Protocol / GCP Violation Reporting Form

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| **Guidance for the person completing this form** |
| 1. This form must be submitted to ACCORD via email ([QA@accord.scot](mailto:QA@accord.scot)) **within 3 days** of any trial location member becoming aware of the violation. 2. **Do not include** personal identifiers (patient names, initials, dates of birth, CHI numbers, etc) on this form. 3. Complete the form as far as possible. The form can be updated/signed and re-submitted as new information becomes available. Any updates should be added to the original form.   **VIOLATION: A deviation that may significantly impact the completeness, accuracy, and/or reliability of the**  **study data or that may significantly affect a participant’s rights, safety, or well-being.**  ***NB: Please complete an entry in the Protocol / GCP Deviation log (CR010-T01) if the event could NOT potentially have significantly impacted upon;***   1. ***Participant safety, rights or well-being and/or*** 2. ***Scientific Value*** |

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| **1. Report Details** | | | | | | |
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| **Trial Name:** | |  | | **Location Number:** |  |  |
|  | | | | | | |
| **REC Number:** | |  | | **Name of Location:** |  |  |
|  | | | | | | |
| **Participant ID:** | |  | | **Principal Investigator:** |  |  |
|  | | | | | | |
| **Country Violation Reported:** | |  | |  |  |  |
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| **2. Assessment to confirm violation** | | | | | | |
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| **Please confirm which of the following MAY have potentially been significantly impacted by the violation:** | | | | | | |
| **Safety, Rights or Well-being of Participant** | Yes  No | | **Details:** | | | |
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| **Scientific Value** (including study data / outcomes) | Yes  No | | **Details:** | | | |
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| **3. Details of violation** | | | | | | | |
| **Date Violation Occurred:** | |  | | | | | |
| **Description of Violation:** | |  | | | | | |
| **Date PI Informed:** | |  | | | | | |
| **4. Actions taken** | | | | | | | |
| **Corrective Action Plan:** | | **Immediate action taken when violation discovered.** | | | | **Sign / Date**  *(when actions complete)* | |
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| **Preventative Action Plan:** | | **Actions taken to ensure the violation is not repeated.** | | | | **Sign / Date**  *(when actions complete)* | |
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| **Root Cause of Violation:** | | **Includes assessing possible impact and risk, and whether the event is part of a systemic issue.** | | | | | |
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| **Conclusion & Justification of Actions:** | | **Did the violation have an actual impact on the participant’s safety, rights or well-being and/or the study outcomes and how this is known.** | | | | | |
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| **Action Required:** | | Participant(s) to remain on trial | | | | | |
| Participant(s) to be withdrawn from trial | | | | | |
| N/A | | | | | |
| **5. Information Source** | | | | | | | |
| **Name / job title of person completing report:** | | | / | | | |  |
|  | | | | | | | |
|  | | | | | | | |
| **PI Name** |  | | | **PI Signature:** | *Date:* | |  |
|  | | | | | | | |
| **ALL reports must be signed and dated by the Principal Investigator**  If signatory is unavailable, the unsigned form must still be sent within 3 days of becoming aware of the violation. | | | | | | | |
| **Form must be filed in the Investigator Site File (ISF) along with any correspondence.**  **ACCORD will retain a copy on file.** | | | | | | | |