Ethics Committee Accreditation under Clinical Trial Program

General Information Brochure

August 2020

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.

International Society for Quality in Healthcare (ISQua) has accredited NABH as an Organization. The hospitals accredited by NABH have international recognition. This provide boost to medical tourism in country.

NABH is an Institutional Member as well as a member of the Accreditation Council of the International Society for Quality in HealthCare (ISQua). NABH is one of the founder member of Asian Society for Quality in Healthcare (ASQua).

There has been demand from SAARC/ASIAN countries for NABH accreditation and to meet this requirement, NABH has launched NABH International and to begin with Philippines is the first overseas destination for extending NABH accreditation services.

About NABH

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

The objective of NABH standards is to improve healthcare quality and patient safety.

NABH currently operates the following accreditation, certification and empanelment programs

Accreditation programs:

1. Hospitals
2. Small Healthcare Organizations
3. Blood Banks
4. Medical Imaging Services
5. Dental Facilities/Dental Clinics
6. Allopathic Clinics
7. AYUSH Hospitals
8. Primary Health Centre
9. Clinical Trial (Ethics Committee)
10. Panchakarma Clinics
11. Eye Care Organization

Certification programs:

1. Entry Level Hospital
2. Entry Level Small Healthcare Organizations
3. Entry Level AYUSH Centre
4. Entry Level AYUSH Hospital
5. Nursing Excellence
6. Medical Laboratory Programme
7. Emergency Department
8. MVTF Empanelment Certification

Empanelment programs:

NABH is the nodal body representing Quality Council of India for conducting assessments of healthcare organizations for empanelment under Central Government Health Scheme (CGHS) and Ex-Servicemen Contributory Health Scheme (ECHS).

Introduction to Accreditation

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 the nature of protocols reviewed and the number of ongoing trials mentioned 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. The program was started in the year November 2016. The program was made mandatory with effect from 1st January, 2018 by the Ministry of Health and Family Welfare.

An expert committee under the chairmanship of Prof. Ranjit Roy Choudhry formed by the MOHFW recommended for accreditation of Ethics committee, Investigators, Clinical Trial sites. Given its expertise in the area, Quality Council of India was assigned the task for creating a system for accreditation of Ethics committee investigators and clinical trials by CDSCO.

The main objectives of this program are as follows

1. In order to strengthen the clinical evaluation of new drugs, clinical trials should be conducted in accredited sites by accredited investigator with the oversight of accredited ethics committees.

2. A well thought accreditation program can evaluate the capability or performance of any of the three components (CT site/Investigator/Ethics Committee) as an entity. It also established confidence in India's research capabilities.

3. To ensure transparency in every step followed, in clinical trials and to promote and improve the standard for clinical trial practices in India.

4. In order to bring clinical trial procedures on par with global standards and to ensure well being/protection of trial participants than being treated as guinea pigs.

The key benefits of this accreditation include building confidence to the subjects that they will not be subjected to any unjustified or hazardous trial. This accreditation will be a wake-up call for the regulatory authority to device more robust and patient friendly transparent mechanism so that the safety of trial participants is ensured to the maximum possible extent.
The public and civil society gain confidence that the clinical trials been carried out are justifiable both on ethical and scientific grounds.

The target customers for this accreditation include Institutional and Independent Ethics Committees registered by DCGI who are involved in reviewing and approval of drug trials.

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/Investigational product.

Confidence in accreditation is obtained by a transparent system of monitoring over the functioning of the ethics committees and an assurance is given by the accreditation body that ethics committee constantly fulfills the accreditation criteria.

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 centres, 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.

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 subject's safety.
- The subjects are serviced by credential medical staff under the proper supervision of the Investigator duly following the protocols.
- 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 complying to regulatory guidelines and standard.

Benefits for Site Staff

- The staff at the Sites/Institution is 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.

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 New Drugs & Clinical Trial Rules (NDCT), Indian GCP and other applicable regulatory requirements as laid down by DCGI.

NABH Standards for Ethics Committee

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.

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

Ten chapters of Ethics Committee Standards are:

1. Authority for formation of Ethics Committee
2. Standard Operating Procedures (SOPs)
3. Ethics Committee Composition
4. Protection of subject rights, safety and wellbeing
5. Administrative support
6. Review Process
7. Decision making and post meeting activities
8. Monitoring
9. Self-Assessment
10. Record keeping and archival

Methodology for Accreditation

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.

Eligibility to apply for Ethics Committee accreditation

Ethics Committee that fulfils the following requirements:

CDSCO Registered Institutional & Independent Ethics Committees involved in review & approval of drug trials (new Investigational product).

