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) **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:** |  |  |
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| **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:* |  |
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| **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.** |