# Note to File - Instructions

## Notes to File **are written to identify and record:**

* **A discrepancy, error, or problem in the conduct of the research study;**
* **The root cause of the identified problem;**
* **The corrective action(s) taken to ensure the problem has resolved; and**
* **T**he **preventive action(s) taken to prevent recurrence of the problem.**

## A Note to File should be printed on institution letterhead, include the study title, and should be authored and signed by the individual responsible for its content. This would include the Principal Investigator for issues related to protocol compliance, data integrity, human subject protection, etc. Additional sign-off or approval may be required, e.g., the Associate Dean of Research, supervisors.

## The Note to File should be retained and stored in the site regulatory file.

Please remove instructional and descriptive template language from the final Note to File.

**<Institution Letterhead>**

# Note to File

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| **Date:** | <Date that the Note to File is written> |
| **Study:** | <Protocol number and Study Title> |

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| **Issue:** | <Provide an explanation of why the error or omission occurred (e.g., human error, technical glitch, oversight); can be formatted as a paragraph, numbered list, or bulleted items. This table can be copied to document multiple issues with different action plans within the same note to file.> |
| **Root Cause:** | <The reason(s) that the issue arose. Conduct a root cause analysis. If the root cause is unknown at the time of the note, indicate that a further investigation will follow.> |
| **Corrective and Preventive Action (CAPA) Plan:** | <Description of the corrective actions and steps taken or planned. Identify the person(s) responsible for making the correction and how information was disseminated to study staff, as applicable, and record the date the correction was made.Outline any steps that will be taken to prevent the error or omission from recurring in the future. This could include training, process changes, or system upgrades.  Attach copies of any relevant documentation that supports the identification of the error, the documentation, and the corrective action taken.>  |
| **Resolution:** | <Description of the procedures used to document resolution of the problem. Include supporting documentation as required. Evaluate and document whether the error had any impact on downstream processes, decisions, outcomes, or other projects and if those have been resolved.> |
| **Effective date of resolution:** | <Effective date for CAPA Plan implementation. If processes are ongoing include the planned completion date.> |
| **Additional Information:** | <Any additional comments or information not noted above.> |

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| **Approval:** | <Name, title, and signature of the person authoring the Note to File. This table can be copied if multiple signatures are required.> |