National Accreditation Board for Hospitals and Healthcare Providers (NABH)

Accreditation Standards for Ethics Committees

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SUMMARY

The criteria to be followed for accreditation of Ethics Committee, Investigator and the Site where clinical trials are to be carried out are given in Section 1, 2 and 3 respectively of this document. A summary is given below:

Section	Standards and objective Elements	list of applicable Policies / Procedures
Section 1: Accreditation of Ethics Committee	**Standards: 10** Objective Elements: 49	• Composition, procedures for new induction and resignation of members. • Frequency of ethics committee meetings. • Receipt, review and decision making of proposals. • Review of protocol amendments. • Procedure for deliberations and maintaining minutes. • Periodic review and oversight. • Procedure to be followed for Vulnerable population. • Review of Informed Consent Document (subject information sheet and informed consent form) and informed consent process. • Reporting, analysis of SAEs and making opinion on compensation. • Handling issues related to non-compliances, protocol violation, complaints by the participants and other stakeholders. • Declaration of conflict of interest and conidentiality agreement. • Financial declaration of payments received and disbursed. • Training for committee members • Communication with different stakeholders.

Section 1
Accreditation of Ethics Committee

Objective of Section 1: 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.

Outcome of Section 1:

- Ethics Committee competently assesses risk and scientific validity of trials.
- Ethics Committee has appropriate measures to ensure protection of subject rights, safety and wellbeing.
- There shall be transparency in Ethics Committee functioning and procedures are followed for all essential activities.

Summary of Standards

1.1	**Authority for formation of Ethics Committee:** There shall be documented procedures to establish the authority for formation of Ethics Committee as per applicable rules and regulations.
1.2	**Standard Operating Procedures (SOPs):** The Ethics Committee has and follows written SOPs for its different functions as per applicable rules and regulations.
1.3	**Ethics Committee Composition:** The Ethics Committee meets the requirement for membership as per applicable rules and regulations. Procedures are documented and followed.
1.4	**Protection of subject rights, safety and wellbeing:** The Ethics Committee follows documented procedures for subject protection.
1.5	**Administrative support:** The Ethics Committee follows documented procedures/ terms of reference to ensure that administrative support for its activities is adequate.
1.6	**Review Process:** The Ethics Committee follows documented procedures for initial review of the trial related documents, review of amendments and periodic reviews.
1.7	**Decision making and post meeting activities:** The Ethics Committee follows documented procedures for decision making process and post meeting activities.
1.8	**Monitoring:** The Ethics Committee follows documented procedures for monitoring and for-cause assessment.
1.9	**Self-Assessment:** The Ethics Committee has and follows documented procedures for self-assessment.
1.10	**Record keeping and archival:** The Ethics Committee follows documented procedures for record keeping and archiving.

Standards and Objective Elements

Standard

1.1	**Authority for formation of Ethics Committee: There shall be documented Procedures to establish the authority for formation of Ethics Committee as per applicable rules and regulations.**

Objective Elements

1.1.1 Procedures shall be followed to specify the authority under which the Ethics Committee is established and administratively governed.

1.1.2 There shall be a documented policy to ensure the independence of the Ethics Committee in its functioning and decision making.

1.1.3 Ethics Committee shall function as per applicable rules and regulations.

Standard

1.2	**Standard operating Procedures (SOPs): The Ethics Committee has and follows written SOPs for its different functions as per applicable rules and regulations.**

Objective Elements

1.2.1. Procedures shall be in place and well denied for the development, review and revision of SOPs.

1.2.2. List of mandatory procedures for Ethics Committee are as follows:

a. Terms of reference for Ethics Committees

i. Composition (names and qualification of the members), new induction, resignation, replacement or removal of members.

ii. Declaration of conflict of interest and conidentiality agreement.

iii. Frequency of ethics committee meetings.

iv. Financial declaration of payments received and disbursed.

v. Policy regarding training for new and existing committee members.

vi. Policy of communication with different stake holders.

