|  |
| --- |
| Title of study: Principal Investigator (Name, Designation and Affiliation): |

|  |  |
| --- | --- |
|  | Date of EC Approval: Click here to enter a date. |
|  | Date of Start of Study: Click here to enter a date.Date of study completion: Click here to enter a date. |
|  | Provide details of:a) Total no. of study participants approved by the EC for recruitment: b) Total no. of study participants recruited: c) Total number of participants withdrawn from the study (if any):  Provide the reasons for withdrawal of participants\*:     |
|  | Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared): |
|  | Describe the main Ethical issues encountered in the study (if any):  |
|  | State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study periodDeviations: Violation: Amendments:  |
| 1.
 | Describe in brief Plans for archival of records / Record Retention:  |
|  | Is there a plan for post study follow-up Yes  No If yes, describe in brief:  |
|  | Do you have plans for ensuring that the data from the study can be shared/ accessed easily? Yes  No  . If yes, describe in brief: |
|  | Is there a plan for post study benefit sharing with the study participants? Yes  No If yes, describe in brief:  |
|  | Describe results (summary) with Conclusion\*\*: |
|  | Number of SAEs that occurred in the study:  |
|  | Have all SAEs been intimated to the EC: Yes  No  |
|  | Is medical management or compensation for SAE provided to the participants? Yes  No If yes, provide details |

\*Explanation for the withdrawal of participants whether by self or by the PI.

\*\*For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready.

Signature of PI:

Signature of Co-PI:

Signature of Investigators:

Click here to enter a date.

* In case any of the PI/Co-PI/ Investigator left institution his/her consent regarding the submission of Study completion/ Final report needs to be submitted along with this form.