Exclusions: Ethics Committee involved in review & approval of Observational studies, Registry Trials, Non-Interventional trials, PG Thesis on Clinical Trials/Research, Biomedical Health Research

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 empanelled assessors.

Assessment team are assigned online at NABH portal. After online assignment the assessment team has rights to view the following documents:

- Application form.
- Self-assessment toolkit submitted.
- Applicable documents (Manuals, SOPs, Protocol) of the ethics committee.
- Assessment Guidelines and Forms
- Confidentiality form
- Signed Declarations (Ethics Committee, Investigators & Trial Sites)
- EC membership list, List of Ongoing Trials & List of SAEs as per defined format

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.

Methodology for Accreditation

Ethics Committee in consultation with hospital/institution management shall first decide about getting accreditation from NABH. It is important for an Ethics Committee in 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 may refer to the Ethics Committee Standards which is available free at NABH website https://www.nabh.co/CT_Standard.aspx under Documents category. 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 standard from NABH website 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.

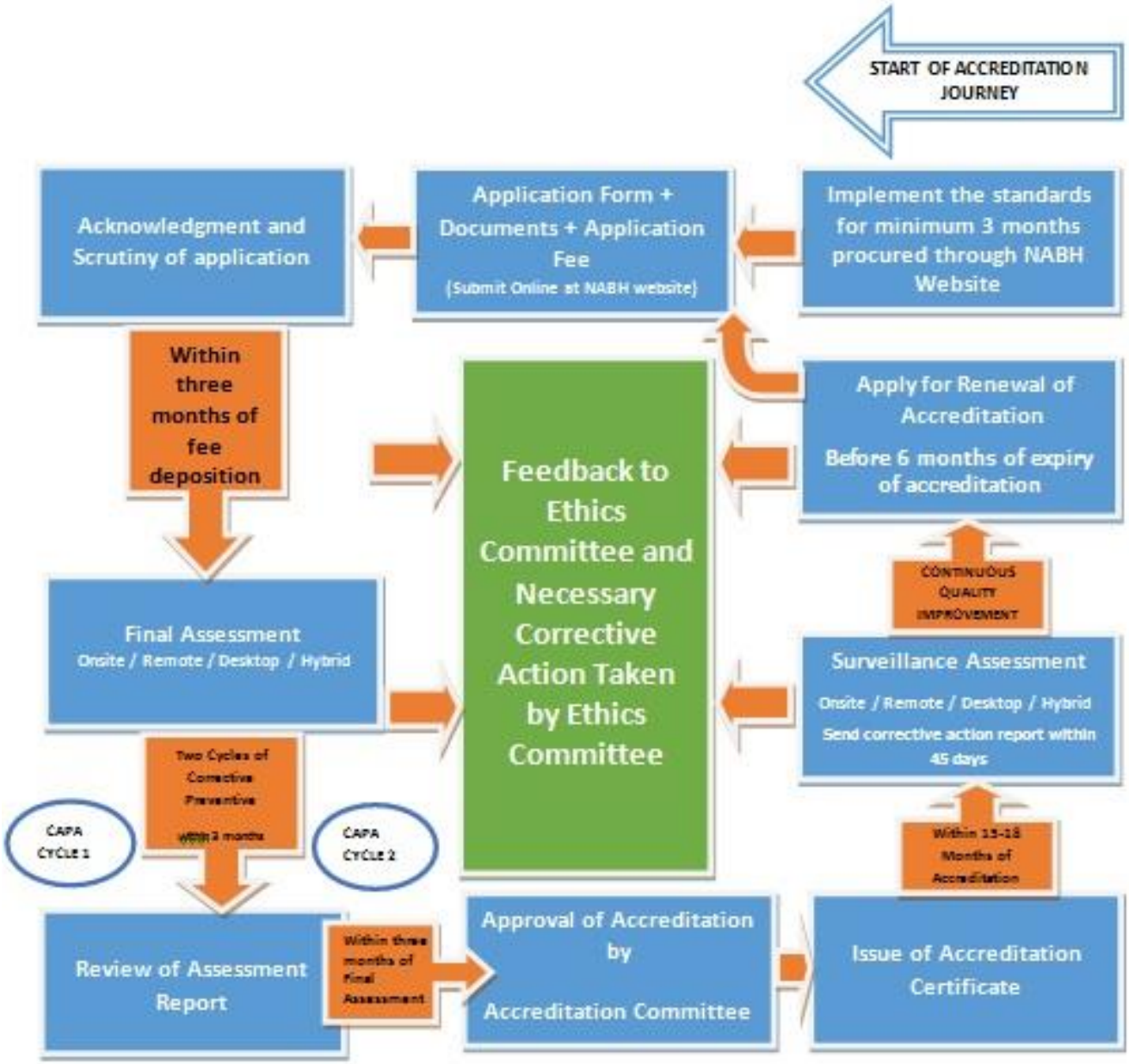
How to apply?

