

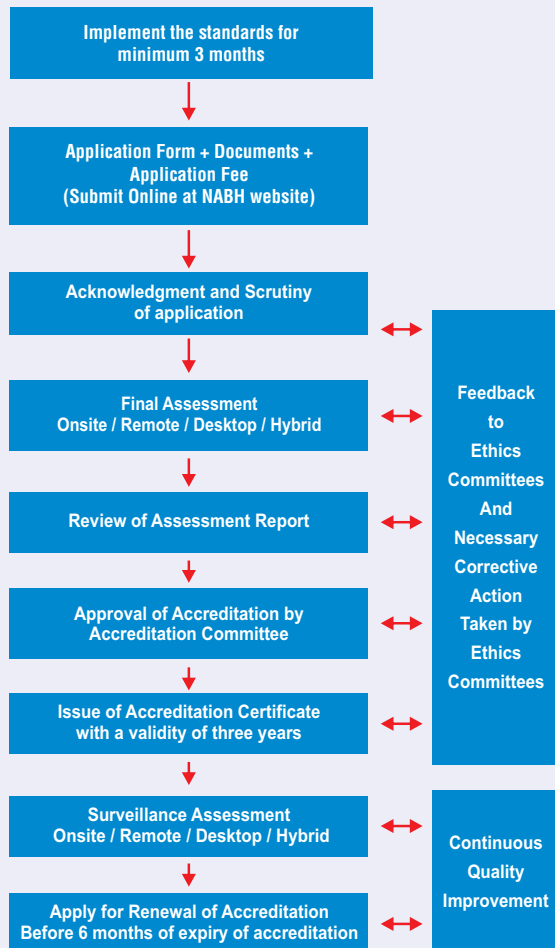


National Accreditation Board for Hospital & Healthcare Providers

Accreditation of Clinical Trial (Ethics Committees)



Accreditation Procedure



Introduction to NABH: National Accreditation Board for Hospitals and Healthcare Providers (NABH) is a constituent board of Quality Council of India (QCI) which is established with a vision to be the apex national healthcare accreditation and quality improvement body, functioning at par with global benchmarks. NABH as an organization is accredited by the International Society for Quality (ISQua) and is an institutional member of ISQua and ASQua.

Ethics Committee Accreditation: 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. The laid down standards on Ethics Committee Accreditation are the basic minimum requirements which needs to be adhered in order to improve the safety of the process of Clinical Trials in India. It is an attempt at standardizing the quality of clinical research in India.

Benefits of Accreditation

- ❖ Patients are the biggest beneficiary as accreditation ensures safety and wellbeing of research participants.
- ❖ It ensures public trust and confidence as the rights of the research participants are protected and there is a robust concerned process to ensure patient safety.
- ❖ Ethics committee accreditation process improves efficiency, effectiveness of overall clinical trial process.
- ❖ It also provides assurance to other stakeholders that all the procedures carried out at the site(s) are complying to regulatory guidelines and standard.

Who can apply?

CDSO 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

How to apply for Accreditation?

All aspiring Ethics Committees desirous to achieve accreditation can apply online by registering at NABH website. Kindly refer the General information brochure in the Ethics Committee Accreditation page at NABH website.

What is the fee structure for getting accredited?

To view the complete fee structure please visit important links on NABH website followed by fee structure under quick links.

Does NABH support the organizations in the accreditation journey?

NABH has taken a new initiative to conduct free master classes on various topics under the rubric "NABH Quality Connect-Learning with NABH". NABH conducts various training and awareness programmes round the year regularly. It is advisable that the aspirant healthcare organizations attend Training Programme on Implementation (POI) for better understanding the standards. 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 Trial Rules very soon.

How to procure a copy of the standards?

The standard is freely available and can be downloaded online from the NABH website.



Click here to download your free copy of the standards

For further details please visit the NABH website

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Quality, Safety, Wellness