**Accreditation of Ethics Committees by National Accreditation Board for Hospitals and Health Care Providers in India (NABH): An Overview**

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NABH (National Accreditation Board for Hospitals & Healthcare Providers),established in 2006 , is a constituent board of Quality Council of India, set up to establish and operate accreditation programme for healthcare organizations(HCOs).Ethics Committee Accreditation is a public recognition by a National Healthcare Accreditation body, of the achievement of accreditation standards demonstrated by an Independent external peer assessment of the ethics committees in relation to the confirmed standards.

The NABH accreditation of ethics committees in India started from 28th November 2016 .It is important that all pharmaceutical products go through a standard quality, safety and efficacy study, both during the pre-marketing evaluation and also during the post-marketing review. For that purpose, clinical trials are conducted. Accreditation is an incentive to improve quality as well as capacity of registered Ethics Committee to confirm an ethical research on new drugs. Confidence in accreditation is obtained by a transparent system of monitoring over the accredited ethics committee and an assurance is given by the accreditation body that ethics committee constantly fulfils the accreditation criteria.**1**

**The Accreditation criteria**

The criteria are broadly categorised comprising of ten standards and forty nine elements. The details of standards and elements under each standard are as follows**2:**

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1.Authority for formation of Ethics Committee: There shall be documented procedures to establish the authorityfor formation of Ethics Committee as per applicable rules and regulations. (3elements)

1.1. Procedures shall be followed to specify the authority under which the Ethics Committee is established and administratively governed**.[Accreditation requirement]**

1.2 There shall be a documented policy to ensure the independenceof the Ethics Committee in its functioning and decision making**. [Accreditation requirement]**

1.3. Ethics Committee shall function as per applicable rules and regulations.**(Accreditation and regulatory requirement)**

2.Standard operating procedures (SOPs): The ethics committee has and follows written SOPs for its different functions as per applicable rules and regulations(2 elements)

2.1. Procedures shall be in place and well defined for the development, review and revision of SOPs.**(Accreditation and regulatory requirement)**

2.2. List of mandatory procedures for Ethics Committee is as follows**(Accreditation and regulatory requirement)**

2.2.1 Terms of reference for Ethics Committees

2.2.2. Protocol submission

2.2.3. Ethical review

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

2.2.5 Documentation and archiving

3. Ethics Committee Composition: The Ethics Committee meets the requirement for membership as per applicable rules and regulations. Procedures are documented and followed (6 elements)

3.1. Composition is multidisciplinary and multi-sectorial and has adequate gender representation **(Accreditation and regulatory requirement)**

3.2. Subject experts and representatives of vulnerable subjects are invited as required.**[Accreditation requirement]**

3.3. Membership, appointment, reconstitution and resignation are defined as per terms of reference **[Accreditation requirement]**

3.4. Roles and responsibilities of members are well defined

3.5. Ethics Committee members are trained (initial and ongoing) in applicable rules and regulations and Ethics Committee SOPs

3.6. Conflict of interest and confidentiality is addressed at the time of composition.**[Accreditation requirement]**

4.Protection of subject rights, safety and wellbeing– The EC follows documented procedures for subject protection (9 elements)

4.1. Rights and responsibility of subject are documented **[Accreditation requirement]**

4.2. Subject’s participation and withdrawal from the trial is voluntary**(Accreditation and regulatory requirement)**

4.3.Subjects are informed and comprehend (initial and ongoing) of the associated risks and benefits of the trial**(Accreditation and regulatory requirement)**

4.4. Confidentiality and privacy of subjects is protected **[Accreditation requirement]**

4.5.Monitoring of trials is done to ensure equitable selection of subjects, with special attention to vulnerable and high risk subjects **[Accreditation requirement]**

4.6. Compensation provided to subjects for participation in the trial is appropriate and asper the rules and regulation and is reflected in the contract**(Accreditation and regulatory requirement)**

4.7. Serious adverse events are addressed, adequate medical care provided and an appropriate reporting mechanism is followed as per applicable regulations **(Accreditation and regulatory requirement)**

4.8. Compensation for injury to the subject is as per the regulations and monitored for noncompliance **(Accreditation and regulatory requirement)**

4.9 Complaints and concerns of subjects are addressed and managed appropriately **[Accreditation requirement]**

5. Administrative support – The EC follows documented procedures (TOR) to ensure that administrative support for its activities is adequate (3elements)

5.1.Adequate financial, human resource allocation and secretariat for administrative work and record keeping is ensured.**(Accreditation and regulatory requirement)**

