**SOP 10-V 3.2 / ANX 03-V 2.0**

# Status / Progress Report/Application for Renewal of IHEC Approval

# (To be filled by PI)

|  |  |
| --- | --- |
| PSG IMS&R IHEC Proposal No. |  |
| Protocol Title: |
| Name of the PI: |  |
| **\*** Abstract |  |
| Date of Commencement of Study |  |
| Number of participants recruited so far |  |
| Number of participants withdrawn |  |
| Change in investigators / co-investigators |  |
| Protocol amendments, if any |  |
| Protocol deviations, if any |  |
| Protocol violations, if any |  |
| Change in the informed consent, if any |  |
| Serious adverse events |  |
| **\*\*** DSMB Reports |  |
| **\*\*** Statement on ongoing studies by the investigators **(Annexure – SOP 03- V 4 / ANX 05 – V 2.0Pharma Sponsored Studies)** |  |
| Renewal Requested | YES / No |
| Reason for renewal |  |
| Signature of the PI with 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.)

\*\*Applies to clinical trials only

 Acknowledgement by IHEC: