

Annexure 7
Ongoing Approved Research Review Submission Form

1. Protocol number
2. Month / Year of approval
3. Number of ongoing review
4. Title of the research proposal

5. Name of the Principal Investigator (PI) with qualification and designation

6. Name of the Co-investigator(s) (Co-PI) with qualification and designation

7. Duration of the Project
8. Source of funding & financial allocation for the project / trial
9. Has subject recruitment begun? If Yes:
 - a. How many subjects have been screened?
 - b. How many subjects have been recruited?
 - c. Is subject recruitment continuing?
 - d. Are there any 'drop outs'?
 - e. Are subjects still receiving active intervention?
10. Have there been any adverse events? If yes, give details (attach a separate page if needed)
11. Have there been any Serious Adverse Events adverse events? If yes, give details. (attach separate page)
12. Have there been any unanticipated study-related problems?

13. If subject recruitment has not begin, give reasons

14. Is there any new risk or benefit information? If yes, give details.

15. Are there any interim changes to the protocol or consent form? If yes, give details including submission of revised protocol and consent form for approval.

16. Does the scientific literature indicate changes in knowledge relevant to the conduct of the study? (If yes attach copy of same)
17. Any other information

Note: The above information and enclosures should be furnished wherever necessary depending upon the nature of study proposal.

Signature of Principal Investigator and Co- Investigators