ETHICS COMMITTEE: ROLE, RESPONSIBILITIES AND FUNCTIONS

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Outline

• Introduction
• Composition
• Responsibilities of IEC
• Responsibilities of IEC Members
• Changed Responsibilities of IEC as per Sch. Y
• Check lists of protocol submission
• Functions of IEC
Ethics Committee

Committee comprising of medical, non-medical, scientific and non-scientific members whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a clinical trial.

IEC
IERB, IRB, ERB, REB
IEC(I nd)
Composition of EC
Composition (as per ICMR guidelines)  

8-12 Members 

1. chairperson 
2. one-two persons from basic medical sciences 
3. one-two clinicians 
4. one legal expert or retired judge 
5. one social scientist/ representative of NGO 
6. one philosopher/ ethicist/ theologian 
7. one lay person from the community 
8. member secretary
Composition (as per revised Schedule Y of D&C Act, 1940) 2005

At least one representative from the following groups:

1. one basic scientist
2. one clinician
3. one legal expert or retired judge
4. one social scientist/ representative of NGO/ philosopher/ ethicist/ theologian
5. one lay person from the community
Composition

Chairman - Outside the institution
Not head of the institution

Member Secretary - Inside the institution
Conduct the business of the committee

Lay person - Representative of community

Independence and Competence
Composition

IECs can have members from other institutions

Based on the requirement of research area, members from specific patient groups can be included in the committee

Eg. HIV, Genetic disorders, etc.
Composition

Age and gender representation in the EC to safeguard the interests and welfare of all sections of the community/society

If required subject experts could be invited to offer their views. Eg, Cardiologist for cardiac disorders. (No voting right and no role in decision making process)

Members should be conversant with GCP, Sch Y and ethics guidelines for human participant protection
Responsibilities of IEC
Basic Responsibilities of IEC

To ensure **competent review** of all ethical aspects of the project proposals.

Advice the researchers on all aspects of the **welfare and safety of the research participants** (after ensuring the scientific soundness of the proposed research through appropriate SRC).

Dual responsibility- scientific and ethics review

Abide relevant regulations and institutional policies
Responsibilities of IEC

• To protect the dignity, rights and wellbeing of the potential research participants.

• To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.

• To assist in the development and the education of a research community responsible for local healthcare requirements.
Responsibilities of IEC Members
Responsibilities of IEC Chairperson

• Preside over fully convened meetings

• Ensure IEC carries out its responsibilities

• Review and approve protocols that qualify for expedited and full review

• Delegate such authority to a qualified IEC member to conduct review and approval

• Ensure the members of the IEC recruited, appointed and oriented such that the IEC is duly qualified to fulfil its obligations to review research protocols
Responsibilities of IEC Chairperson

• Serve as liaison between research community to promote communication and understanding of the concerns of IEC.

• Ensure that reports related to safety, noncompliance, unanticipated problem in research and adverse events are reviewed, attended to and reported as per existing guidelines and laws.

• Respond local and governmental investigations relating to protocols and actions.

• Communication of causality of injury and compensation.

• Revise IEC SOPs as appropriate to current societal thinking, changes in guidelines & regulatory and national best practices.
Responsibilities of IEC Members

- Provide competent review of all ethical aspects of the project
- Undertake review free from bias and influence
- Maintain confidentiality
- Advice researchers on all aspects of welfare and safety of research participants
Responsibilities of IEC Members

Declare COI

COI is

- a set of conditions, in which,

- professional judgement concerning a primary interest (such as validity of the research)

- tends to be unduly influenced by secondary interest (such as financial gain)
Specific Roles of IEC Members

• Medical, non-medical, clinician, basic scientists-science and ethics

• Legal experts- CTA, insurance policy, institutional policies, other agreements if any

• Non- scientists- IC documents
The Terms of Reference

Should include terms of appointment like:

- duration of term
- policy for removal
- replacement
- resignation procedure
- frequency of meetings
- payment of fees to the IEC for review
- honorarium/ consultancy to the members/ invited experts

IEC should function according to written SOPs - which should be made available to each member.

SOPs are to be updated periodically based on the changing requirements.
Rule 122 DD : Registration of ethics Committees

i. No EC shall review and accord its approval for a CT without prior registration with the licensing authority as defined in clause(b) of rule 21.
Changed Responsibilities of IEC as per Sch.Y
Requirements

- Compulsory registration with CDSCO of all ECs reviewing regulatory clinical trials to approve CTs
- Registration of ECs in accordance with requirements of appendix VIII of Schedule Y
- The ECs do not want to approve CTs need not register with CDSCO
Changed Responsibilities

- Registered ECs have to analyse SAE and forward its opinion to DCGI (As per newly added appendix XII)

- ECs will allow CDSCO to inspect/verify its records

- Initial registration of all ECs is granted for 3 years by DCGI

- Any change in the EC members should be notified to DCGI

- Maintain all documents for audit/inspection by DCGI
Changed Responsibilities

• Qualifications of basic medical scientist and clinician- MBBS + PG
• COI policy- all EC members should sign COI declaration form

Persons with COI:
- Prior disclosure to chairperson
- Should not take part in decision making process
- Record COI in minutes of the meeting
Check lists of protocol submission
Submission of Application (checklists)

The protocol submitted to ECs should have:

1. The title with **signature of PI and Co-PI** as attestation for the conduct of the study

2. Clear research **objectives and rationale** for undertaking the investigation in human participants in the light of existing knowledge

3. Recent **CV** of the investigators

4. Participant **recruitment procedure** and brochures, if any

5. **Inclusion** and **exclusion criteria** for entry of participants
Checklists contd...

