**Purpose:** This form may be used to document a single or a series of related deficiencies and the corresponding CAPA plan. The fields included in this form may be modified or deleted based on the unit’s specific needs.

**Responsibility:** To be used byPrincipal Investigators and study team members who manage reportable events.

**Procedure:**

* This template contains two types of text: instruction/explanatory and example text.
* **Instruction/ explanatory text** are indicated by italics and should be deleted. Footnotes to instructional text should also be deleted. This text provides information on the content that should be included.
* **Example text** is included to further aid in document development and should either be modified or deleted. Example text is indicated in [brackets in regular font]. Within example text, a need for insertion of specific information is notated by <angle brackets>. Example text can be incorporated as written or tailored to a particular document. If it is not appropriate to the document, however, it too should be deleted.

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| **Protocol Title** |  |
| **IRB Protocol ID** |  |
| **Principal Investigator** |  |

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| **ISSUE** |
| **Date Occurred1** | Click here to enter a date. | **Date Identified1** | Click here to enter a date. |
| **Description** | Describe the deviation / deficiency / non-compliance. |
| **Impact** | Describe the impact of the issue on participant safety, rights, and well-being, as well as data integrity. Include a list of affected participants, if applicable. |
| **References** | List any regulation, policy, procedure, or section of the protocol that the issue deviated from. |
| **Root Cause2** | Outline the root cause to the issue. |

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| **CORRECTIVE ACTION** |
| **Date Implemented3** | Click here to enter a date. | **Date Completed3** | Click here to enter a date. |
| **Description** | Describe the corrective action plan in detail. |
| **Attachments** | List documents attached that help support the corrective action (e.g., notes-to-file, reports to sponsor, etc.).  |
| **Person(s) Responsible** | List names of individuals who are responsible for carrying out the corrective action. |
| **[ ]  N/A** | In the event there can be no corrective action, specify the reason. |

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| **PREVENTIVE ACTION** |
| **Date Implemented3** | Click here to enter a date. | **Date Completed3** | Click here to enter a date. |
| **Description** | Describe the preventive action plan in detail.  |
| **Attachments** | List documents attached that help support the preventive action (e.g., verification of staff retraining, new checklists, SOPs, etc.). |
| **Person(s) Responsible** | List names of individuals who are responsible for carrying out the corrective action. |
| **[ ]  N/A** | In the event there can be no preventive action, specify the reason. |

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| **ADDITIONAL COMMENTS** |
| Include any additional comments or information not noted above. If applicable, outline any plan / procedure to evaluate the effectiveness of the CAPA. |

1. If a distinct date is not available, a rough range of dates may be entered.
2. The *root cause* is the initiating, most basic cause of a problem that may or may not lead to a chain of causes or other problems. Eliminating the root cause should prevent a recurrence.
3. Date may be a projected date if the plan is written prior to implementation / completion. Write “N/A” if not applicable.

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| Printed name of Principal Investigator (PI)  |  |  PI Signature |  | Date |