*The following form is 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 organization’s specific needs.*

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| **Protocol Title / Code** |  |
| **Qualified / 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 Cause** | Outline the root cause to the issue. |

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| **CORRECTIVE ACTION** |
| **Date Implemented2** | Click here to enter a date. | **Date Completed2** | Click here to enter a date. |
| **Description** | Describe the corrective action plan in detail. |
| **Attachments** | List documents attached that help support the corrective action. |
| **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 Implemented2** | Click here to enter a date. | **Date Completed2** | Click here to enter a date. |
| **Description** | Describe the preventive action plan in detail.  |
| **Attachments** | List documents attached that help support the preventive action. |
| **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. 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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| CAPA Written By (Print Name & Title) |  | CAPA Written By (Signature) |  | Date (dd-MMM-yyyy) |

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| CAPA Approved By (Print Name & Title) |  | CAPA Approved By (Signature) |  | Date (dd-MMM-yyyy) |