Annexure 11A

Format of Interventional Research Study Approval letter

Date XX/XX/XXXX
To,
Dr. xxxxxxxxxxxx,
Dept. of xxxxxxxxxxxxx.

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 xxxxxxxxxxxxx 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 reviewed the above mentioned clinical study and approved the following documents submitted for this clinical study at the meeting.

1. Xxx
2. Xxx
3. xxx

The IEC hereby approves the proposal entitled, "xxxxxxxxxxxxx".

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

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

It is the policy of IEC that, it be informed about any onsite serious adverse event or the unexpected adverse event report within 24 hours as per the formats specified in SOP 09/V1 to the IEC or by email if there is holiday. The report of SAE or death after due analysis shall be

forwarded by the Investigator to chairman of the IEC and the head of the institution where the trial is been conducted within 10 calendar days of SAE or death

In case of injury or death occurring trial subject the sponsor (whether a pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial shall make payments for medical management of the subject and also provide financial compensation for the clinical trial related injury or death.

No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by IEC of an appropriate amendment. The IEC expects that the investigator should promptly report to 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 XXXXXXXXXXX.

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