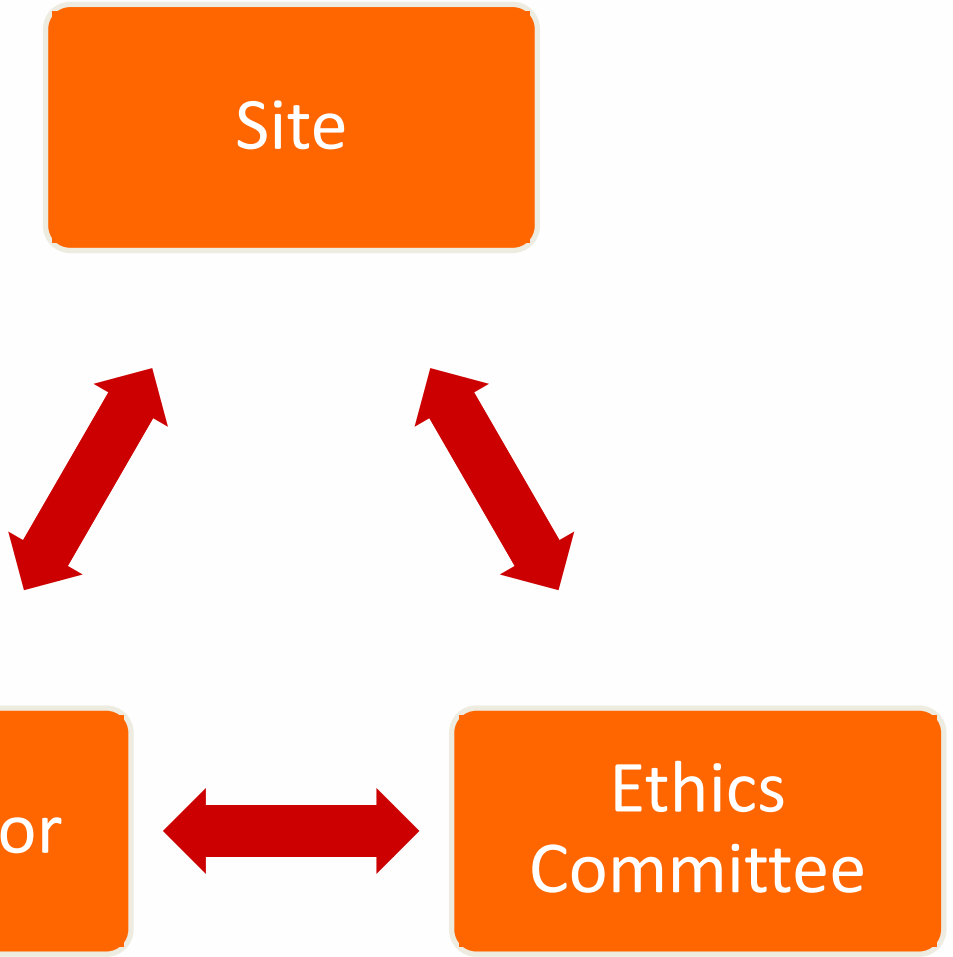
NABH Accreditation of ECs

Module 7 Topic 2

NABH Accreditation



Accreditation of Ethics Committee: Aim

Ethics Committee (EC) is adequately qualified, experienced, and knowledgeable in ethical issues and applicable rules and regulations for conduct of clinical trials ensuring scientific integrity and protection of subject rights, safety and wellbeing

Objectives

Ensure that

- EC has SOPs covering all critical activities
- All activities of the EC are conducted as per SOPs
- Records reflect the actual conduct of the EC functions
- The above lead to complete protection of subjects

Appointment of EC

- Appointment of EC and its members is the function of the Organization head.
- Reflected both in the SOP and the appointment letters. Check both.
- Is the Chairperson appointed or elected? Check the SOP and the appointment letter.
- Qualifications of individual members

Independence

- The EC should be independent, though appointed by the Organization head.
- NABH wants evidence about the independence of the EC in that it should be stated in the appointment letter that the EC is an “Independent Body”
- Check the letter of appointment

Roster

- The EC roster should be complete with roles of individual members, qualifications, experience, contact details and affiliation.
- The above details should be included in every MoM and approval letters sent to PIs.
- All appointment letters should be updated

Basic Medical Scientist

- Pharmacologist (would a microbiologist or virologist do?)
- Draft ICMR Guidelines (2016) state that medical or non medical qualifications are acceptable. What does NABH say?
- New drug law says "The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialisation, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members"

Legal Expert

- Basic qualification LLB/LLM. Is legal practice a requirement?
- Should the person be a practicing lawyer or judge?
- Is a legal advisor/a non practicing lawyer acceptable?
- New drug rule 2019 does not specify.