6. Precise description of methodology of the proposed research with sample size study design, intended intervention, dosage of drugs, route of administration, duration of treatments

7. Plan to withdraw or withheld standard therapies during the course of research

8. Plan for statistical analysis of data

9. Procedure for seeking and obtaining IC with sample of PIS. IC forms in English and local languages.

10. Safety of proposed intervention and any drug or vaccine to be tested including results of relevant laboratory, animal and human research
Checklists contd...

11. For research involving more than minimal risk, an account of **management** of such risk/injury

12. Proposed **compensation** and **reimbursement** of incidental expenses and management of research related injury/unrelated injury/illness during and after the research period.

13. An account of **storage and maintenance of data** collected during the trial

14. Plans for **publication** of results by maintaining the privacy and confidentiality of the study participants

15. A statement on probable **ethical issues** and steps taken to tackle the same like justification for washout of standard drugs or the use of placebo control
Checklists contd…

16. All other **relevant documents** related to the study protocol like investigators brochure for trial on drugs/ devices/ vaccines/ herbal medicines and statement of relevant regulatory clearances

17. Agreement to comply with **national and international** GCP protocols for clinical trials

18. Details of **funding agency/ sponsors** and fund allocation

19. **International Collaborative Study** details of foreign collaboration and documents for review of HMSC and DCGI

20. For exchange of **biological material** in International Collaborative Study- MoU/MTA between partners.

21. A statement on **COI**, if any.

Appropriate regulatory approach also need to be obtained before commencing a proposal.
“Whew! That was close!
We almost decided something!”

Functioning of EC
Types of Review

Depending on the risks involved, proposals are categorised into:

- Exempted
- Expedited
- Full review
Types of Review

- Minimal risks are one which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population

- An investigator cannot decide that his/her proposal falls in the exempted category without approval from the IEC
Types of Review

1. Exempted from review
   Proposals present **less than minimal risk**
   eg: - Research on educational practices
       - educational strategies
       - effectiveness of instructional techniques
       - comparison among instructional techniques
       - curricula
       - classroom management methods
Types of Review

2. Expedited Review

Proposals presenting no more than minimal risk

a. minor deviation from originally approved research during the period of approval

b. revised proposal previously approved through full review by the IEC where there is no additional risks.

c. research involving clinical materials.

Eg:- data, documents, records or specimens collected for clinical purposes.
d. In emergency situations like serious outbreaks/disaster

- A full review of the proposal is not possible
- Prior written permission of IEC may be taken before use of test intervention
- Approval given only for pilot study or preliminary work to study the safety and efficacy of the intervention
- The same participants should not be involved in the clinical trial that may be initiated later based on the findings of the pilot study
Expedited Review - Emergency situations

- Research should be essential
- Community participation must be evident
- Research should protect privacy and confidentiality
- Research should confer direct or indirect benefit to the community affected
- International collaboration must be with local partner on equal partnership basis
- Transfer of biological material must respect GOI rules
Types of Review

3. Full Review

- All research presenting with more than minimal risk
- Proposals do not qualify for exempted/expedited review
- Proposals involving vulnerable population & special groups

Full review done by all the members of The IEC
Reporting Protocol Violations and Deviations

Protocol deviations

• Must be reported at the time of the annual reports to the IEC or as required by the study sponsor.

Protocol violations

• Must be reported to the IEC within ten (10) working days of discovery
• It is the responsibility of the PI to ensure proper reporting to the IEC
• Reports of protocol deviations and violations should be submitted to the sponsor as outlined in the sponsor’s protocol
Special Consideration

Additional safeguards/protection and special consideration for the IEC require in research involving:

• Children
• Pregnant and lactating women
• Vulnerable participants
• Persons with diminished autonomy
• Issues pertaining to commercialization of research
• International collaboration
**Monitoring**

- After IEC gives a certificate of approval it is the duty of the IEC to monitor the approved studies
- An oversight mechanism should be in place
- Site visits in the event of reporting of adverse events or violations of human rights
- Require submission of periodic status reports, SAE reports
- Appropriate action should be taken by the IEC based on the reports

For SAE, IEC is responsible to check for to see if appropriate compensation was provided.
Record Keeping

• **Documentation**
  
  Documents and communication of IEC- dated, filed and preserved according to written SOPs

• **Confidentiality**
  
  Strict confidentiality to be maintained during access and retrieval procedures.
Records to be Maintained by EC

- Composition of members of EC
- CV of all EC Members
- SOPs
- National and international guidelines
- Copy of CRF, IB, Protocol, data collection formats, etc.
- Agenda and minutes of all EC meetings- sign of chairperson on each page of minutes
Records to be Maintained by EC

- Copy of all communication with EC members and PI
- All notifications for suspend/termination of a study with reasons
- Final report of study - hard and soft copy
- Time of record maintenance- minimum 5 years from the date of termination of a study.
Administration and Management

For an IEC to function well:

• Full time secretariat
• Space for record keeping
• Members to be compensated reasonably for their time
• Reasonable fees for review and administrative processes
• Allocation of reasonable amount of funds by the concerned institution
Accreditation

Global organisations undertake accreditations of ECs are:

• SIDCER
• AAHRPP
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