**ANNEXURE.12:**

**Format for submission of Study Completion reports for Investigators**

*Kindly Send a soft copy also on* [*iec.igmc.sml@gmail.com*](mailto:iec.igmc.sml@gmail.com) *for easy redressal*

1. **Principal Investigator details:**
2. Name:
3. Designation:
4. Department:
5. Email:
6. **Study details:**
7. Title
8. IEC Number
9. IEC Approval date
10. Sponsor/ Grant agency
11. CTRI number (in case of Clinical Trial):
    1. If not registered, give reason
12. Date of start of study
13. Date of completion of Study
14. **Summary of work done:**

**(**along with results of the study and publications from the study, if any)

1. **Serious Adverse Events (SAEs)** /**any unexpected adverse event**

Were all SAEs/ unexpected adverse event reported to IEC

* 1. If yes, reference number and dates
  2. (if no, give reason)

1. Whether reports of SAEs at other sites have been submitted

to the IEC IGMC Shimla:

1. **Protocol amendments (if any)**
2. Were these amendments approved by the IEC

(if no, give reason).

1. **Protocol violations**

Any major protocol violations (if any)

* 1. If yes, were they reported to IEC
  2. (if no, give reason)

1. **Annual Reports submitted regarding the study**

(reference no. and dates)

1. **Signature of PI with date.**