Ethics Committee Monitoring Toolkit

Monitoring of Trials by Ethics Committee

Monitoring of clinical trials is important to ensure adherence to study protocol, to safeguard the rights of research participants and to achieve compliance with principles of Good Clinical Practice (GCP). Recent regulatory changes in India require Ethics Committees (ECs) to keep an oversight of approved ongoing clinical trials including on-site monitoring.

Currently how does the Ethics Committees (ECs) conduct monitoring of clinical trials?

- Review of annual reports of ongoing trials submitted by the Principal Investigators
- Review of Serious Adverse Events Reports and other important notifications
- Review of sponsor monitoring reports
- On-site and/or remote monitoring by EC monitors

The on-site monitoring by ECs does not seem to be a common practice. An ongoing real-time monitoring by ECs can be instrumental in guiding clinical trials towards following ethical principles. Hence,

Ethics Council of Indian Society for Clinical Research (ISCR) developed Ethics Committee Monitoring Toolkit which includes SOP process related to the monitoring procedures to be carried out by the Ethics Committees (EC) along with 7 attachments.

List of Attachments:

1. EC monitoring Visit Agenda Template
2. EC monitoring Checklist Template
3. EC monitoring Report Template
4. Memo to File Template
5. EC monitoring Annual Calendar and Tracker Template
6. Template for Composition of Sub-Committee for EC monitoring
7. EC Monitoring SOP Flowchart

The draft documents are for stakeholder's review. Stakeholder's to utilize the Feedback form to provide their comments/inputs/suggestions etc….

Stakeholders to complete the feedback form by **21st January 2022** and mail to info@iscr.org