Scenarios in Medical Ethics-4: Ethics Committee-Registration and Accreditation

It is mandatory for all ethics committees in India reviewing biomedical and health research studies to register with the Department of Health Research (DHR) under the Ministry of Health and Family Welfare. This information has been added to the New Drugs and Clinical Trials Rules, 2019 with details of the registration procedure.[1] About 1225 Institutional Ethics Committees (IECs) have registered with Central Drug Standard Control Organization (CDSCO) to date.[2] Institutes doing both regulatory and biomedical health research need to register with the CDSCO as well as with DHR. However, accreditation is only optional for the IECs. Accreditation recognizes the functioning of the IECs as per the latest guidelines and rules. A two-day workshop was organized to train IEC members during September 2019 at the Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, in association with ICMR bioethics unit, Bengaluru.[3,4]

The workshop consisted of six-panel discussion sessions. In a variation from the usual ethics workshops,[4] we planned each session to have a lecture followed by case discussions. Each session included a series of 3–6 scenarios followed by 1–3 questions. After presenting each scenario, the participants were invited to give their comments. After a thorough discussion, a set of panelists, who were experts in biomedical ethics, were invited to discuss the scenario and provide more informed and authoritative opinions. The discussions were quite lively and we believe that the case scenarios should be of wider interest.

In this piece, we present the panel discussion on Ethics Committee Registration and Accreditation. The answers provided by the participants are listed first followed by the expert opinion by the panelists.

Scenario 1

An educational institution has been following a set of standard operating procedures (SOPs) for the past 10 years for smooth functioning of IEC with suitable revisions as and when necessary. The SOPs were revised in 2019 for accreditation by the Strategic Initiative for Developing Capacity in Ethical Review. Subsequently, three IECs were formed to split the huge burden of proposals for review between the three committees.

Questions

i. Should all IECs follow the SOPs as revised in 2019? If not, what would be the procedure for formulating new SOPs for each committee?
ii. Should each IEC have their own SOPs?

Participants Answers

- Each IEC must have a separate SOP
- All SOPs need to be updated incorporating the changes suggested in the latest guidelines.

Additional Question

- The chairperson of IEC approves SOP. When the head of the institute constitutes the IEC, why should he/she not approve the SOP?

Comments of the Panelists

- ICMR ethical guidelines mention the list of SOPs. Forum for Ethics Review Committees in India (FERCI) gives details of the components of an IEC SOP which could be tailored to suit the local needs of IECs without merely copying and pasting from that of other institutions
- An SOP for the SOPs should also be available to state how often the SOPs need to be revised, the need for circulation to all the members, etc
- The chairperson approves the final SOP and it is accepted by the Head of the Institution for implementation
- For one institution, a basic SOP needs to be followed, and depending on the functioning of each EC, separate instructions could be laid down.

Scenario 2

The National Accreditation Board for Hospitals and Healthcare Providers (NABH) is the body which deals with accreditation of IECs in India. The Institutional Ethics Committee of a medical college applies to NABH in prescribed application form (common form) along with self-assessment toolkit, relevant documents, and application fee.

Questions

i. What is the timeline for accreditation of IECs by NABH?
ii. What is provisional accreditation from NABH? How long is it valid?
iii. When does the provisional accreditation become continued? What is the process to be followed for that?

Comments of the Panelists

- An IEC needs to apply online for NABH registration. A self-assessment needs to be done by the IEC and a score 8 or more out of 10 is recommended to get accreditation with a minimum of 7.5

- Currently, NABH registration is for three years, it is most likely to be extended following the central licensing authority norms.[5,6]

Scenario 3

The IEC of a medical institution deals with a large numbers of proposals every month. Annual report is submitted only once a year by the investigators. The procedure for periodic review and oversight is practically difficult due to this situation. Monitoring each proposal is practically impossible.

Question

i. What is the practical method to monitor large number of research proposals as it is mandatory for accreditation?

Participants Answer

- All investigators could submit a six-monthly report to IEC. Two to three studies could be randomly picked up every month and monitored for compliance with the ethical standards.

