**Sunway Medical Centre Independent Research Ethics Committee (SREC)**

**RESEARCH PROGRESS REPORT FORM**

*(The First Report should be submitted within* ***30 days*** *before the annual anniversary from the date of issue of the SREC decision notification form for full approval and thereafter annually until the research ends. SREC may require more frequent progress reports for studies with higher risk to the subjects.)*

|  |  |  |
| --- | --- | --- |
| **Title of Research Project** |  | |
| **Protocol No.** |  | |
| **Principal Investigator** |  | |
| **Sponsor** |  | |
| **Initial SREC Approval No.** |  | |
| **Official Commencement Date of Research** |  | |
| **Official Scheduled Date of Research Closure/End** |  | |
| **Total Number of Subjects Enrolled** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **(commencement date of trial : dd/mm/yy)** | **No:** |
| **Number of Subjects Enrolled and Subsequently Withdrawn *(provide details in Table 1)*** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **(commencement date of trial : dd/mm/yy)** | **No:** |
| **Number of Serious and/or Adverse Events Reported**  ***(provide details in Table 2)*** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **(commencement date of trial : dd/mm/yy)** | **No:** |

Has any new information or new findings changed the risk versus benefit to subjects significantly since this research project was first approved by SREC?

Yes No

If yes, please describe.

The above-stated research project has been carried out according to the SREC-approved research protocol and the requirements of Sunway Medical Centre Independent Research Ethics Committee have been followed. All subjects enrolled have signed and received copies of the informed consent forms and written subject information (if applicable) approved by SREC for this project.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator: Date:

**TABLE 1**

**Number of subjects enrolled and withdrawn from this research from**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**(commencement date of trial : dd/mm/yy)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **Subject Initials** | **Date subject withdrawn** | **Reason for withdrawal** | **Was study drug restarted again?** |
| **1** |  |  |  |  |
| **2** |  |  |  |  |
| **3** |  |  |  |  |
| **4** |  |  |  |  |
| **5** |  |  |  |  |
| **6** |  |  |  |  |
| **7** |  |  |  |  |
| **8** |  |  |  |  |
| **9** |  |  |  |  |
| **10** |  |  |  |  |

**TABLE 2**

**Summary of Serious and/or Unexpected Adverse Events reported in this research from**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**(commencement date of trial : dd/mm/yy)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **Subject Initials** | **Serious and/or unexpected adverse event (If diagnosis is not available, please state the sign or symptom)** | **Date of SAE onset** | **Date reported to SREC (dd/mm/yy)** |
| **1** |  |  |  |  |
| **2** |  |  |  |  |
| **3** |  |  |  |  |
| **4** |  |  |  |  |
| **5** |  |  |  |  |
| **6** |  |  |  |  |
| **7** |  |  |  |  |
| **8** |  |  |  |  |
| **9** |  |  |  |  |
| **10** |  |  |  |  |

*Please return the completed form with supporting documents to:*

*SREC Secretariat, c/o SunMed Clinical Research Centre,*

*Sunway Medical Centre,*

*No. 5 Jalan Lagoon Selatan,*

*Bandar Sunway 47500 Petaling Jaya, Selangor*

*Tel: 03-8601 1079 Fax: 8601 1069*