

**Information Brochure for Ethics Committee
Accreditation Program**

Dec 2016



Introduction to Ethics Committee Accreditation under Clinical Trial Program

National Accreditation board for hospitals and Healthcare Providers (NABH), Quality council of India has developed a system of accreditation for Ethics Committee (EC). Applicant is ethics committee and accreditation shall be granted to them as per details and scope provided in the application form.

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 ethics committee's level of performance in relation to the confirmed standards.

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.

In India there has been a significant increase in the number of clinical drug trials being conducted in developing countries for wide range of disease like HIV, Malaria, Cancer, Tuberculosis, Kala-azar etc and it raises the concern for the quality of operation and most importantly safety of the subjects (patients).

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 fulfills the accreditation criteria.



Benefits of Accreditation

Benefits for Subjects: Subjects are the biggest beneficiary among all the stakeholders. Accreditation of ethics committee results in high quality of care and subjects safety. The subjects are serviced by credential medical staff under the proper supervision of the Investigator. Rights and welfare of the subjects are respected and protected including confidentiality of their identification.

Benefits for Sites/Institution: Accreditation of an ethics committee stimulates continuous improvement. It enables sites in demonstrating commitment to quality care. It raises community and subject confidence in the clinical trials. It also provides assurance to other stakeholders that all the procedures carried out at the site(s) are in compliance to regulatory guidelines and standard.

Benefits for regulatory bodies: Accreditation provides access to reliable and certified information on facilities, infrastructure and process followed in conducting clinical trials. It provides assurance and a sense of satisfaction to ethics committee/regulatory bodies that all the procedures and process of carrying out research are in accordance with laid principles as per schedule Y, GCP guidelines and other applicable regulatory requirements.

Benefits for Site Staff: The staff at the Sites/Institution are satisfied a lot as it provides continuous learning, good working environment, leadership and above all ownership of clinical trial processes by the ethics committee. It improves overall professional development of an Investigator, research professionals & nursing staff.



About NABH

National Accreditation Board for Hospitals and Healthcare Providers (NABH) is a constituent board of Quality Council of India (QCI), set up to establish and operate accreditation programme for healthcare organizations. NABH has been established with the objective of enhancing health system & promoting continuous quality improvement and patient safety. The board while being supported by all stakeholders, including industry, consumers, government, has full functional autonomy in its operation.

NABH provides accreditation to Ethics committee in a non-discriminatory manner regardless of their ownership, legal status, size and degree of independence.

International Society for Quality in Healthcare (ISQua) has accredited “Standards for Hospitals”, 4th Edition, December 2015 developed by National Accreditation Board for Hospitals & Healthcare Providers (NABH, India) under its International Accreditation Programme for a cycle of 4 years (December 2015 to December 2019). The approval of ISQua authenticates that NABH standards are in consonance with the global benchmarks set by ISQua. The hospitals accredited by NABH have international recognition. This will provide boost to medical tourism.



About Clinical Trial

Clinical trial is part of Clinical Research. Clinical research includes trials that test new treatments and therapies as well as long term natural history studies, which provide valuable information about how disease and health progress.

Clinical Trial means a systematic study of new drugs in human subjects to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamics and pharmacokinetics) and/or adverse effects with objective of determining safety and/or efficacy of the new drug. During a trial, more information is gained about an experimental treatment, its risks, and its effectiveness.

The goal of clinical trials is to determine if a new drug or treatment works and is safe. Clinical trials can also look at other aspects of care, such as improving the quality of life for people with chronic illnesses. People volunteer to participate in carefully conducted investigations that ultimately uncover better ways to treat, prevent, diagnose, and understand human disease.

Who Conducts Clinical Trials?

Every clinical study is led by a principal investigator with prior approval from the ethics committee, who is often a medical doctor. Clinical studies also have a research team that may include doctors, nurses, social workers, and other health care professionals.

