**SREC Protocol Deviation Reporting Form**

| **Project Title** |  |
| --- | --- |
| **Protocol No.** |  |
| **Site Name/ Number** |  |
| **SREC No** |  |
| **SREC PD # Year**  |  |
| **Principal Investigator**  |  |
| **Main Study Coordinator** |  |
| **Staff/ Monitor Completing this form and designation**  |  |
| **Contact Information (H/P Number**  |  |
| **Contact information (E-mail Address)**  |  |
| **Acknowledged/ Signed by Principal Investigator (Signature and Stamp)** |  |

Reporting Timeline

* Minor in 30 days
* Major in 7 days

| **Description of Event** |
| --- |
| Date of awareness |  |
| Subject ID number (N/A if not applicable) |  |
| Date of Deviation/ Violation |  |
| Type of Deviation (Please refer to attachment A) | Minor Major |
| Description of protocol deviation/violation  |  |
| Subject visit details (if relevant)  |  |
| Description of SAE (if relevant) |  |
| Is the event of protocol deviation/ violation repetitive?  | Yes No  |
| **Corrective action** done for this event? Please explain: (If any training is done, please append/ upload the supporting document such as training log, etc.) |  |
| **Prevention Action**Please explain the preventive action plan that you have put in to prevent the event from recurring in future (If any training is done, please upload supporting document in section VII such as training log, etc.) |  |
| Date Reported to SREC |  |
| If this report was submitted more than 30 days after awareness of the event, please explain why and how late submission will be avoided in the future |  |

**Kindly attached supporting document(s) for the Correction Action and Prevention Action carried out.**

|  |  |
| --- | --- |
| Protocol Deviation reported by  | Principal Investigator  |
| Name |  |
| Sign  |  |
| Date |  |

| **Recommendations by Review Team** |
| --- |
|  🞏 No further action  |
|  🞏 Recommend further action. Please specify :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  🞏 Reviewed and further information requested from Investigator. Please provide :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  🞏 Pending, if major clarifications are required before a decision can be made: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| --- |
| **SREC:** 🞏 Reviewed and acknowledged  🞏 Reviewed and action taken. Please specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Name of SREC secretary:  |  |  | Date:  |  |
|  |  |  |  |  |
| Signature of SREC secretary:  |  |  |  |  |
|  |  |  |  |

Attachment A

| **Example of Major Protocol Deviations or Violation**  |
| --- |
| **Deviations/ Violations related with Informed Consent**  |
| Conducted research activity PRIOR or **without SREC approval** |
| Continuation of **research activities during lapse of SREC approval** |
| **Initiation of study prior to completion of informed consent process** |
| **Informed consent process** (Use of incorrect informed consentdocuments / inappropriate signatory / inappropriate process /others) |
| **Enrollment of participants ineligible** under approved protocol |
| **Randomisation error** |
| **Medication Error**  |
| **Incorrect research treatment or interventions** / IP dosage given |
| **Procedures were not performed** and additional procedures performed which affecting safety and wellbeing of the subject |
| **IP compliance** not within protocol range  |
| **Any other deviation/violation that risking the safety and wellbeing of the subject and data integrity of the research project**  |