vii. Any other or to do all such other lawful acts, deeds and things as are incidental & conducive to attainment of objects of any of them.

b. Protocol submission

i. Procedure for receipt of applications – original, revised, amended with supporting annexes.

c. Ethical review

i. Review and decision making of proposals.

ii. Procedure to be followed for vulnerable population.

iii. Procedure for risk-benefit analysis.

iv. Procedure for review of Informed Consent Document (subject Information Sheet and Informed Consent Form) and informed consent process.

v. Generally to do all such other things as are incidental or conducive to the attainments of above objects.

d. Decision making , minutes recording , post meeting activities including monitoring

i. Procedure for deliberations and maintaining minutes

ii. Procedure for reporting, analysis of SAEs and making opinion on compensation.

iii. Procedure for periodic review and oversight.

iv. Procedure for handling issues related to non-compliance, protocol violation, negligence, complaints by the participants and other stake holders.

v. Procedure for review of protocol amendments.

e. Documentation and archiving

i. Procedure for control and archiving of records with conidentiality.

Standard

1.3	**Ethics Committee Composition: The Ethics Committee meets the requirement for membership as per applicable rules and regulations. Procedures are documented and followed.**

Objective Elements

1.3.1 Composition shall be multidisciplinary and multisectorial and adequate for its functioning.

1.3.2 Subject experts and representatives of vulnerable subjects shall be invited as required with prior intimation.

1.3.3 Membership, appointment, reconstitution and resignation shall be denied as per terms of reference.

1.3.4 Roles and responsibilities of members shall be well denied.

1.3.5 Ethics Committee members shall be trained (initial and ongoing) in applicable rules and regulations and Ethics Committee SOPs.

1.3.6 Conflict of interest and conidentiality shall be addressed at the time of composition.

Standard

1.4	**Protection of subject rights, safety and wellbeing: The Ethics Committee follows documented procedures for subject protection.**

Objective Elements

1.4.1. Rights and responsibilities of subject shall be documented and are specified.

1.4.2. Subject's participation and withdrawal from the trial shall be voluntary and with prior intimation.

1.4.3. Subjects shall be informed and comprehend (initial and ongoing) of the associated risks and benefits of the trial.

1.4.4. Conidentiality and privacy of subjects shall be protected.

1.4.5. Monitoring of trials shall be done to ensure equitable selection of subjects, with special attention to vulnerable and high risk subjects.

1.4.6. Compensation provided to subjects for participation in the trial shall be appropriate and as per the rules and regulation and is reflected in the contract.

1.4.7. Serious adverse events shall be addressed, adequate medical care provided and an appropriate reporting mechanism is followed as per applicable rules and regulations.

1.4.8. Compensation for injury to the subject shall be as per the rules and regulations and monitored for noncompliance.

1.4.9. Complaints and concerns of subjects shall be addressed and managed appropriately, if the need arises.

Standard

1.5	**Administrative support: The Ethics Committee follows documented procedures / terms of reference (TOR) to ensure that administrative support for its activities is adequate.**

Objective Elements

1.5.1. Adequate finance, human resource allocation and secretariat for administrative work and record keeping shall be ensured, with due care and conidentiality.

1.5.2. There shall be financial transparency of Ethics Committee activities and functioning.

1.5.3. There shall be a procedure for communication between ethics committee, investigator/ relevant site staff, institution and regulatory authority.

Standard

1.6	**Review Process: The Ethics Committee follows documented procedures for initial review of the trial related documents, review of amendments and Periodic review.**

Objective Elements

1.6.1 Review shall be done by the Ethics Committee in a formal meeting within a reasonable time following appropriate submission of documents by investigator as per rules and regulations and Ethics committee requirement.

1.6.2 Initial review of proposed clinical trial shall evaluate the scientific validity of the protocol, risk to subjects, expected benefit and ethical standards as per applicable rules and regulations.