Clinical studies can be sponsored, or funded, by pharmaceutical companies, academic medical centers, voluntary groups, and other organizations. Physicians, health care providers, and other individuals can also sponsor clinical research.



Where are Clinical Studies Conducted?

Clinical trials can take place in many locations, including hospitals, universities, doctors' offices, and community clinics. The location depends on who is conducting the study and what kind of study are to be conducted.

How long do clinical trials last?

The length of a clinical study varies depending on what is being studied. Participants are told how long the study will last before enrolling.

Reasons for conducting clinical trials

In general, clinical studies are designed to add to medical knowledge related to the treatment, diagnosis, and prevention of diseases or conditions. Some common reasons for conducting clinical studies include:

- Evaluating one or more investigational drugs for treating a disease, syndrome, or condition.
- Finding ways to prevent the initial development or recurrence of a disease or condition. These can include medicines, vaccines, or lifestyle changes, among other approaches.
- Examining methods for identifying a condition or the risk factors for that condition.
- Exploring and measuring ways to improve the comfort and quality of life through supportive care for people with a chronic illness.



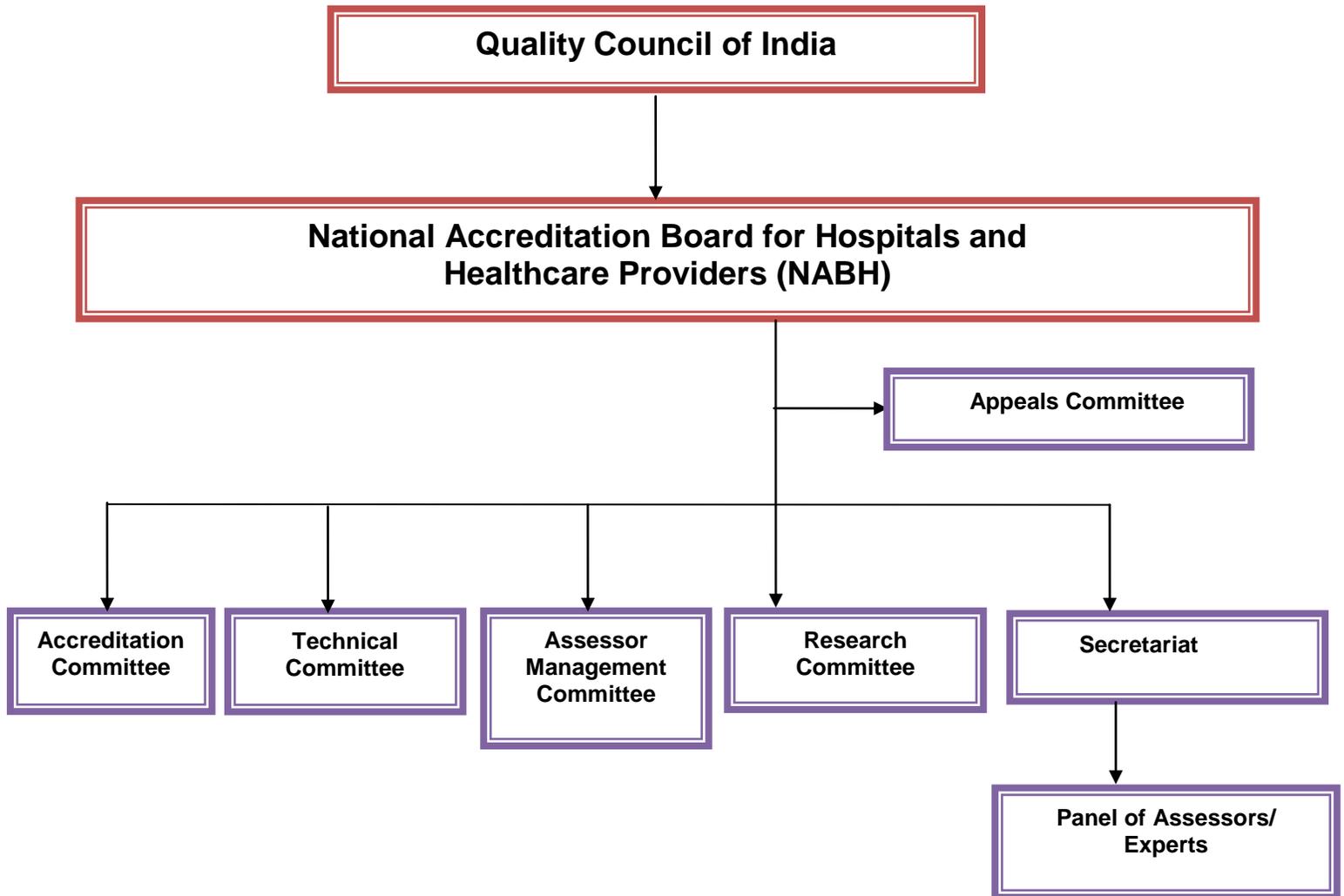
Who can participate in a clinical study?

Clinical studies have standards outlining who can participate, called eligibility criteria, which are listed in the protocol. Some research studies seek participants who have the illnesses or conditions that will be studied, other studies are looking for healthy participants, and some studies are limited to a predetermined group of people who are asked by researchers to enroll.

Eligibility. The factors that allow someone to participate in a clinical study are called inclusion criteria, and the factors that disqualify someone from participating are called exclusion criteria. These are based on things such as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions.



Organizational Structure



Organizational Structure

Accreditation Committee

The main functions of Accreditation Committee are as follows:

- Recommending to board about grant of accreditation or otherwise based on evaluation of assessment reports & other relevant information.
- Approval of the major changes in the Scope of Accreditation including enhancement and reduction, in respect of accredited ethics committee.
- Recommending to the board on launching of new initiatives

Technical Committee

The main functions of Technical Committee are as follows:

- Drafting of accreditation standards and guidance documents
- Periodic review of standards

Appeals Committee

The Appeal Committee addresses appeals made by the ethics committee against any adverse decision regarding accreditation taken by the NABH. The adverse decisions may relate to the following:

- Refusal to accept an application.
- Refusal to proceed with an assessment.
- Corrective action requests.
- Changes in accreditation scope.
- Decisions to deny, suspend or withdraw accreditation, and
- Any other action that impedes the attainment of accreditation.



Organizational Structure

NABH Secretariat

The Secretariat coordinates the entire activities related to NABH Accreditation to Ethics committee.

Panel of Assessors and Experts

NABH has a panel of trained and qualified assessors for assessment of Ethics committee.

Principal Assessor

The Principal Assessor is overall responsible for conducting the assessments of the Ethics committee.

Assessors

NABH has empanelled experts for assessment of Ethics committee. They are trained by NABH on ethics committee accreditation and various assessment techniques. The assessors are responsible for evaluating the ethics committee compliance with NABH Standards.



NABH Standards

NABH Standards for ethics committee accreditation prepared by technical committee contains complete set of standards for evaluation of Ethics committee for grant of accreditation.

The standards provide framework for quality of care for patients and quality improvement for ethics committee. The standards help to build a quality culture at all level and across all the functions of Ethics committee.

Outline of NABH Standards: NABH for accreditation of Ethics committee has 10 standard and 49 objective elements.

A] Summary of Standards for Ethics committee

- Authority for formation of Ethics Committee
- Standard Operating Procedures (SOPs)
- Ethics Committee Composition
- Protection of subject rights, safety and wellbeing
- Administrative support
- Review Process
- Decision making and post meeting activities
- Monitoring
- Self-Assessment
- Record keeping and archival



Assessment criteria & Methodology

Ethics Committee willing to be accredited by NABH must ensure the implementation of NABH standards.

The assessment team will check the implementation of NABH Standards by the ethics committee. The ethics committee shall be able to demonstrate to NABH assessment team that all NABH standards, as applicable, are followed.