5.2. There is financial transparency of Ethics Committee activities and functioning.**(Accreditation and regulatory requirement)**

5.3. There is a procedure for communication between Ethics Committee, investigator/relevant site staff, institution and regulatory authority.**(Accreditation and regulatory requirement)**

6. Review process – The EC follows documented procedures for initial review of the trial related documents, review of amendments and periodic review (9 elements)

6.1. Ensure regulatory compliance of ethics committee functioning.**(Accreditation and regulatory requirement)**

6.2. Initial review of proposed clinical trial evaluates the scientific validity of the protocol, risk to subjects, expected benefit and ethical standards as per applicable rules and regulations **(Accreditation and regulatory requirement)**

6.3. Informed consent document, assent form (as applicable) and translations are reviewed for appropriateness of language, accuracy and completeness of information.**(Accreditation and regulatory requirement)**

6.4. Ethics Committee reviews the informed consent processes proposed to be followed at the site for a particular study to ensure that subject/LAR are provided appropriate information, adequate time is given and impartial witness used as applicable.**(Accreditation and regulatory requirement)**

6.5 Recruitment strategies are evaluated

6.6. Proposals involving Special group (pregnant mother and children) and vulnerable population are evaluated as per regulations

6.7. Contract and budget is evaluated, for indemnity, compensation, roles and responsibility as per applicable rules and regulations

6.8. Review of amendments to the originally approved protocol, consent forms, investigators brochure is done in formal meetings to evaluate the risk to trial subjects

6.9. Periodic review of study is done for continuation, risk evaluation and adverse event monitoring

7. Decision making and post meeting activities – The EC follows documented procedures for decision making process and post meeting activities (8 elements)

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

7.2. Ensure that subject is recruited into the trial only after written favourable opinion from Ethics committee and approval by regulatory authority

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

7.4. Decisions are based on risk assessment, scientific validity and adherence to ethical principles for the initial and periodic approvals.

7.5.Deliberations and decisions made during the meetings are documented approved signed and maintained

7.6. Protocol deviations, violations and noncompliance are evaluated and appropriate actions are taken.

7.7. Serious adverse events are analysed and compensation amount assessed and reported to regulatory authority as per rules and regulation.

7.8. All decisions/opinions are notified to the investigator in writing.

8. The ethics committee follows documented procedures for monitoring and for cause assessment (4elements)

8.1Subject’s rights, safety and wellbeing shall be monitored.

8.2. Adequacy and continuity of consent process shall be ensured.

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

8.4. Opportunities for improvement shall be identified and appropriate actions are initiated.

9. Self-Assessment – The EC has and follows documented procedures for self-assessment(2elements)

9.1.Periodic self-assessments shall be conducted.

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

10.Record keeping and archival – The EC follows documented procedures for record keeping and archival (3elements)

10.1 Security, confidentiality 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 confidentiality

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

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.

In summary, out of a total 49 elements, elements that broadly cover accreditation and regulatory requirements are 16; only accreditation 9 and others are24. However, based on the experiences during 2017-18, two year period, these standards are going through a process of review & revision and the next version will follow soon.

**EC and NABH accreditation.**

The accreditation process commenced from 2016 on a voluntary basis, and from January 2018, Government of India has made NABH accreditation of ECs mandatory3. The applicant is an EC overseeing regulatory clinical trials and registered with Drugs Controller General of India. As per the guidelines available from the website of NABH, the EC submits the application online with a fee payment. Then the mandatory documents are submitted online under the application form by Ethics Committees. Once the documents are accepted by NABH, Ethics committee becomes eligible for assessment schedule. Assessment is scheduled on a particular date which is feasible for the ethics committee members including chairperson.

**Assessment Process**

This is a well-planned activity. A notification is issued on the website of NABH inviting applications from eligible candidates for a 3 days training for enrolling as assessors forNABH accreditation of ethics committees. The candidates are selected based on the credentials provided in the application and on payment of a training fee, undergo the training. An end course assessment /examination is conducted and only those successful are enlisted in a panel. The enlisted assessors are to initially go as “observers” to two onsite NABH accreditation assessments along with a Principal Assessor (PA) / senior assessor and on satisfactory feedback from the PA and applicants are enrolled as regular assessors.

A team of two assessors (Principal Assessor and Assessor) are allotted an ethics committee / HCO/hospital by NABH with adequate advance notice to both the assessors and hospital. Assigned team can check the documents submitted by the ethics committees using their login credentials.With adequate initial appraisal of SOP, minutes of the meetings, line listing of clinical trials, DCGI related information, etc. of the EC from the NABH site, the assessment team prepares for the on-site visit in liaison with the HCO and NABH secretariat.

