**`**

**PROTOCOL DEVIATION\_VIOLATION REPORTING FORM**

|  |
| --- |
| 1. **Deviation/Violation Details**
 |
| **1.1** | **Date of Event**  | \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ ***D D / M M / Y Y Y Y***  |
| **1.2**  | **Type of Event**  | **🞏 Deviation 🞏 Violation**  |
| 1. **Deviation/Violation Description**
 |  |
| **2.1** | **Provide a description of the deviation/violation: State whether the study participants were adversely affected by the deviation/violation; whether the deviation/violation placed the study participants at greater risk; whether the study participants were informed of the deviation/violation and whether the deviation/violation affects the integrity of study data, where applicable.** |
| **2.2**  | **Provide an explanation as to why the deviation/violation occurred.** |
| **2.3**  | **Describe the measures taken to address the deviation/violation.**  |
| **2.4** | **Describe the measures taken to preclude future recurrence of the deviation/violation.**  |
| **2.5**  | **Subject withdrawn?**  | **🞏 Yes 🞏 No**  |
| **2.6** | **Indicate whether the study sponsor has been notified:** *(Sponsor means “CHAIN Coordination Centre “* | **🞏 Yes 🞏 No**  |
| **2.6.1** |  **If No, give reason:**  | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **3.0** | **CRF Completion** |
| **3.1** | 1. **Deviation/violation reported by**

*Do not sign if any fields are empty* |   \_\_ \_\_ \_\_ |
| 1. **Date**
 |  \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ ***D D / M M / Y Y Y Y***  |
| 1. **Time**
 |  ***\_\_\_ \_\_\_*:\_\_\_ \_\_\_\_** ***24 h clock*** |