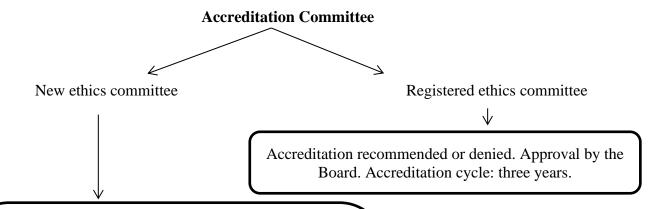
NABH ACCREDITATION OF EC

GENERAL GUIDELINES

(http://www.nabh.co/Images/PDF/AccreditationProcess_ClinicalTrial.pdf)



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after taking prior permission from the competent authority within this period failing which accreditation will be withdrawn and ethics committee shall have to apply afresh.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

1. Important Timelines for Accreditation

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

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

$\qquad \qquad \bigvee \longleftarrow \text{ Within 30 days of receipt of }$

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

After Accreditation

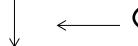
Surveillance onsite assessment between fifteen to eighteen months from the date of accreditation. Second year fee payment

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Submission of the closures of the non-conformities by the accredited entity

Review of the closures by NABH secretariat and the assessment team

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



Submission of third year annual accreditation fee

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.

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