**Undertaking**

To

The Chairperson

Institute Ethics Committee,

AIIMS, Raipur (C.G.)

Title of Study/Project:

**Subject: Undertaking for GCP, SAE reporting and study not initiative etc.**

I …………………………………… (Name of PI) undertake the following facts as Principal Investigator (PI):

|  |  |  |
| --- | --- | --- |
| **Sr. No.** | **Undertaking** | **Tick the mark (✓) where ever applicable** |
| 1 | I will report all Serious Adverse Event (SAE) to IEC-AIIMS Raipur (if applicable). |  |
| 2 | I will comply with Good Clinical Practices (GCP) guidelines for human studies issued by ICMR, NDCT-2019, MDR-2017 and ICH-GCP and their amendments from time to time. |  |
| 3 | I will submit Good Clinical Practices (GCP) training certificate. |  |
| 4 | I had not initiated the study/project. |  |
| 5 | I will follow and take clearance from HMSC/DCGI/DBT/BARC, if obtained (One Copy) |  |
| 6 | I will submit MOU or CTA, In case of institutional collaboration, relevant documents through proper channel (One Copy) |  |
| 7 | I or my sponsor will bear the expenditure of injury related to the project(One Copy) |  |
| 8 | I will take Permission to use copyrighted Questionnaire/Proforma (One Copy) |  |
| 9 | I will declare to study participant about the use of leftover sample/ tissue (One Copy) |  |

Signature

Name and seal

Designation

Name of the Institute

Date:

Place: