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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](mailto: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](mailto: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:** |  |
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| **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:** |  |
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