1.6.3 Informed consent document, assent form (as applicable) and translations shall be reviewed for appropriateness of language, accuracy and completeness of information.

1.6.4 Ethics Committee shall review the informed consent processes proposed to be followed at the site for a particular trial to ensure that subject/LAR/ impartial witness are provided appropriate information, adequate time is given and impartial witness used as applicable.

1.6.5 Recruitment strategies shall be evaluated.

1.6.6 Proposals involving special group and vulnerable population shall be evaluated as per rules and regulations.

1.6.7 Contract and budget shall be evaluated, for indemnity, compensation, roles and responsibilities as per applicable rules and regulations.

1.6.8 Review of amendments to the originally approved protocol, consent forms and investigators brochure shall be done in formal meetings to evaluate the risk to trial subjects.

1.6.9 Periodic review of trial shall be done for continuation, risk evaluation and adverse event monitoring.

Standard

1.7	**Decision making and post meeting activities: The Ethics Committee follows documented procedures for decision making process and post meeting activities.**

Objective Elements

1.7.1 Decision making process (approval/disapproval/pending/revoking) shall be as per applicable rules and regulations, ensuring quorum and consensus/voting requirements are fulfilled.

1.7.2 The subject shall be recruited into the trial only after written approval from Ethics Committee and approval by regulatory authority.

1.7.3 Conflict of interest shall be declared prior to the review and voluntary withdrawal during decision making process is documented.

1.7.4 Decisions shall be based on risk assessment, scientific validity and adherence to ethical principles for the initial and periodic approvals.

1.7.5 Deliberations and decisions made during the meetings shall be documented, approved, signed and maintained as minutes of meeting.

1.7.6 Protocol deviations and non-compliances shall be evaluated and appropriate actions shall be taken as per rules & regulations.

1.7.7 Serious adverse events shall be analyzed and compensation amount assessed and reported to regulatory authority as per rules and regulations.

1.7.8 All decisions/opinions shall be notified to the investigator in writing.

Standard

1.8	**Monitoring: The Ethics Committee follows documented procedures for Monitoring and for-cause assessment.**

Objective Elements

1.8.1 Subject's rights, safety and wellbeing shall be monitored.

1.8.2 Adequacy and continuity of consent process shall be ensured.

1.8.3 For-cause assessments shall be conducted following non-compliance and/or complaints for the trials approved by the ethics committee.

1.8.4 Opportunities for improvement shall be identified and appropriate actions initiated.

Standard

1.9	**Self-assessment: The Ethics Committee has and follows documented procedures for self-assessment.**

Objective Elements

1.9.1 Periodic self-assessments shall be conducted.

1.9.2 Corrective and preventive actions (as required) shall be implemented accordingly.

Standard

1.10	**Record keeping and archival: The Ethics Committee follows documented Procedures for record keeping and archiving.**

Objective Elements

1.10.1 Security, conidentiality and integrity of all proposals and associated documents shall be reviewed from time to time and administrative communication shall be maintained as per regulatory requirement and with conidentiality.

1.10.2 Documents and records shall be archived after completion /termination of trial as per applicable rules and regulations.

1.10.3 Record retrieval policies and procedures shall be in place to ensure access to information for inspection and audit and continual protection of trial subjects, post trial closure with prior permission in writing.

Abbreviations

1. **AE:** Adverse Event
2. **BA/BE:** Bioavailability & Bioequivalence Studies
3. **CDSCO:** Central Drugs Standard Control Organization
4. **COI:** Conflict of Interest
5. **DCGI:** Drug Controller General of India
6. **DSMB:** Data & Safety Monitoring Board
7. **EC:** Ethics Committee
8. **ICMR:** Indian Council of Medical Research
9. **GCP:** Good Clinical Practice
10. **IP:** Investigational product
11. **IT:** Information Technology
12. **LAR:** Legally Acceptable Representative
13. **SAE:** Serious Adverse Events
14. **SOP:** Standard Operating Procedures
15. **TOR:** Terms of Reference