Roles and Responsibilities of Ethics Committee Member

Qualification:

- Non-affiliated member (not on the 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.

- Conduct review of research proposals including review of the intervention, benefit-risk analysis, research design, methodology, sample size, sites of study, and statistics.

- Ongoing protocol review (SAR, 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.

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 the 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.

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 various adverse events (SAEs), 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, sites of study, and statistics.
- Ongoing protocol review (SAR, 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
- Individuals 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
- Individual(s) 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.

FOR MORE INFO:

More than 50% Non-Affiliated Members