**SOP 13-V 3.0 / ANX 01-V 3.1**

**Study Completion Report Form**

(To be filled by PI)

|  |  |  |
| --- | --- | --- |
| Proposal No. :  Protocol Title:  Principal Investigator: | | |
| Phone number, email address | |  |
| Sponsor | |  |
| Address | |  |
| Phone, E mail | |  |
| Total no. of study participants recruited | |  |
| Study Initiation Date | |  |
| Total no. of study participants approved by the IHEC for recruitment | |  |
| **\***Abstract | |  |
| On site SAEs  (Total number and type) | |  |
| Off site SAEs  (Total number and type) | |  |
| Whether all SAEs intimated to the IHEC (Yes/No) If no give reason | |  |
| No. of participants withdrawn | |  |
| Reasons for withdrawal | |  |
| Protocol deviations-Violations  (Number and nature) | |  |
| Publications / presentations, if any | | |
| Any Ethical Issue encountered during the study | | |
| Undertaking: I hereby declare that contents of the soft and hard copies of this document submitted to the IHEC are the same. | | |
| Signature of PI Date: |  | |

**\*** Extended abstract may be prepared under the following headings: Introduction (this section includes

Review of Literature and justification), Objectives, Methods (Design, setting, participants, etc.,), Results

and Conclusions. (Tables, if included, must be referred to in the report and attached as annexure.