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| --- | --- | --- | --- | --- |
| **CAPA reference ID or date CAPA form completed:** *Delete all guidance in red italics before finalising* | | | | |
| **Project Number:**  **Project abbreviated title:** |  | **Site Number:**  **Site Address:**  **Country:**  **Principal Investigator**: | |  |
| 1. **Description of Issue/Non-compliance** | | | | |
| *Identify the issue/problem and define this non-conformance in a few sentences. Consider the extent and impact of the issue i.e. Is it systemic or isolated issue?* | | | | |
| 1. **Is the issue considered significant non-compliance?** *Select YES or NO* | | | **YES**  **NO** | |
| 1. **Root Cause of Issue/Finding**  **N/A**   *List all root causes below* | | | | |
| *Perform a root cause analysis to determine the root cause(s): What is the problem?, What events led to the problem?, Where is the problem occurring?, When did problem first occur?, How widespread is the problem?, How was the problem identified? Who is impacted by the problem? Use tools e.g. fishbone diagram or 5 whys if needed to identify root cause(s).*  1.  2. etc | | | | |
| 1. **Corrective Action**   *Action to eliminate root cause(s) of a detected/existing nonconformity or other undesirable situation* | | | | |
|  | | | | |
| **Due Date of corrective action** | | | **Responsible Person for corrective action** | |
| <DDMMMYYYY> | | | <full name, title> | |
| 1. **Preventive Action**   *Action to eliminate the root cause(s) of a potential nonconformity or other undesirable potential situation* | | | | |
|  | | | | |
| **Due Date of preventive action** | | | **Responsible Person for preventive action** | |
| <DDMMMYYYY> | | | <full name, title> | |

Note: This CAPA must be adequately documented, reviewed and followed up until closure.