Once the standards are implemented in the organization, the organization can apply for accreditation online from the website www.nabh.co

(a) Use a new email id for registration
(b) Choose 'Clinical Trial (Ethics Committees)' as Application Type
(c) NABH shall activate the email id and provide you the login and password

Using the above login and password – you can fill the application form.

Accreditation Process



NABH Accreditation Procedure

Preparation of Policies and Manuals:

The Ethics Committee shall prepare the Standard Operating Procedures (SOPs) and other protocols required as per the NABH standards.

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 Declaration forms (Ethics Committee, Trial Sites & Investigator)
- 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:

Reference ID for the application is generated once the Ethics Committee pays the application fees from 'Make Payment' option of the online application form. NABH officer shall scrutinize the application form for its completeness. Ethics Committee may correspond to NABH via writing in 'Remarks column' of online portal of the Ethics Committee.

Notification of Principal Assessor and Assessment Team:

NABH shall appoint Principal Assessor who shall have the overall responsibility of conducting the assessment for the Ethics Committee and a team of other assessors. He/ She will evaluate the adequacy of all the documents including the standard operating protocols and other trial related data as mandated by the standards.

Types of Assessment conducted by NABH

NABH in coordination with the Ethics Committee may choose to follow one of the following methods for conduct of the assessments based on environmental factors prevailing in the region in order to ensure business continuity in its operations without compromising on quality.

Onsite assessment: In onsite assessment, the assessors nominated by NABH makes a visit to the Ethics Committee Organization for a predefined man days based on the number of ongoing clinical trials in the hospital, the assessors verifies the documents, facilities and conducts interviews in person at the Ethics Committee Organization. The Ethics Committee Organization needs to bear the cost of the assessor's travel and stay.

Desktop assessment: In this type of assessment the Ethics Committee Organization will submit information & documents as per the checklist which is based on applicable standards for Committee Organization & the same shall be reviewed by NABH assessor. The decision on continuation of accreditation shall be based on the recommendations made by the assessor.

Remote assessment: In this type of assessment, the assessor (s) does not go to the Ethics Committee in person, but conducts the entire assessment from a remote location through the use of virtual platforms. Ethics Committee need to provide the online platform, there are nominal overhead charges for Ethics Committee which they need to pay.

Hybrid assessment: In this type of assessment, one assessor may be physically present in the Ethics Committee during the audit, and the other assessor(ors) will be doing the audit from a remote location through the use of virtual platform.

Communication Channel

All applicant and accredited Ethics Committee Organization are strongly advised to use the "Remarks column" at the online portal for all communication. Committee Organization are strongly discouraged to communicate through telephone or emails to secretariat members as this communication cannot be saved as part of particular HCO record and may not be available for future references. The matrix for communication is available at NABH website. **https://www.nabh.co/Announcement/NABH%20Communication%20Matrix.pdf**

NABH Accreditation Procedure

Final 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 number of ongoing trials mentioned in the application form. The date of final assessment shall be agreed upon by the ethics committee management and assessors. Before the Assessment, the Ethics committee has to pay the 1st year accreditation fees. Based on the assessment by the assessors, the assessment report is prepared by the Principal assessor in a format prescribed by NABH and submitted online at NABH portal.

The details of non-conformity (ies) observed during the assessment are uploaded at NABH portal through assessor login account and the NCs reported is forwarded to the Ethics committee for taking corrective actions.

Scrutiny of assessment report:

NABH shall examine the assessment report. Once all the NCs are closed and accepted by the Assessor or otherwise in 2nd cycle, the report is taken to the accreditation committee. Depending on the adequacy of trial related data 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 the scope of accreditation.

The applicant Ethics Committee must make all payment due if any to NABH, before the issue of certificate.

NABH Accreditation Procedure

Surveillance and Re assessment:

Accreditation to the Ethics Committee shall be valid for a period of three years. NABH shall conduct surveillance before completion of 15-18 months since the date of accreditation of the accredited Ethics Committee.

The Ethics Committee shall pay the annual fees every year. The first annual fees is paid before the final assessment and is valid till the end of first year from the date of accreditation. Since then, the annual fees shall be due on the same date/ month every year.

The Ethics Committee need to apply online 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 an organization or media.