NABH Secretariat on intimation from the ethics committee about the preparedness to take up assessment, appoints an assessment team comprising principal assessor and assessor from the pool of empaneled assessors.

Following documents are provided to the assessment team for carrying out the assessment:

- Copy of application form.
- Copy of self-assessment toolkit submitted.
- Applicable documents (Manuals, SOPs, Protocol) of the ethics committee.
- Assessment Guidelines and Forms
- Confidentiality form

In order to obtain evidence on compliance with respect to NABH standards and applicable rules & regulations, different methodology for onsite assessment is practiced which includes facility inspection, document and records review & interview of staff and subjects.

During assessment, assessment objectives are discussed with the ethics committee and a copy of detailed report is handed over to the management of ethics committee at the end of the assessment.



Preparing for NABH Accreditation

Ethics Committee in consultation with hospital/institution management shall first decide about getting accreditation from NABH. It is important for a hospital/institution to make a definite plan of action for obtaining accreditation and nominate a responsible person to co-ordinate all activities related to seeking accreditation. An official nominated should be familiar with existing quality assurance system.

Ethics Committee shall procure a copy of standards from the NABH Secretariat against payment. Further clarification regarding standards can be got from NABH Secretariat in person, by post, by e-mail or on telephone.

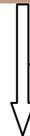
Ethics Committee looking for accreditation shall understand the NABH assessment procedure and ensure that the standards are implemented in the organization.

Ethics committee can download the application form for NABH accreditation from the web-site and must have conducted self-assessment against NABH standards at least 3 months before submission of application and must ensure that it complies with NABH Standards.



Process of NABH Accreditation

Ethics committee applies to NABH in prescribed application form along with self-assessment toolkit, relevant documents and application fees.



Within 10 days of receipt of application

Application form is screened at NABH Secretariat and an acknowledgement letter is issued to the ethics committee along with the unique reference number



Within 30 days of receipt of application

Self-assessment toolkit and other documents submitted by the applicant are reviewed and the feedback is shared with the ethics committee



Within 60 days of receipt of application

On site assessment is planned upon receiving correct documents, if any and payment of accreditation fee



On site assessment conducted. Copy of the report provided to the ethics committee

