**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 cause of the identified problem;
* The 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 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.
* A copy should be sent to the sponsor when requested.

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| **NOTE TO FILE** | |
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| **Date:** Click here to enter text. | **IRB#:** Click here to enter text. |
| **Study Title:** Click here to enter text. | |
| **Investigator:** Click here to enter text. | |
| **Subject ID:** Click here to enter text. | |
| **Explanation of Issue:** | |
| Click here to enter text. | |
| **Cause of the Problem:** | |
| Click here to enter text. | |
| **Describe Corrective Action Taken:** | |
| Click here to enter text. | |
| **Resolution:** | |
| Click here to enter text. | |
| **Effective date of resolution:** Click here to enter text. | |
| **Comments:** Click here to enter text. | |

Signature of Person Identifying Issue: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_

Signature of Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_