Focus Assessment:

Focus assessments are done in Ethics committee organizations when there are any significant changes with regard to the Ethics committee activities and operations, such as change in scope of accreditation, change of address/ location, change in environment, key technical personnel etc. Ethics committees are requested to view policy and procedure related to Focus visit to an accredited Ethics committee organization by visiting the following link.

https://www.nabh.co/Policy_for_Focus_Assessment.aspx


NABH

POLICY & PROCEDURE FOR FOCUS ASSESMENT OF AN ACCREDITED/CERTIFIED HEALTHCARE ORGANISATION (HCO)

NABH Accreditation Procedure

Surprise Assessment:

NABH may conduct surprise assessments at accredited ethics committee organizations periodically to evaluate the compliance to the accreditation standards, as ethics committees are expected to adhere to the NABH accreditation standards at any given point of time once Ethics committee is accredited. Surprise visit can also happen in response to adverse media report. Ethics committees are requested to view policy and procedure related to Surprise visit to an accredited Ethics committee organization by visiting the following link.

https://www.nabh.co/SURPRISE-VISIT.aspx

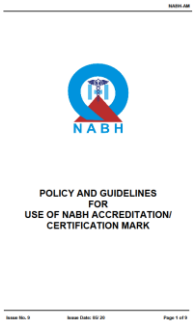
NABH POLICY AND PROCEDURE
FOR SURPRISE VISIT TO AN
ACCREDITED/ CERTIFIED HCO

NABH Accreditation Procedure

Guidelines for using the accreditation mark:

Accredited ethics committees should ensure the guidelines related to display NABH Logo / accreditation mark are adhered. Any misuse of the logo / accreditation mark can lead to adverse action being taken against the ethics committees by NABH besides legal action. Ethics committees are requested to view guidelines related to use NABH logo / accreditation mark by visiting the following link.

https://www.nabh.co/Images/pdf/Policy_and_Guidelines_for_use_of_NABH_Accreditation_Certification_Mark.pdf



POLICY AND GUIDELINES
FOR
USE OF NABH ACCREDITATION/
CERTIFICATION MARK

NABH Accreditation Procedure

Disclaimer & Indemnity:

NABH reserves the right to take action or even cancel the accreditation awarded to an ethics committee in following conditions -

1. If the required fee is not paid on time
2. Any adverse actions taken by any regulatory bodies against the ethics committee.
3. Serious patient safety issues, etc.
4. Failure to comply with the standards at any given point of time etc.

Ethics committees are also advised to check the NABH portal time to time for any important announcements, change in standards etc. which needs to be adhered by accredited ethics committees.

Training

The journey of Accreditation/Certification i.e. from applying to grant of Accreditation/ Certification involves the awareness & training of all the members of the healthcare organizations about the various Chapters, Standards & Objective Elements of NABH Standards booklet. The staff needs to imbibe the culture of NABH by getting trained in the standards, understanding the applicable standards in a right way so that the same can be implemented, measured and monitored in the right manner by the healthcare organization.

NABH conducts trainings on Good Clinical Practice (GCP) & awareness programmes on Ethics Committee Standards for better understanding of the Accreditation requirements NABH is going to start training program on New Drugs and Clinical Trials Rules very soon.

NABH Secretariat organizes training sessions on understanding of NABH standards and implementing them in the organizations in form of Programme on Implementation (POI), for healthcare organizations desirous of taking their organizations for accreditation. These sessions are taken by faculty from NABH who are senior assessors. The details of these trainings, dates, venue and fee information are available in the NABH website

NABH has taken a new initiative to conduct free master classes on various topics under the rubric "NABH Quality Connect-Learning with NABH". The master classes are conducted every month. The topics include: Key Performance Indicators (KPI), Hospital Infection Control, Management of Medication, Document Control, Clinical Audits, Continual Quality improvement, Hospital infection prevention etc

Apart from this guidance material is available at "Resource" page of NABH web portal

Kindly visit the below link to attend training programmes being conducted by NABH.

https://www.nabh.co/EducationTraining.aspx

Fee Structure

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	5,000/-	30,000*/-

***The fee structure is based on the number of man days required for assessment. If ongoing trials are more than 10, then man days shall be 2x2 and application fee shall increase by Rs.15000/-**

GST: w.e.f. 01.06.2016 a service tax of 18% or as applicable will be charged on all the above fees. You are requested to please include the service tax in the fees accordingly while sending to NABH.

CONTACT DETAILS

NATIONAL ACCREDITATION BOARD FOR HOSPITALS AND HEALTH CARE PROVIDERS

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