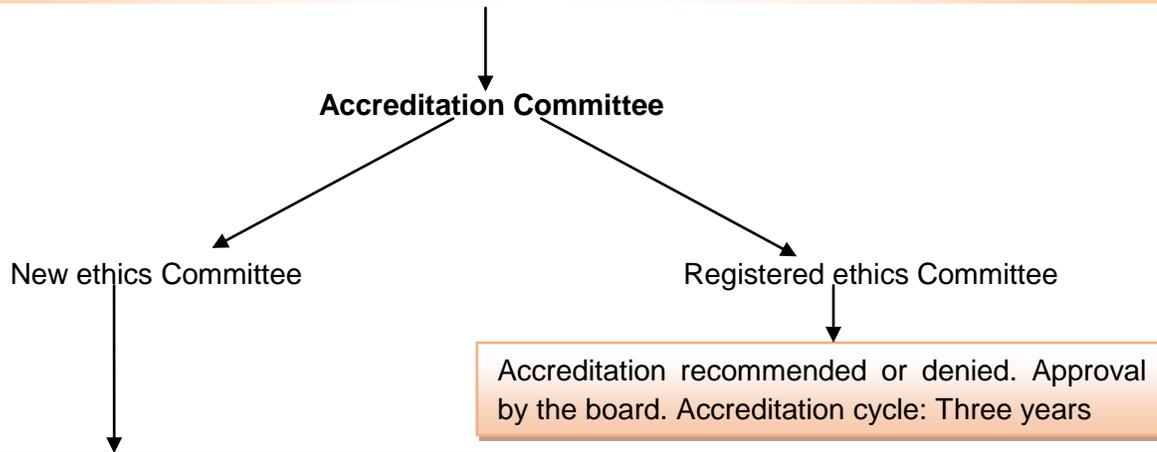


Within 3 months of onsite application

Submission of corrective actions, if any by the ethics committee



Process of NABH Accreditation

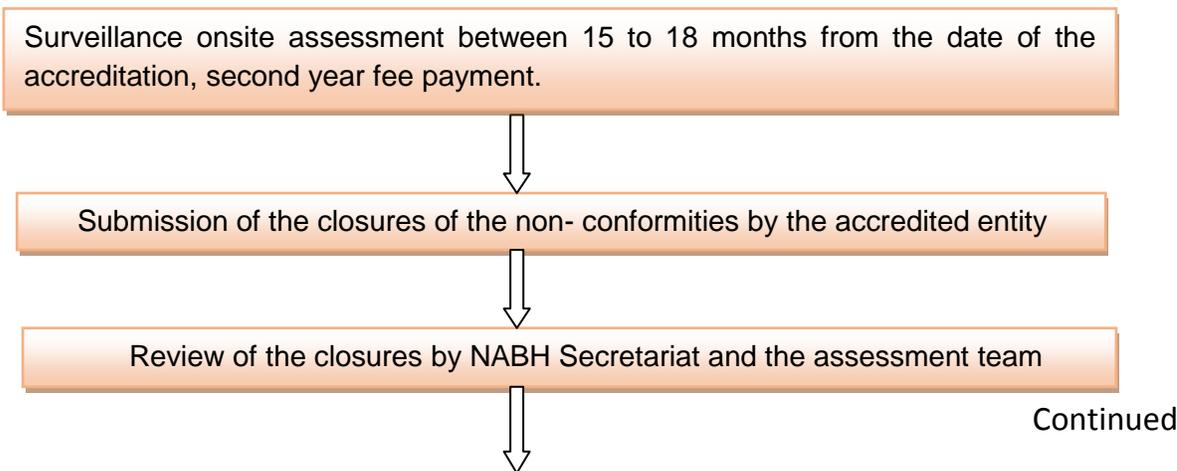


NABH would grant provisional accreditation in situations wherein ethics committee has not initiated reviewing, monitoring & approving trials but qualify for accreditation based on documentation and on-site assessment by NABH assessment team. Such accreditation if granted, will be valid for a maximum of 12 months and ethics committees must initiate trial approval process after taking prior permission from the competent authority within this period failing which accreditation will be withdrawn and ethics committee shall have to apply afresh.

During the provisional accreditation, ethics committee shall keep NABH informed on contracting with a sponsor, approving & monitoring first trial including sites & Investigators. So NABH can accordingly arrange a visit to ethics committee for verification of implementation of standards at an appropriate time.

Based on the assessment report, the accreditation committee may either recommend for continuation of accreditation or withdrawal of provisional accreditation.

After Accreditation



Process of NABH Accreditation

Review of the assessment report and closures by the accreditation committee and recommendation of continuation of accreditation or adverse decision

Submission of third year annual accreditation fees

Accredited entity applies to NABH secretariat 6 Months before expiry of accreditation for renewal along with the renewal application, fee and relevant documents

Further process remains same as for new application except generating reference number



Application for Accreditation

Ethics committee shall apply to NABH in the prescribed application form. The application shall be accompanied with the following:

- Prescribed application fee as detailed in the application form
- Signed copy of 'Terms and Conditions for Maintaining NABH Accreditation', available free on the web-site.
- Filled in Self-Assessment Toolkit, available free on the web-site.
- Relevant documents (as per NABH standards).

Self-Assessment toolkit is for self-assessing itself against NABH Standards. The self-assessment shall be done by the applicant in a realistic manner.

Scrutiny of application:

NABH Secretariat receives the application form and after scrutiny of application for its completeness in all respect, acknowledgement letter for the application shall be issued to the ethics committee with a unique reference number. The ethics committee shall be required to quote this reference number in all future correspondence with NABH.