Lay Person

- What can be the qualifications of the lay person?
- What is the role of the lay person?
- Informed Consent Forms
- Trial procedures
- SAE analysis/compensation etc.

Training

- Members must have been trained as mentioned in the SOP.
- Training may be given by any body (registered?)
- Training certificates should be accompanied by a copy of training material used by the trainer.
- Attendance should be recorded and signed.

Experts

- Whenever experts are invited, their cv should be filed along with their written opinion.
- Do we need experts for all protocols. (New drug rule says that an expert **may** be appointed)
- Presence of experts, and that they did not vote, must be recorded in the MoM.

Meeting

- Frequency of the meetings
- Advance notice for the meeting
- Time for members to study the documents
- Proposals in hard copies or electronic
- Individual member attendance
- Meeting without quorum

Risk Analysis

- How do we analyse risks?
- Is any quantitation possible?
- Can the risk in every trial be graded as
  - Less than minimal
  - Minimal risk
  - Moderate risk
  - Serious risk

Benefit Analysis

- Define if the subject would benefit or whether the study is for societal benefit
- Is quantitation of the benefit possible?
- Can benefit be graded as
  - Increase the comfort of the patient
  - Reduction of morbidity
  - Reduction in mortality

ICF Review

- There needs to be a process for review of the ICF objectively.
  - Make a checklist of essential elements
  - Checklist of important elements
  - Language easy to understand
  - Risks and burdens accurately described
  - Compensation clause

ICF

- When are LAR/witness used?
- Is there a policy to define LAR?
- Who is chosen as a witness?
- Are back translations checked?
- Does the SOP define vulnerable population (what is the reference?)
- Storage of signed ICF

SAE Management

- What is your process?
- Has your EC recommended compensation for any subject?
- How do you do causality analysis?
- Any quantitative method?
- Have you had trouble with sponsors over compensation?

Approval Letters

- Who signs the approval letters?
- Are the approval letters exactly as given in Schedule Y?
- Details given in the approval letters
  - Proposal and document details
  - Members details
  - Queries if any
  - Conditions for approval

Protocol Deviations

- How are protocol deviations addressed?
- When spotted who all are informed of them?
- Who proposes CAPA?
- Who takes CAPA?
- How is closure ensured?
- Is there a record of the deviations noted last year?

Quality

- Does quality manager monitor the studies?
- Are monitoring reports shared with EC?
- Are CAPA taken and how are they monitored?
- Does the EC audit the studies in progress?
- Any records of auditing by EC?

For Cause

- If a complaint is received, how is it handled?
- Are adequate records of complaints maintained?
- What CAPA is taken?
- How many for cause audits are conducted?

Appraisal

- Are the activities of EC members appraised? By whom? How frequently?
- Any CAPA taken?
- Any extra trainings suggested?
- Any proactive actions to improve the quality of EC review?

Minutes of the Meeting

- Time gap between meeting and minutes
- Quorum and COI
- Is EC compliant with rules and regulations
- Attendance with roles and addresses
- Details of proposals
- Detailed discussions of EC included
- Details of decisions taken

Critical Findings

- Composition
- Quorum
- Training of members
- Documentation
- Frequency of meetings
- Minutes of the meeting
- CAPA

Composition

- Total number of members
- Basic Medical Scientists
- Directors of the Institute
- Conflict of Interest
- Alternate members
- NGO/Social workers/Philosopher

Quorum

- What is the minimum quorum?
- Is it verified at the beginning of meeting?
- Any meetings held with incomplete quorum?
- What is done when quorum is incomplete?
- Tally attendance records with minutes of meetings.

Training

- Are EC members trained?
- Are there training certificates available?
- Is there any evaluation of EC members knowledge?
- Is there annual appraisal of members?
- How are members replaced?
- Have any members been dropped?

Documentation

- Completeness of documentation
- Availability of all documents
- Errors in documentation
- Necessary signatures in place
- Dates in place with signatures
- Tallying documents with SOPs and actual activities

Frequency

- What is the cycle of meetings?
- How many meetings are held in the year?
- How many meetings are adjourned for want of quorum?
- Attendance of individual members?
- What is minimum attendance required?

MoM

- Accuracy of the MoM
- Completeness of the MoM, as per New drugs, ICMR and other guidelines
- Timeliness of preparation of MoM
- Do MoM reflect actual conduct of the meeting in full

CAPA

- Mistakes will and do occur
- Are they detected in time?
- Is any action taken, is it timely and is it recorded?
- What steps are taken to prevent such occurrence?
- How effective are the steps?