**Note to File**

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| --- | --- |
| **Date:** | (*Date that the note to the Study File is written)* |
| **Re:** | *(subject of Note To File)* |
| **PI:** | *(PI name, credentials)* |
| **IRB #:** | *(IRB study number)* |
| *(Include study title here)* | |
|  | |

*Describe the topic/process/problem being documented in this section; it can be formatted as a paragraph, numbered list, or bulleted items.*

*Include the following, as appropriate:*

* *Root Cause: The reason(s) that the issue arose*
* *Corrective Actions: Description of the corrective actions taken or planned by the study personnel.*
* *Comments: Any additional comments or information not noted above*

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Signature\* *(of study team member documenting the item above)*

*\*Be sure to include signee’s name, job title/study responsibility and department in the section below the signature line*