Ethics Committee
Composition
Roles & Responsibilities

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Outline

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• Overview of amendment 122 DD (Schedule Y)
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Institutional Review Board (IRB)

ICH GCP 1.31: “An Independent body constituted of 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 trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects”
Introduction (2/2)

Synonyms

• IERB (Institutional Ethics Review Board)
• IRB (Institutional Review Board)
• IEC (Independent/Institutional Ethics Committee)
• ERB (Ethics Review Board)
• REB (Research Ethics Board)
• EC (Ethics Committee)
ICMR Guidelines: 08-12 Members

1. Chairperson
2. One-two persons from basic medical science area
3. One-two clinicians from various institutes
4. One legal expert
5. One Social Scientist/representative of NGO
6. One philosopher/ethicist/theologian
7. One lay person from the community
8. Member Secretary
Composition (2/3)

Quorum as per Schedule Y

• Basic medical Scientist
• Clinician
• Legal expert
• Social Scientist/ethicist/theologist /philosopher
• Lay person
Composition (3/3)

Characteristics of IEC

- Independence and Competence
- Multidisciplinary and Multisectorial members
- Appropriate age and gender representation
- The Chairman from outside Institute
- The Member Secretary from same Institute
- Subject Expert Invitee, if required
- No convenient switchover of representation
Roles & Responsibilities (1/2)

Basic Responsibilities of IEC

• To protect the dignity, rights, safety and well being of potential research participants.
• To ensure universal ethical values in terms of local community values & customs.
• To ensure that international scientific standards are followed by researcher.
• To assist in development & education of a research community responsive to local health care requirements.
Roles & Responsibilities (2/2)

• To ensure a competent scientific review of the proposed research

• To ensure a competent review of all ethical aspects of the proposed study

• To abide by relevant regulations and relevant institutional policies

• Review of Essential Documents

• Review of Progress of Study at regular intervals
Schedule Y:
Overview of Amendment

GSR 72(E) 08 Feb 2013
Rule 122 DD:
Requirement of 122 DD

- Compulsory registration of IEC with CDSCO
- Registration of IEC in accordance with requirements of Appendices VIII of Schedule Y
- IEC to carry ongoing review of trial at appropriate intervals
- Analyze SAE and forward its opinion to DCGI (As per newly added appendix XII)
Overview of Amend (2/3)

- Allow **CDSCO to inspect/ verify** its records.
- Initial registration of all IEC is granted for **3 YEARS** by DCGI.
- Any change in the IEC members should be notified to DCGI.
- Maintain all documents for audit/inspection by DCGI.
Overview of amend (3/3)

- Qualification of Basic Medical Scientist and Clinician
  - Min PG after MBBS (preferably one pharmacologist)

- Special case - HIV, genetic patient groups may be represented in IEC

- Experts can be invited as and when required; No decision making power to such guest experts

- Conflict of Interest (COI) policy- All IEC members sign COI declaration

- Person with COI-
  - Prior disclosure to chairperson
  - Should not take part in decision
  - Record COI in minutes of meeting.
Records (1/3)

Records in Place

- Composition of IEC
- CV of all IEC members
- National and International guidelines
- Agenda and minutes of all IEC meetings (Sign of chairperson on each page of minutes)
- Training documents of IEC members
- Term of Reference for IEC members
- Attendance Record of IEC members
SOPs for IEC

- Membership
- Documents required for review
- Procedure for receipt and review of proposals
- Procedure for disposal of proposals
- Procedures for expedited reviews
- Procedures for resignation & replacement
- Conflict of Interest handling
Study Related Records

- All communications with PI (regarding application, decision and follow-up)
- Copy of CRF, IB, protocol, data collection formats, etc.
- All notifications for suspend/termination of a study with reasons
- Interim report & Final report of the study
- Time of record maintenance - Min 5 yrs from the date of termination of a study (both in hard and soft copy)
Why Review Process?

The IEC has to ascertain acceptability of proposed research in terms of:

- Scientific Rationale
- Ethical Consideration
- Regulations & Applicable laws
- Standards of professional conduct & practice
- Institutional commitments
Types of Review

1. EXEMPTION
2. EXPEDITED
3. FULL
Minimal risk

Harm/discomfort not greater than that encountered in routine daily life activity of general population or during the performance of routine physical or psychologic examinations or tests.
Exemption of Review

Studies which present less than minimal risk to study participants, do not require review.
Exemption Examples

• Effectiveness of teaching/educational methods while preserving anonymity of subjects
• Anonymous surveys or interviews
• Passive observation of public behavior without collection of identifiers
• Retrospective chart reviews
• Systematic reviews
Expedited Review

The study poses NO MORE than minimal risk

- Expedited review by Member secretary and Chairperson/member nominated by the Chairperson under the following circumstances:
  - Originally approved research reviewed in full
  - Minor deviation causing no risk, data analysis
  - Administrative or minor changes in Protocol/ICF
  - Emergency Situation: Outbreaks/ disasters, full review not possible
  - Analyses of discarded pathological specimens without patient identifiers (anonymised secondary use)
Full Review

- Full review is done by ALL members/quorum of the IEC
- For Research presenting more than minimal risk to study participants
- Which do not qualify for exemption/expedited review
- Involving vulnerable groups/special groups
Monitoring & Assessment by IEC

• SOP and checklist for monitoring
• Subject’s rights, safety and wellbeing
• Adequacy of consent process is ensured
• For-cause assessments are conducted following non-compliance and/or complaints
• Opportunities for improvement are identified and appropriate actions are initiated.
• Oversight mechanism should be in place (Audit plan, site visit, review of study documents)
Monitoring (2/2)

- Additionally, periodic status reports must be asked for based on safety concerns, SAEs or Deaths
- SAE reports from site as well as other sites are reviewed by IEC and appropriate action taken
- IEC may also seek reports of monitoring done by the sponsor and recommendations of DSMB
- Interact with the study participants for feedback
- Watch AV recording of informed consent process
- Accreditation by NABH coming soon
Non-compliance (1/2)

Non-compliance Issues

- Submission not in App VIII format
- MOM of IEC meeting missing, not at site
- Inadequate content of IEC approval letter
- SOPs either not in place or inadequate or not followed
- IEC members not reviewed consent process or not visited the site
- Inadequate or inappropriate quorum at meeting
- Confirmation of suggested corrections
Non-compliance issues

- Inconsistency in list of members and members attending
- Money matters- IEC members give least priority but review of books must be documented (at least once a year)
- IEC spending. Why only training of IEC members and not training of investigators?
Thank You