**Adverse Event Reporting Form**

**Ethics Review Committee**

**Faculty of Medicine, University of Jaffna**

**Reference number:**

**Protocol title:**

**Principal investigator:**

**Sponsor’s name:**

**Study site(s):**

**Patient identification number:**

**2. Suspected adverse drug reaction**

|  |  |
| --- | --- |
| **Date of onset:**  | **Date of recovery:**  |
| **Description of the event:**  |
| **Outcome (tick the appropriate box)** |
| Recovered | Recovering | Continuing | Hospitalised | Fatal  |
|  |  |  |  |  |
| **Laboratory reports**  |
| **Seriousness (tick the appropriate box)** |
| Life threatening  |  | Death |  |
| Results in hospitalisation |  | Birth defect |  |
| Prolongation of hospitalisation expected |  | Other (specify)  |
| Permanent disability  |  |
| Impairment or damage to organs |  |
| **Relevant medical history**  |

**3. Study drug / device**

|  |  |
| --- | --- |
| **Batch no.:**  | **Expiry date:**  |
| **Date started:** | **Date stopped:** |
| **Dosage form** | **Route** | **Dose**  | **Frequency** |
|  |  |  |
| **Other drugs used**  |
| **Name**  | **Dosage form** | **Route** | **Dose &****frequency** | **Date** **started** | **Date****stopped** | **Reason for using** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **Adverse event on discontinuation of the drug/ reduction of dose (tick the appropriate box)** |
| Drug stopped (date) | Dose reduced (indicate the reduced dose) (date) |
| Status of adverse event (tick the appropriate box) |
| Disappeared | Improved | Persisted | Not known |
| **Reappearance of adverse events on reintroduction (tick the appropriate box)** |
| Yes |  | No |  | Not known |  |

**4. Reporting person**

Name:

Address:

Designation:

Status in the research team:

Contact number:

Date of reporting:

Signature:

Date: