

Scenarios in Medical Ethics-1: Composition and Functioning of Ethics Committees

A bioethics training workshop for Institutional Ethics Committee (IEC) members was organized on 16th–17th September 2019 at Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry in South India in association with Indian Council of Medical Research (ICMR) Bioethics Unit, Bangalore, India.^[1] It was attended by eighty delegates from 18 institutions. ICMR bioethics unit at Bangalore has been actively involved in educating Indian researchers on medical research ethics since the latest version of the guidelines “National Ethical Guidelines for Biomedical and Health Research” has been released in 2017.^[2,3] The workshop was planned to train IEC members on the ICMR Ethical guidelines for biomedical research on human participants 2017 as well as the New Drugs and Clinical Trials (NDCT) rules 2019 in addition to having topics of recent relevance such as stem cell research, vaccine research, public health research, and IEC registration and accreditation.

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 discuss the first-panel discussion on “Composition and functioning of ethics committees.” The answers provided by the participants are listed first followed by the expert opinion by the panelists.

SCENARIO 1

The IEC of an institution where regulatory clinical trials are conducted is constituted as shown in Table 1.

Question

- I. Comment on the composition of IEC provided in Table 1, based on ICMR 2017 guidelines and NDCT 2019 rules.

Participant answers

- Fifty-percent of IEC members need to be nonaffiliated
- There is lesser female representation
- Qualification of the social scientist is inadequate
- Even number of IEC members may not be acceptable.

Comments of the panellists

- As per the ICMR 2017 guidelines and NDCT 2019 rules,

50% of the IEC members need to be nonaffiliated and the layperson preferably not be affiliated to the institution where the IEC is constituted^[5]

- A person with degree in sociology cannot be a layperson and the legal expert needs to be a practicing lawyer
- The total number of IEC members can be even or odd, only the quorum involved in decision-making needs to be odd as mentioned in the ICMR 2017 guidelines.

SCENARIO 2

In an IEC for reviewing regulatory studies with ten members, two members served the role of the clinician. One of them is MD (Pediatrics) with 4 years of experience post-MD and the second clinician is MBBS, Ph.D. with 10 years of experience post-MBBS.

Questions

- i. Comment on the suitability of these two members for their role as clinician in an IEC
- ii. What do the ICMR guidelines and NDCT 2019 rules specify regarding the qualification of clinicians in IEC?

Participant answers

- A postgraduate medical degree is required for qualification as a clinician in an IEC
- Ph.D. is not an earned degree; hence it cannot be considered.

Comments of the panellists

- According to the ICMR guidelines, either of the qualifications in the above scenario is acceptable (a recognized degree with some experience)
- But for regulatory trials, as per the NDCT 2019, a post graduate degree in the relevant clinical speciality with sufficient experience is mandatory for a person to qualify for the role of clinician in the IEC.

SCENARIO 3

Situation 1: The chairperson of an IEC is a retired district judge. He serves a dual role in the IEC— as a chairperson and as a legal expert.

Situation 2: Dr. XYZ is a dermatologist. He serves both as Member Secretary and as a clinician in the IEC.

Situation 3: Dr. ABC is a psychiatrist and his main area of interest is sociobehavioral research. He serves as a clinician as well as a social scientist in the IEC.

Questions

- i. Comment on the above three situations
- ii. Can a person serve dual role in IEC?

Table 1: Composition and role of members of an IEC

Name of the member	Gender	Qualification	Role in IEC	Affiliated to the institution (Yes/No)
Dr. A	Male	MD (Gen Med)	Chairperson	No
Dr. B	Male	MD (Pharmacology)	Member-Secretary	Yes
Mrs. C	Female	MSc (Sociology)	Lay Person	Yes
Mr. D	Male	MA, BL	Legal Expert	Yes
Dr. E	Male	MS (Gen Surgery)	Clinician	Yes
Dr. F	Male	MD (Pharmacology)	Basic Scientist	Yes
Mr. X	Male	MA, MPhil	Social Scientist	No
Dr. Y	Male	MD (Geriatrics)	Clinician	Yes

IEC=Institutional Ethics Committee

Participant answer

- The first and second situations are acceptable and the third one is not.

Additional question

- Can a retired judge who is not practicing serve as a legal expert in IEC?

Comments of the panellists

- No person other than chairperson and the Member Secretary can have a dual role, as per the ICMR 2017 guidelines. The positions of chairperson and the Member Secretary are additional administrative responsibilities and persons holding these can play the specific roles in the IEC that they qualify for
- Quorum is a specialization, if chairperson is a legal expert, he/she will be counted as a legal expert in the quorum
- A retired judge can be the chairperson. However, in that case, another legal expert who is a currently practicing lawyer should be included in any IEC that reviews regulatory trials.

SCENARIO 4

A phase III clinical trial protocol for an investigational anti-cancer drug that acts by modulating the immune system was submitted for IEC review. The chairperson of the IEC referred the proposal to a medical oncologist located in Mumbai and invited him as a subject expert in the IEC meeting. The subject expert expressed his inability to attend the meeting but agreed to participate through video conferencing. During the voting process, the chairperson counted the expert's vote.

Questions

- Can a subject expert participate in an IEC meeting through video conferencing?
- Does a subject expert who is not a member of IEC have voting rights?

Participant answers

- Participation by video conferencing may be acceptable but without any voting rights
- Video conferencing is acceptable only if included in the particular IEC's Standard Operating Procedures (SOP).

Comments of the panelists

- Video conferencing for obtaining an expert opinion is acceptable provided it is included in the SOP of the IEC. However, such subject experts do not have voting rights
- Any subject expert invited to provide opinion must sign the confidentiality and conflict of interest agreements before participating in the IEC meeting.

SCENARIO 5

Dr. PQR is a renowned clinician and researcher. Despite his busy clinical practice, he spares as chairperson in three different IECs in the same city. He spares 3 days in a month exclusively for chairing the meetings of these IECs.

Questions

- Can a person serve as a chairperson in more than one IEC?
- Can a person be a member of more than one IEC?

Participant answers

- The audience felt it was acceptable.

Additional questions

During the panel discussion, many other questions were raised such as:

- How should conflict of interest regarding the relationship between a researcher and a member of the IEC be handled?
- If a PI is aggrieved at the decision of the IEC, can he/she appeal?
- Can the PI request a particular member of IEC not to review his/her protocol?

Comments of the panellists

- The panelists also agreed that a person can chair multiple IECs, but he must be able to spare enough quality time to go through the proposals and attend the meetings
- If a researcher feels that there is a conflict of interest and the IEC member agrees, the latter needs to declare a conflict of interest and must stay away from the review procedure for that particular proposal
- Every researcher has a right to appeal against a member of the IEC or the decision of the IEC to the head of the institution, who may ask for a response from the IEC or a particular member, consult an external expert regarding the decisions taken by the IEC if needed. It is for this

reason that the head of the institute must not be a part of the IEC.

Other panel discussions will be discussed subsequently.

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