National Accreditation Board for Hospitals and Healthcare Providers (NABH), Quality Council of India has developed a system of accreditation for Ethics Committees (EC). Accreditation shall be granted as per details and scope provided in the application form.



Ethics Committee applies to NABH in prescribed application form (common form) along with self-assessment toolkit, relevant documents and application fee.

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 ethics committee are reviewed and the feedback is shared with the applicant

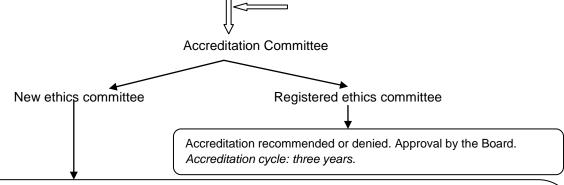
Within 60 days of receipt of application

Onsite assessment is planned upon receiving corrected documents, if any and payment of accreditation fee

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

Within 2 months of on-site assessment

Submission of corrective actions, if any by the ethics committee

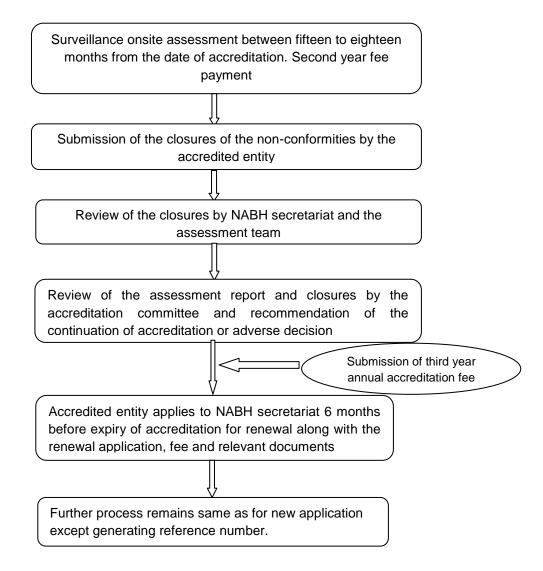


Provisional Accreditation: NABH would grant provisional accreditation in situations wherein ethics committee has not initiated reviewing, monitoring & approving trials but qualify for accreditation based on documentation and on-site assessment by NABH assessment team. Such accreditation if granted, will 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after taking prior permission from the competent authority within this period failing which accreditation will be withdrawn and ethics committee shall have to apply afresh.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



In addition to the regular surveillance assessment, NABH may call for an un-announced visit, which could be a Surprise Assessment or based on any concern/ complaint/ feedback reported by any individual or organization or media.