Roles and Responsibilities of **Ethics Committee Member**

Composition of an Ethics Committee

1. Between 7 and 15 members
2. Adequate representation of age and gender
3. Multi-disciplinary and multi-sectoral
4. More than 50% Non-Affiliated Members

Chairperson/ Vice Chairperson

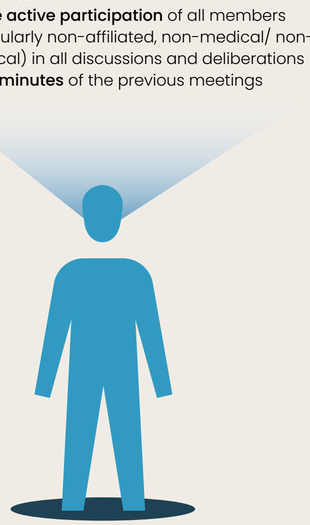
Qualification:
- **Non-affiliated member** (not on roll of the institution)
- **Well-respected person** from any background with prior experience of having served/ serving in an ethics committee.

Responsibility:
- **Conduct EC meetings** and be accountable for independent and efficient functioning of the committee.
- **Ensure active participation** of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations
- **Ratify minutes** of the previous meetings

Member Secretary/ Alternate Member Secretary

Qualification:
- **Affiliated member** (on roll of the institution)
- Possess knowledge and experience in clinical research and ethics
- Motivated and a good communicator

Responsibility:
- Establish an effective and efficient procedure for receiving, preparing, circulating, maintaining proposals, and archiving all ethics committee records
- **Ensure proper EC functioning**
- **Schedule EC meetings**, prepare agenda, ensure quorum during meeting and draw minutes of meeting
- **Organise trainings** of EC members
- Prepare for, and respond to, audits and inspections



Basic Medical Scientist

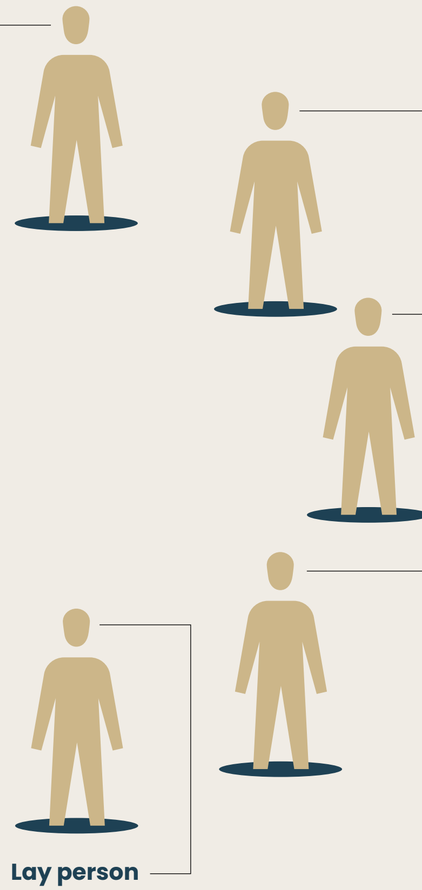
Qualification:
- Affiliated or non-affiliated member
- **Non-medical or medical person** with qualifications in basic medical sciences

Responsibility:
- **Review research proposals**
- **Ensure continuing review process** of serious adverse event (SAE), protocol deviation, progress and completion report.
- Conduct benefit-risk assessment

Clinician

Qualification:
- Affiliated or non-affiliated member.
- Individual/s with **recognized medical qualification**, expertise and training.

Responsibility:
- **Scientific review of protocols** including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics.
- Ongoing **protocol review** (SAE, protocol deviation or violation, progress and completion report)
- **Review medical care**, facility and appropriateness of the principal investigator, provision for medical care, management and compensation



Social scientist/ philosopher /ethicist/theologian

Qualification:
- Affiliated or non-affiliated member
- Individual with **qualification and expertise in social/ behavioural science or philosophy/theology**
- **Sensitive to local cultural and moral values**

Responsibility:
- Review the proposal and ICD with an **ethics lens**
- **Assess impact on community involvement** socio-cultural context, religious or philosophical context
- **Serve as a patient/ participant/ societal/ community representative** and bring in ethical and societal concerns.

Lay person

Qualification:
- Non-affiliated literate person from the public or community
- Individual **not involved in a medical science/ health** related career in the last 5 years
- **Representative of the local community**
- Aware of the local language, cultural and moral values of the community

Responsibility:
- Review the proposal for ethical considerations like reviewing ICD along with translation(s)
- Evaluate benefits and risks from the participant's perspective and bring in ethical and societal concerns.

Legal expert

Qualification:
- Affiliated or non-affiliated member
- Individuals with **basic degree in law** from a recognized university with experience

Responsibility:
- Undertake the **ethical review of the proposal** and key documents (informed consent document (ICD), MoU, Clinical Trial Agreement (CTA), regulatory approvals etc.)
- **Interpret and inform** EC members about new regulations, if any

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FOR MORE INFO: