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

**SERIOUS ADVERSE EVENT REPORT FORM**

*(Serious Adverse Event Report Form (All Serious Adverse Events (SAEs) and Adverse Drug Reactions (ADR)) that are both serious and unexpected occurring in the Sunway Medical Centre are to be reported to SREC within one working day from first knowledge by the investigator or his research team using this form. SAEs reported outside Sunway Medical Centre (eg. Those received via CIOMS reports in Multicentre Studies) are to be notified to SREC within three month of its receipt by the Investigator or his/her research team. Such reports need to be submitted with an accompanying letter only.)*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Title of Research Project** |  | | | | | | | |
| **Protocol No.** |  | | | | | | | |
| **Principal Investigator** |  | | | | | | | |
| **Sponsor** |  | | | | | | | |
| **Type of SAE Report *(tick one)*** | □ | New / initial | | | □ | Follow – up | | |
| **Subject Initials** |  | | | Age |  | | Sex |  |
| **Date of SAE Onset** |  | | | Date of SAE resolution | | |  | |
| **Date when SAE was *first* informed to Investigator or Research Team** |  | | | | | | | |
| **Description of SAE** |  | | | | | | | |
| **Tick Appropriate Outcome** | □ | | Resulted in death | | | | | |
| □ | | Is life threatening | | | | | |
| □ | | Requires inpatient hospitalization or prolongation of existing hospitalization | | | | | |
| □ | | Results in persistent or significant disability/incapacity | | | | | |
| □ | | Is congenital anomaly/birth defect | | | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Information on suspected drug** | | | | | | |
| **Name of Drug(s)** |  | | **Dose** | |  | |
| **Route of Administration** |  | | **Indication** | |  | |
| **Treatment Dates** | From (start date) | | | To (end date/ongoing) | | |
| **Concomitant Drug(s)** | Name | |  | | | |
| Route of Administration | |  | | | |
| Dose | |  | | | |
| **Do you consider this SAE to have causal relationship to the suspected drug? *(tick appropriate answer)*** | □ | Definite | | | | |
| □ | Probable | | | | |
| □ | Possible | | | | |
| □ | Unlikely | | | | |
| □ | Not related | | | | |
| □ | Insufficient information | | | | |
| **What were the measures taken?** | □ | Suspected drug discontinued | | | | |
| □ | Dose reduced | | | | |
| □ | Drug treatment for the SAE | | | | |
| □ | No drug treatment given for the SAE | | | | |
| □ | Discontinuation of concomitant drug(s) | | | | |
| □ | Non-drug treatment (specify) | | | | |
| **Does this SAE significantly alter the risk-benefit analysis to the research subjects in this research project?**  ***(to be commented by investigator only)*** |  | | | | | |
| **Name of Reporter** |  | | | | Date |  |
| **Signature of Reporter** |  | | | | | |

*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 46150 Petaling Jaya, Selangor Tel: 03-8601 1079 Fax: 8601 1069*