The NABH assessment team during onsite visit to HCO checks EC compliance to the NABH standards and elements. The process involves interaction with the EC& Principal investigators of clinical trials (CT), visits to the relevant sites in the HCO like EC office, participant enrolment site, IP storage, record and archival facility, clinical facilities for patient care like the OP room, emergency room, diagnostic facility,etc. It also involves a thorough perusal of thedocuments like bio data of EC members, their appointments, etc., SOP, minutes of the meeting, communications with DCGI, details of CT and other relevant documents. The Principal Assessor (senior/experienced of the two assessors) finally prepares the reportin a transparent way from the HCO site using the standard reporting format provided by NABH (CTAF forms I-IV) with due diligence and with the participation of the EC (mostly chairperson, member secretary and EC coordinator). The soft copies are uploaded by the PA from his login at NABH portal which become immediately visible to EC/HCO and NABH. A paper copy of the report is handed over with a list on non-conformities/non-compliances (NCs) with an advice of how to resolve them. Thus, in a way the process of assessment is also an enriching experience both to the EC/HCO and assessment team. A period of up to 60 days (2 months) is provided to EC/HCO to resolve these NCs and submit corrective action along with evidences online using their login credentials.

**Accreditation process**

The assessors report is perused by the NABH secretariat and on receipt of the CAPA (corrective Action and preventive action) report by the EC/HCO on the NCs reported by the assessment team, the same is referred to PA for giving their comments. Once the CAPA are accepted by the PA and the same is being reported to NABH secretariat, the matter is then referred to accreditation committee of NABH < Delhi for decision. Once, the accreditation committee (AC committee) is satisfied with the assessment and CAPA report, EC accreditation is given fora duration of three years. At the end of fifteen to eighteen months of initial accreditation, a surveillance (follow up assessment)assessment is done by a NABH team and on similar lines of initial/first assessment process, the NCs if any reported by assessment team need to be resolved by a CAPA report from EC/HCO. Six months before the expiry of the initial accreditation period, an application for renewal must be submitted by EC/HCO for continuation of the accreditation. The process of assessment, etc. continues in a cyclic way as was before. A flow chart giving further details is given separately (Source: NABH, New Delhi, 2017)

**Current scenario**

The current scenario of EC accreditation process by NABH is given below (Table -1)

Table -1: EC accreditation process: Current Status (Till February, 2019)

|  |  |  |  |
| --- | --- | --- | --- |
| No.of re-registered ECs at CDSCO website | No.of ECs  applied for NABH  accreditation | No. of ECs  NABH accredited | No. of ECs shown interest in EC accreditation |
| 970 | 298 | 85 | 222 |

Further updates may be viewed at the website vide- <https://www.nabh.co/frmViewAccreditedClinicalTrial.aspx>

Besides NABH undertakes various awareness programs and conducts assessors training programs and the details are vide below (Table -2)

Table -2: Awareness and 2 days training programmes conducted by NABH (Till February, 2019)

|  |  |  |  |
| --- | --- | --- | --- |
| No. of training programs and webinars conducted | No. of persons attended NABH training program | No. of assessors trainings conducted | No of qualified, active empanelled assessors |
| 18 | 411 | 04 | 74 |

**Conclusion**

The NABH provides third –party accreditation to ethics committees in India. It ensures that ethics committees, whether Institutional or independent play their expected role in national health system. This country and culture specific accreditation system safeguards the subject’s rights and wellbeing, also involves fewer cost as compared to other accreditation organization and better accepted. This gives confidence to the regulators, civil society, patient advocacy groups, sponsors of the study, funding agencies and other stake holders that the clinical trials/research being carried out are justifiable, both on ethical and scientific ground and this data is of high quality and integrity4.

**References:**

1. <https://www.nabh.co/ClinicalTrial.aspx> accessed on 13th February, 2019

2. National Accreditation Board for Hospitals and Healthcare Providers. Guide book to standards for accreditation of ethics committees, 1st Edition, 2016, New Delhi .

3. Government of India. Accreditation of ethics committees-regarding. F.No. 12-01/14-DC Pt.47/DRS. Ministry of Health and Family Welfare, dt. 28th November, 2016. New Delhi

4. National Accreditation Board for Hospitals and Healthcare Providers. Assessors guide, Accreditation standards for ethics committee, January, 2016. New Delhi.

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