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| **Guidance for the person completing this form** |
| 1. This deviation log must be submitted to the ACCORD office via email (QA@accord.scot) **quarterly**, unless a specific timeframe for reporting is specified in the protocol.
2. If no deviations are reported during the quarter, then please notify the ACCORD office (QA@accord.scot).
3. **Do not include** personal identifiers (patient names, initials, dates of birth, CHI numbers, etc) on this form.
4. A new deviation log should be started at the beginning of each reporting period, continuing the event number sequence from the previous deviation log.

**DEVIATION: Any change, divergence, or departure from the study design and / or procedures defined in the protocol or GCP that does not significantly affect a participant’s rights, safety, or well-being, or study outcomes*****NB: Please complete a Protocol / GCP Violation Reporting Form (CR010-F01) if the event could potentially have significantly impacted upon;***1. ***Participant safety, rights or well-being and/or***
2. ***Scientific Value***
 |

Protocol / GCP Deviation Log

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| --- |
| **Log Details** |
|  |
| **Trial Name:** |  |  **Principal Investigator:** |  |  |
|  |
| **REC Number:** |  | **Location Number & Name:** |  |  |
|  |
| **Quarter Reporting Period:** | [ ]  Q1 [ ]  Q2 [ ]  Q3 [ ]  Q4  | **Year:** |  |  |
|  |
| **Log Reviewed by PI** | **PI Signature:** |  **Date:** |

| **Event****No.** | **Event****Date** | **Participant****No.** | **Description of Deviation** | **Could Deviation****Potentially Significantly Impact:** |  **Actions***(Immediate actions taken when deviation discovered)**(Actions taken to ensure the deviation is not repeated. Includes investigation into the root cause, assessing possible impact and risk, and whether the event is part of a systemic issue)* | **Sign/Date****(action complete)** |
| --- | --- | --- | --- | --- | --- | --- |
| **Safety, Rights or Well-being of Participant?** | **Scientific Value?** |
|  |  |  |  | Yes [ ] No [ ]  | Yes [ ] No [ ]  | **Corrective Action Plan:** |  |
|  |
| **Preventative Action Plan:** |  |
|  |
|  |  |  |  | Yes [ ] No [ ]  | Yes [ ] No [ ]  | **Corrective Action Plan:** |  |
|  |
| **Preventative Action Plan:** |  |
|  |

| **Event****No.** | **Event****Date** | **Participant****No.** | **Description of Deviation** | **Could Deviation****Potentially Significantly Impact:** |  **Actions***(Immediate actions taken when deviation discovered)**(Actions taken to ensure the deviation is not repeated. Includes investigation into the root cause, assessing possible impact and risk, and whether the event is part of a systemic issue)* | **Sign/Date****(action complete)** |
| --- | --- | --- | --- | --- | --- | --- |
| **Safety, Rights or Well-being of Participant?** | **Scientific Value?** |
|  |  |  |  | Yes [ ] No [ ]  | Yes [ ] No [ ]  | **Corrective Action Plan:** |  |
|  |
| **Preventative Action Plan:** |  |
|  |
|  |  |  |  | Yes [ ] No [ ]  | Yes [ ] No [ ]  | **Corrective Action Plan:** |  |
|  |
| **Preventative Action Plan:** |  |
|  |

| **Event****No.** | **Event****Date** | **Participant****No.** | **Description of Deviation** | **Could Deviation****Potentially Significantly Impact:** |  **Actions***(Immediate actions taken when deviation discovered)**(Actions taken to ensure the deviation is not repeated. Includes investigation into the root cause, assessing possible impact and risk, and whether the event is part of a systemic issue)* | **Sign/Date****(action complete)** |
| --- | --- | --- | --- | --- | --- | --- |
| **Safety, Rights or Well-being of Participant?** | **Scientific Value?** |
|  |  |  |  | Yes [ ] No [ ]  | Yes [ ] No [ ]  | **Corrective Action Plan:** |  |
|  |
| **Preventative Action Plan:** |  |
|  |
|  |  |  |  | Yes [ ] No [ ]  | Yes [ ] No [ ]  | **Corrective Action Plan:** |  |
|  |
| **Preventative Action Plan:** |  |
|  |