

Annexure 14
Approval letter format in case of Expedited Review

Date: xxxxxxxxxxx

To,

Dr. xxxxxxxxxxxxxxxx,

Dept. of xxxxxxxxx.

Ref: Your project no. **xxxxxxxx** entitled, “xxxxxxxxxxxxxxxx”.

Dear Dr. xxxxxxxxx,

The following documents of the above mentioned project were reviewed and approved through an expedited review process.

1. xxx

2. xxxxxxxx

3. xxxxxxxxxxx

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

The IEC approves the above mentioned study.

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 any unexpected adverse event report within 24 hours as per the formats specified in SOP 09 to IEC or by email if there is holiday. The report of SAE or death after due analysis shall be forwarded by the Investigator to the chairman of 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 of participant(s) occurring during the trial, 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 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 xxxxxx.

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

Sincerely yours

xxxxxxxxxxxx

Member Secretary/ Chairperson

Date of approval of the study: xxxxxx