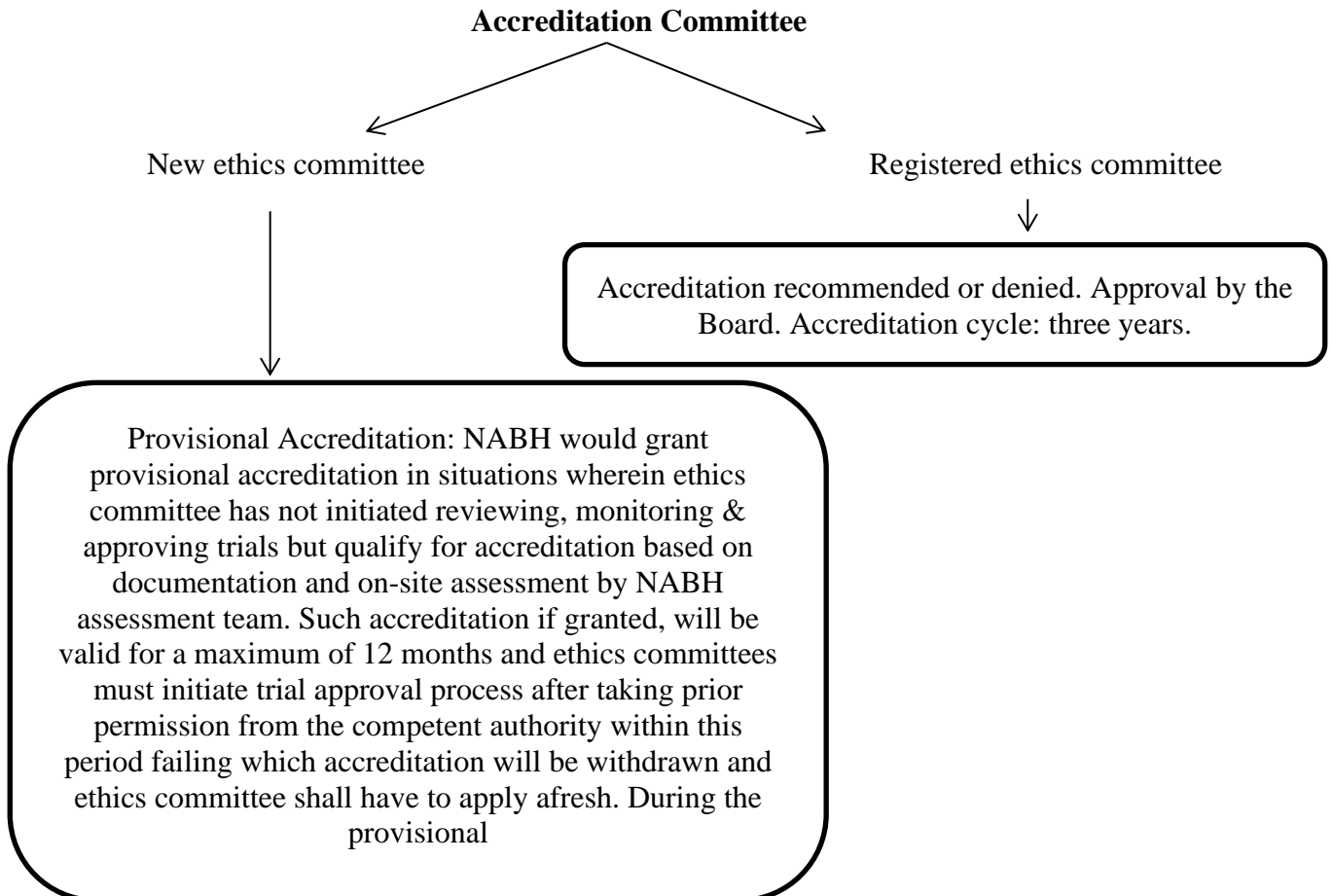


## NABH ACCREDITATION OF EC

### GENERAL GUIDELINES

([http://www.nabh.co/Images/PDF/AccreditationProcess\\_ClinicalTrial.pdf](http://www.nabh.co/Images/PDF/AccreditationProcess_ClinicalTrial.pdf))



### 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.

↓ ← **Within 10 days of receipt 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

### **After Accreditation**

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



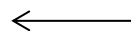
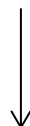
Submission of the closures of the non-conformities by the accredited entity



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