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| Form number | **51.008A** | Version  | **4.0** |
| Title | **Protocol Deviation Reporting Form** |

This Form should be completed by sites to report a Protocol Deviation and sent to the Project Manager and Sponsor clinical trial monitor

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| **Study title** |  |
| **R&I Reference Number**  |  |
| **Site Name**  |  |
| **Principal Investigator**  |  |
| **Date form completed**  |  |
| **Date of deviation**  |  |
| **Date PI became aware** |  |
| **Date reported to the trial team /Sponsor\* and name of Project manager, CI or monitor** |  |

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| 1. Please provide a detailed description of the deviation  |
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| **2. Principal Investigator Assessment**  |
| Did any patient (s) come to harm as result of this deviation |
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|  |  |
| --- | --- |
| Yes |  |

Provide detail |
| Provide the Study ID(s) of all affected participants: |
|

|  |  |
| --- | --- |
| No |  |

Briefly justify |
| Please provide any further information such e.g. did this impact on the safety of the participant , did it result in an SAE or SAR |
|  |
| If the deviation were to happen again is there a possibility that patients would come to harm? |
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| --- | --- |
| Yes |  |

Explain |  |
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|  |  |
| --- | --- |
| No |  |

Briefly justify |  |

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| **3. What do you consider to be the root cause of this protocol deviation?**  |
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**Note**: The Sponsor may request additional CA/PA upon receipt of this form.

If no CA/PA have been taken at the time-point of completion of this form please consult with the Sponsor and use this space to document Sponsor CA/PA guidance/requests.

Corrective actions are those taken to fix the immediate issue, i.e. fix what has gone wrong.

Preventative actions are those taken to stop it from happening again on a different occasion.

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| 4. Please specify what corrective actions have been taken  |
| Include details e.g. patient to attend for repeat assessment / bloods, re-consent patient, remove patient from study |

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| 5. Please specify what preventive actions have been taken  |
| Include details e.g. re-training on protocol, better scheduling of study visits to ensure they take place within permitted timeframe |

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| 6. Please specify what action you have taken to inform the affected participant (s), if applicable |
| Include details e.g Participant ID, Contact method and details of discussion, Willingness to continue participation |

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| Reported by |
| Name |  |
| Designation |  |
| Signature |  | Date |  |

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| Reviewed by (*Principal Investigator or Authorised Designee (as specified on the Site Staff Responsibilities Log)* |
| Name |  |
| Designation |  |
| Signature |  | Date |  |

**Once complete, please send to the Project Manager and the Clinical Trial Monitor and file the original within your site file.**

**Ensure this has been added to the site non-compliance log (Form 51.008C)**

**Please ensure a response has been received from the monitor or project manager**

***P.T.O for form completion guidelines***

**Protocol Deviation Form**

**Completion Guidelines**

Details on Protocol Deviations and other types of Non-Compliance are explained in Guideline 51.008C.

Protocol Deviations occur when, during a clinical trial, there are unplanned departures from the protocol, and the schedule of visits, procedures, data collection and documentation that are derived from them.

It is a requirement of Good Clinical Practice that clinical trials adhere to an approved and current protocol. In general, all study activity should be conducted strictly as defined by the protocol; however there may be occasions where this does not happen; e.g. where a trial participant is unable to attend a visit within the required timeline.

A deviation is where a study activity is conducted, but unknowingly not as defined in the protocol. Examples: a trial participant attending a visit out of timeline or missing it altogether; a trial participant receiving an investigational drug, or other study specific medication, at a dose different to that specified in the protocol; missing a dose of medication; a trial participant taking a drug prohibited by the protocol; a blood sample is not taken.

Often there are good reasons for these incidents. It is, however, critical that these departures are documented, citing the reason for the incident, assessing the impact on the trial participant and the study data, identifying corrective actions that may be required to ensure patient safety and data integrity, and implementing preventative actions to avoid recurrence. It will be the responsibility of the Principal Investigator to assess what action, if any, is needed.

***NB It is not appropriate to record deviations as file notes.***

***NB It is not acceptable to plan to or knowingly deviate from the trial Protocol, other than in the event of protecting the safety of a participant.***

The Sponsor and Chief Investigator must always be informed of Protocol Deviations. Where appropriate, processes must be followed, as defined in the protocol, for reporting adverse events, and overdoses if applicable.

All questions above must be answered. For questions 2 - 5, if the answer is none, specify none or not applicable.

When completed, the form must be signed by the Principal Investigator, or delegated designee (as listed in the Site Staff Responsibilities Log), either as the reporter or, where the report is completed by someone else, as the reviewer.

The form should be sent to the Sponsor (Clinical Trial monitor , Project manager and the Chief Investigator. A copy of the signed form should be retained in the Protocol section of the Investigator Site File.

**Action required in the event of consequential impact**

**Safety**

If the investigator deems the incident to have a consequential impact on any trial participant, then the Sponsor/Chief Investigator will determine, in conjunction with the Principal Investigator (for multi site trials), whether or not the participant continues in the trial. This decision and its rationale will be documented in the case notes. Additionally, there must be full discussion with the trial participant, which must also be documented. On occasion, where the impact is on going, or where there is a risk of a recurrence, it may be necessary for the trial participant to re-consent. This would be at the discretion of the Principal Investigator.

For multi site studies, the Principal Investigator will have the final decision on what action is taken.

***NB The process described above does not replace the need for adverse event reporting. Where an adverse event occurs, the process described in the protocol must always be followed.***

**Data**

If the incident is deemed to have a consequential impact on the quality, accuracy or integrity of data derived from any trial participant, the Chief Investigator will determine whether or not all or part of that participant’s data should be discounted. The decision and its rationale must be documented in the participant’s case notes. Additionally, there must be full discussion with the trial participant, which must also be documented. Where it is decided that no data or only partial data from the participant can be used, the participant mustbe informed and his/her continuing consent confirmed. This need not necessitate re-consent, but the discussion must be documented in the participant’s case notes.

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