Comments of the Panelists

- It is mandatory for all investigators whose studies are approved by the IEC to submit annual reports. IECs need to look at these reports and if there is some indication for violation of ethical principles (e.g., wide discrepancy in the number of participants recruited), more stringent monitoring of such studies like asking for more frequent reports or an onsite monitoring could be undertaken.
- Routine monitoring can be done by picking up some studies at random and doing a site monitoring. For the high-risk studies, a more detailed monitoring can be planned and two members of the IEC may be nominated to do the detailed onsite monitoring. Logbook needs to be maintained by the IEC noting all details about the site monitoring conducted.

Scenario 4

List of mandatory procedures for ethics committee includes documentation and archiving of records with confidentiality. Issues regarding control and archiving of records with confidentiality need special attention during the accreditation.

Questions

1. What are the best practices to be followed in this regard?
2. Should the SOPs be changed to be compliant with the best practices?
3. Should archiving of the IEC protocols be on a private server (Cloud) or a separate server in public domain with adequate security precautions to protect confidentiality of the data?

Participants Answers and Comments

- Data need to be archived on a reliable source with long-term sustainability rather than a local one which has the chance of a breakdown
- There is always a risk of losing data in accidents such as fire or computers getting corrupted if archived at a single geographical location.

Comments of the Panelists

- IEC documents are confidential and need to be archived. The means of archiving will require upgradation with advances in technology. Multiple methods for archiving must be followed and the latest technology needs to be used
- The eEC portal developed by FERCI in collaboration with Program for Appropriate Technology in Health (PATH) an international NGO, is password protected and potentially secure.
- SOPs need to be regularly updated.

Other panel discussions will be discussed in the forthcoming articles.

Acknowledgment

We are thankful to Dr. Rakesh Aggarwal for the valuable inputs for both conduct of the workshop as well as preparation of this manuscript. We would like to acknowledge the resource persons Dr. Vasantha Muthusamy, Dr. Paul Kumaran, Dr. Bikas Medhi, and Dr. Prasanth Ganesan for their valuable contributions as panelists for this session. We also would liketo express our sincere gratitude to Dr. Roli Mathur and team from ICMR Bioethics Unit for the constant guidance provided and ICMR for funding the workshop.

Financial support and sponsorship

We thank ICMR for partly funding the workshop.

Conflicts of interest

There are no conflicts of interest.

Medha Rajappa, Jayanthi Mathaiyan[1], Rajendran Priyadharsini[1]

Departments of Biochemistry and [1]Pharmacology, Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, India

Address for correspondence: Jayanthi Mathaiyan, Department of Pharmacology, 3rd Floor, Institute Block, Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry - 605 006, India.
E-mail: drjayanthi2008@gmail.com

References

1. Ministry of Health and Family Welfare. Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf. [Last accessed on 2020 Mar 22].
2. Central Drugs Standard Control Organization. Available from: https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/Ethics-Committee/Ethics-Committee-Re-Registration/. [Last accessed on 2020 Apr 23].
3. Indian Council of Medical Research Bioethics Unit. ICMR NCDIR. Available from: http://ethics.ncdirindia.org//asset/pdf/DisseminationReport2020.pdf. [Last accessed on 2020 Mar 18].
4. ICMR Workshop on Ethical Guidance for Biomedical Research.

Available from: http://ethics.ncdirindia.org/asset/images/dissemination_images/Puducherry_2019/broucher_JIPMER.pdf. [Last accessed on 2020 Mar 18].
5. National Accreditation Board for Hospitals & Healthcare providers. Available from: https://www.nabh.co/Images/PDF/CT_Brochure.pdf. [Last accessed on 2020 Jun 02].
6. National Accreditation Board for Hospitals & Healthcare providers. Available from: https://www.nabh.co/Images/PDF/AccreditationProcess_ClinicalTrial.pdf. [Last accessed on 2020 Jun 02].

Access this article online

Quick Response Code:

Website: www.jpharmacol.com

DOI: 10.4103/jpp.jpp_174_20

How to cite this article: Rajappa M, Mathaiyan J, Priyadharsini R. Scenarios in medical ethics-4: Ethics committee-registration and accreditation. J Pharmacol Pharmacother 2020;11:151-3.

Received: 24-12-2020 **Revised:** 26-12-2020
Accepted: 29-12-2020 **Web Publication:** 14-05-2021