# Note to the Study File - Instructions

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

* **A discrepancy or problem in the conduct of the clinical research study;**
* **The root cause of the identified problem;**
* **T**he **corrective action taken to prevent recurrence of the problem; *and***
* **The corrective action that has resolved the problem.**

## **A Note to Study File may be appropriate to**:****

* Clarify or add information regarding site specific regulatory file requirements;
* Clarify or add information regarding source document standards; *and*
* Document and address any issue that is protocol and/or site-specific that cannot be resolved without a change from previous procedures.

## A Note to the Study File should be printed on institution letterhead and should be initiated and authored by the individual or organization responsible for its content, as follows****:****

* **If the issue relates to site performance, the appropriate credentialed individual from the site should write and sign the note to file.**
* **If the issue relates to PI responsibilities (e.g., human subject protection, data integrity at the site), the PI should write and sign the note to file.**
* **If the issue relates to actions taken by the sponsor or monitor (e.g., clarification of a protocol section), an appropriate credentialed individual from the sponsor should write and sign the note to file.**

## A Note to the Study File should be retained and stored, as follows:

* Kept on file in the site regulatory file and made available to the clinical site monitors reviewing the site’s documents and procedures.
* If a data management center (DMC) is handling the data management of the clinical research study, a copy should be sent to the DMC.

# Note to the Study File - Template

**<Institution Letterhead>**

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| --- | --- |
| **Date:** | <Date that the Note to the Study File is written> |
| **To:** | <Protocol number followed by “Study File”> |
| **From:** | <Name, title, and the site or institutional affiliation of the person authoring the Note to the Study File, and this individual’s signature> |

|  |  |
| --- | --- |
| **Issue:** | <Brief description or outline of the topic/process/problem being documented; can be formatted as a paragraph, numbered list, or bulleted items> |
| **Root Cause:** | <The reason(s) that the issue arose> |
| **Corrective Action:** | <Description of the corrective actions taken or planned by the site personnel. If the site was instructed to perform these corrective actions (i.e., by the sponsor or monitor), indicate by whom and as of what date. If status of reports, records, or data will remain incomplete or unavailable, make a statement regarding your failed attempts or describe when/how the records will be retrieved or completed.> |
| **Resolution:** | <Description of the procedures used to document resolution of the problem.> |
| **Effective date of resolution:** | <Effective date for corrective action (may be the same date as in the memo header)> |
| **Comments:** | <Any additional comments or information not noted above> |