

NOTIFICATION

Ref: No/YU/REG/ACA/SOP/YEC 2/2024

Dated: 01.02.2024

Sub: Yenepoya Ethics Committee- 2 Standard Operating Procedure Manual (SOPM)
Ref: Your letter dated 01.02.2024

Standard operating procedure Manual (SOPM) of the Yenepoya Ethics Committee 2, Yenepoya (Deemed to be University), Mangalore, version 2 (referred to in short as YEC-2 SOP/v2 is hereby notified with effect from 24 Feb 2024. These SOP's (all twenty-five chapter listed below) are in accordance with the current national guidelines, the same shall be made available to all researchers on the Yenepoya (Deemed to be University) website to take note and comply.

No	SOP Code	Title of the SOP
1	SOP01/v2	Preparation of Standard Operating Procedure Manual for YEC -2
2	SOP02/v3	Constitution of Yenepoya Ethics Committee- 2 (YEC-2); Selection, Roles and Responsibilities of the YEC-2 Members
3	SOP03/v2	Handling Conflict of Interest among Ethics Committee Members
4	SOP04/v2	Selection and Responsibility of Independent Consultant YEC2
5	SOP05/v2	Procedure for allowing Guest Observer to visit Yenepoya Ethics Committee- 2 or attend meeting
6	SOP06/v2	Management of submission of protocol and protocol related documents
7	SOP07/v2	Categorization of protocol for review
8	SOP07A/v2	Full Review of Protocol
9	SOP07B/v2	Expedited Review
10	SOP07C/v2	Exemption from Review
11	SOP08/v2	Minutes of Meeting
12	SOP09/v2	Resubmission
13	SOP10/v2	Continuation of protocol
14	SOP11/v2	Protocol Deviation and protocol Violations : Review and Management
15	SOP12/v2	Adverse Events (AE) and Serious Adverse Event Reports: Review and Management
16	SOP13/v2	Review Study Completion Reports
17	SOP14/v2	Terminations/Suspension/Discontinuation of a Research Protocol
18	SOP15/v2	Waiver of Informed Consent
19	SOP16/v2	Site Monitoring Visit post – Monitoring Activities
20	SOP17/v2	Dealing participant's / Complaint's
21	SOP18/v2	Maintenance , archival, retrieval and disposal of protocols and protocol related documents
22	SOP19/v2	Review Proposal Involving vulnerable populations
23	SOP20/v2	Preparing for Yenepoya Ethics Committee-2 Audit/ Inspection
24	SOP21/v2	Yenepoya Ethics Committee -2 Members Training Assessment and Feedback
25	SOP22/v2	Special consideration for Clinical trials in Ayurveda, Siddha, Unani, Yoga and Naturopathy protocol submission in Yenepoya Ethics Committee -2

[Handwritten Signature]

REGISTRAR

Registrar
YENEPOYA
(Deemed to be University)

Copy to:

1. Member Secretary, YEC – 2
2. File Copy