

Standard Operating Procedures (SOP)

1. Overview:

The Yamini Innovations Ethics Committee (YIEC) is an Independent Ethics Committee registered under **CDSCO** (Reg. No.: **ECR/2125/INST/UP/2025**). The committee reviews, approves, and monitors human participant research including clinical, biomedical, device-based, and wellness research.

Affiliation: Yamini Innovations LLP

Meeting Frequency: Bi-monthly

Guidelines Followed: ICMR National Ethical Guidelines, ICH-GCP, CDSCO regulations

2. Purpose of the SOP

This SOP outlines the structure, roles, review procedures, submission requirements, conflict of interest guidelines, decision-making process, and administrative procedures of the YIEC.

3. Committee Composition

YIEC consists of multidisciplinary experts ensuring scientific rigor, ethical integrity, and independence in research review.

Sr. No.	Name & Qualification	Designation / Role
1	Prof. Anand K. Mishra, MD (Anatomy, IMS-BHU)	Chairman & Basic Medical Scientist
2	Prof. Kiran Giri, MD (Pharmacology, IMS-BHU)	Pharmacologist & Member
3	Dr. V.B. Singh, MD (Medicine), Neurologist	Clinician & Member
4	Dr. Suyash Tripathi, DM (Cardiology), IMS-BHU	Clinician & Member
5	Vaidya Sushil K. Dubey, PhD, FoA, IMS-BHU	Ayurveda Expert & Member
6	Mr. Amit Dwivedi, LLB	Legal Expert & Member
7	Mr. Ritesh Kumar Tiwari	Social Scientist & Member
8	Mr. Ravindra Pratap Singh	Layperson Representative
9	Prof. Y.B. Tripathi, PhD	Ethics Expert & Member Secretary

4. Responsibilities of the Committee

- Review and approve research involving human participants.
- Ensure protection of participant rights, safety, and well-being.
- Maintain compliance with ethical guidelines and regulatory requirements.
- Monitor approved studies, amendments, and adverse events.
- Ensure proper documentation, record keeping, and confidentiality.

5. Submission Requirements

Investigators must submit a complete application package:

- Study Protocol & Synopsis
- Informed Consent Documents

- Investigator CV & Valid GCP Certificate
- Insurance / Compensation Proof (if applicable)
- Any supporting material

Processing Time: Scheduled for next bi-monthly meeting if the application is complete.

6. Review Process

1. Secretariat screens submissions for completeness.
2. Applications are circulated to members.
3. Review occurs during scheduled meetings.
4. Decisions include **Approved, Modifications Required, Deferred, or Not Approved.**
5. Communication is sent within a defined timeline.

7. Fee Structure

Administrative charges (exclusive of GST):

Type of Review	Base Fee (INR)	TDS 10%	Total (INR)
Initial Review (New Study)	50,000.40	5,555.60	55,556.00
Amendment / Expedite / Continuing Review	14,999.94	1,666.66	16,666.60

Payment to be made to **Yamini Innovations LLP** with protocol title and EC reference.

8. Meeting Schedule

YIEC meets every two months; however emergency meeting can be convened on the request of PI as a special case—submission cut-off: **14 days before meeting.**

Meeting	Date	Notes
Meeting 1 (FY 2025–26)	January 2025	Submissions close 14 days prior
Meeting 2 (FY 2025–26)	March 2025	—

9. Conflict of Interest (COI)

- Members must submit written declarations of COI.
- Members with COI abstain from review and decision-making.
- COI records retained securely.

10. Record Keeping

YIEC maintains:

- Meeting minutes
- Approved protocols
- Correspondence
- Monitoring reports

Retention Period: Minimum 5 years after study completion.

11. Contact Details (Secretariat)

Email: yaminiinnovationsllp@gmail.com

Phone: +91-9415694450

Address: Yamini Innovations LLP & Swasthaya Wellness Nature Cure Centre
N 4/35 C-6, Mahamana Nagar Colony, Sunderpur, Karaundi, Varanasi – 221005