



**YENEPOYA**  
(DEEMED TO BE UNIVERSITY)  
Recognised under Sec. 3(A) of the UGC Act 1956  
Accredited by NAAC with 'A+' Grade

Ref: No/YU/REG/ACA/SOP/YEC 1/2023

07.06.2023

**NOTIFICATION**

Sub: Yenepoya Ethics Committee-1 Standard Operating Procedure Manual (SOPM)

\*\*\*\*\*

Standard Operating Procedure Manual (SOPM) of the Yenepoya Ethics Committee-1, Yenepoya (Deemed to be University), Mangalore, version 4 (referred to in short as YEC-1 SOP/v4 is hereby notified with effect from 01 July 2023. These SOPs (all twenty six chapters 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/v4	Preparation of Standard Operating Procedure Manual for YEC-1
2	SOP02/v4	Constitution of Yenepoya Ethics Committee-1 (YEC-1); Selection, Roles and Responsibilities of the YEC-1 Members
3	SOP3A/v4	Handling Conflict of Interest among Ethics Committee Members
4	SOP3B/v4	Maintenance of Confidentiality
5	SOP04/v4	Selection and responsibilities of Independent Consultants of YEC-1
6	SOP05/v4	Procedures for allowing Guest/Observer to visit Yenepoya Ethics Committee - 1 or attend meeting
7	SOP06/v4	Management of Submission of Protocol and Protocol-Related Documents
8	SOP07/v4	Categorization of protocols for review
9	SOP7A/v4	Full Review of Protocols
10	SOP7B/v4	Expedited Review of Protocols
11	SOP7C/v4	Exemption of protocols from ethical review
12	SOP08/v4	Agenda preparation, meeting procedures and recording of minutes
13	SOP9A/v4	Review of Resubmission of protocol and related documents
14	SOP9B/v4	Amendment of Protocols and Protocol-related documents: Review
15	SOP10/v4	Periodic Review of Protocols & Extension of validity



**YENEPOYA**

(DEEMED TO BE UNIVERSITY)

Recognised under Sec. 3(A) of the UGC Act 1956

Accredited by NAAC with 'A+' Grade

16	SOP11/v4	Protocol Deviations and Protocol Violations: Review and Management
17	SOP12/v4	Adverse Events (AE) and Serious Adverse event Reports: Review and Management
18	SOP13/v4	Review of Study Completion Reports
19	SOP14/v4	Termination/Suspension/Discontinuation of a Research Protocol
20	SOP15/v4	Waiver of consent
21	SOP16/v4	Site Monitoring Visit and Audit of Protocols
22	SOP17/v4	Dealing with Requests and/or Complaints of all stakeholders to Yenepoya Ethics Committee-1
23	SOP18/v4	Maintenance, archival, retrieval and disposal of protocols and protocol-related documents
24	SOP19/v4	Protocols involving vulnerable populations: Review and Management
25	SOP20/v4	Preparing for Audit of Yenepoya Ethics Committee- 1
26	SOP21/v4	Yenepoya Ethics Committee-1 Members: Training, Assessment and Feedback

*beesomayon*

**REGISTRAR**

**Registrar**  
**YENEPOYA**  
(Deemed to be University)

Copy to:

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

University Road, Deralakatte, Mangaluru - 575 018.

T : +91 824 220 6000 E : registrar@yenepoya.edu.in www.yenepoya.edu.in