Final Assessment:

The ethics committee is required to take necessary corrective action to the non-conformities pointed out during the assessment. NABH shall appoint an assessment team. The team shall include Principal assessor (already appointed) and the assessors. The total number of assessors appointed shall depend on the size of ethics committees mentioned in the application form. The date of final assessment shall be agreed upon by the ethics committee management and assessors.

Based on the assessment by the assessors, the assessment report is prepared by the Principal assessor in a format prescribed by NABH.

The details of non-conformity (ies) observed during the assessment are handed over to the applicant by the Principal assessor and detailed assessment report is sent to NABH.



Application for Accreditation

Scrutiny of assessment report

NABH shall examine the assessment report. The report is taken to the accreditation committee. Depending on the score and compliance to standard would decide the award of accreditation or otherwise as per details given in the process of NABH application.

Issue of Accreditation Certificate

NABH shall issue an accreditation certificate to the ethics committee with a validity of three years. The certificate has a unique number and date of validity. The certificate is accompanied by scope of accreditation.

The ethics committee must make all payment due to NABH, before the issue of certificate.

All decision taken by NABH regarding grant of accreditation shall be open to appeal by the ethics committee, to chairman NABH.

Surveillance and Re assessment

Accreditation to an ethics committee shall be valid for a period of three years. NABH conducts one surveillance of the accredited ethics committee in one accreditation cycle of three years. The surveillance visit will be planned during the 2nd year i.e. after 15-18 months of accreditation.

The ethics committee may apply for renewal of accreditation at least six months before the expiry of validity of accreditation for which reassessment shall be conducted.

NABH may call for un-announced visit, based on any concern or any serious incident reported upon by an individual or organization or media.



Financial Term and Conditions

Monitoring By Ethics Committee	Activities		Accreditation Fee	
	Assessment	Surveillance	Application Fee	Annual Fee
Up to 10 ongoing clinical trials in the hospital/ institution	2x1 man-days	1x1 man-days	10,000/-	40,000/*-

*Annual fee payable for 2nd and 3rd year shall be applicable from the date of accreditation throughout the period of validity of certificate.

Service tax as applicable from time to time will be charged on all the above fees which is to be included in the fees accordingly while sending to NABH.

The man days given above for assessment and surveillance are indicative and may change depending on the facilities.

If ongoing trials are more than 10, then man days shall be 2x2 and application fee shall increase by 20,000/-

Guidance Notes:

- Application can only be considered when complete details of ethics committee are provided and assessment will be done comprehensively. There should be one person responsible for coordinating activities of ethics committee.
- Application form duly filled in are to be submitted online along with self-assessment tool kit, declarations (Annexure 1, 2, 3 as applicable), relevant documents and application fees.
- Fees shall be paid only through online mode (Credit card or Debit card), Bank transfer and is non-refundable. No offline applications and fees shall be entertained.
- The first annual fee is payable before assessment visit.
- 10% discount will be admissible in case, applicant pay for the accreditation fee for three years in one installment.
- The accreditation fee does not include expenses on travel, lodging/ boarding of assessors, which will be borne by the applicant on actual basis.



NATIONAL ACCREDITATION BOARD FOR HOSPITALS & HEALTHCARE PROVIDERS (NABH)

- The accreditation, once granted will be valid for three years. The accredited entity may apply for renewal as per the NABH policy.
- The surveillance visit will be planned during the 2nd year of accreditation which is usually between 15-18 months.
- NABH may call for an un-announced visit, which could be a Surprise Assessment or based on any concern/ feedback/ complaint reported by any individual or organization or media and expenses on such visit shall be borne by NABH.
- The accreditation does not cover entire hospital/staffs/wards or trials performed outside the named unit.
- Clinical trial as per definition of Schedule-Y which excludes Academic studies and Research Thesis.

**NATIONAL ACCREDITATION BOARD FOR HOSPITALS
& HEALTHCARE PROVIDERS (NABH)
Quality Council of India**

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