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**PROTOCOL DEVIATION\_VIOLATION REPORTING FORM**

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| 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| **2.5** | **Subject withdrawn?** | | **🞏 Yes 🞏 No** |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*** |