change, modification or deviation from the protocol. Approval for amendment, changes must be obtained prior to implementation. The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. clause no. etc.).

Investigators should conduct the study as per the recommendation by ICMR, 2017, GCP and other regulatory guidelines. IEC members have the right to monitor the study with prior intimation.



Chairman,
Institutional Ethics Committee
Name: Dr. Olinda Timms
Date: 21st October 2021