**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: