Annexure 12

Study Assessment Form for Expedited Review

IEC Protocol Number :	Date of receipt at IEC office (DD/MM/YY):	
Project Title :_____		
Name of the Principal Investigator	Department	Contact number
Total no. of Participants at the site:		
No. of Study sites:		
Sponsor:		
Duration of the Study:		
Reviewer's name :		
Type of the Study :	☐ Intervention ☐ Epidemiology ☐ Document based ☐ Genetic ☐ Social Survey ☐ Others, specify…….	

Description of the Study in brief: Mark whatever applied to the study.

☐ Randomized ☐ Open-labeled

☐ Double blinded ☐ Placebo controlled ☐ Treatment controlled

☐ Cross-over ☐ Parallel ☐ Interim Analysis

☐ Use of Tissue samples ☐ Use of Blood samples ☐ Use of genetic materials

Comments:

(Review the protocol and related documents as per the guidelines stated in *AX 05/SOP 06/V1)*

Provisional Decision: ☐ Approved ☐ Resubmission
☐ Disapproved ☐ Full Board
☐ Approved with modifications

Reason for disapproval _____

_____

Name of the IEC member _____

Signature_____ **Date** _____

Final Decision:

Approved YES O

If disapproved, reasons for disapproval _____

Further revision or modification required/resubmission

Any Other

Signature of the Chairperson:____ **Date:**

_____