

**Annexure 11B**  
**Format of Observational Research Study Approval letter**

Date

XX/XX/XX

XX

To,

Dr. xxxxxxxxxxxx,

Dept. of xxxxxxxxxxxx.

Ref: The study no. EC/xxx/20xx entitled,  
“xxxxxxxxxx”.

Sub: Letter no.

Dear Dr. XXXXx,

The meeting of the Institutional Ethics Committee (IEC) was held on xxxxx at xxxx, in the  
xxxxxxxxxxxxxx with xxxxx as Chairperson.

xxxx members attended the meeting held on xxxx. The list of members who attended the meeting  
is as follows.

Name of Members	Position on IEC	Designation & Affiliation	Qualification	Gender

It is hereby confirmed that neither you nor any of the study team members have participated in the  
voting/decision making procedures of the committee.

The IEC has reviewed and approved the following documents submitted for the above –  
mentioned clinical study.

1. Xxx
2. Xxx
3. xxx

The IEC hereby approves the proposal entitled, “xxxxxxxxxxxxxx”.

It is understood that the study will be conducted under your direction, in a total of xxxx research  
participants, at Dept. of xxxx, \_\_\_\_\_ as per the submitted  
protocol.

This approval is valid for the entire duration of the study.

No deviations from, or changes of the protocol and Informed Consent Document should be  
initiated without prior written approval by the IEC of an appropriate amendment. The IEC  
expects that the investigator should promptly report to the IEC any deviations from, or changes  
of, the protocol to eliminate immediate hazards to the research participants and about any new  
information that may affect adversely the safety of the research participants or the conduct of the  
trial.

For studies which will continue for more than a year, a continuing review report needs to be  
submitted (within 1 month of the due date i.e. 11 months from the date of approval) on or before  
XXXXXXXXXXXX.

A copy of the final report should be submitted to the IEC for review.

The IEC functions in accordance with ICH GCP, Schedule Y, ICMR guidelines and other  
applicable regulatory requirements.

Sincerely yours

Member Secretary/ Chairperson,

IEC

(Signed and dated by the IEC Chairperson or Member Secretary)

**Date of approval of the study: XX/XX/20XX**