**STUDY NOTE TO FILE TEMPLATE**

**(File in regulatory binder or relevant subject file)**

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

<If issue related to PI responsibilities or clinical issue, note should be from PI.>

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| **Issue:** | <Brief description or outline of the topic/process/problem being documented; can be formatted as a paragraph, numbered list, or bulleted items>  **IF ISSUE WITH STUDY PROCEDURES/TRAINING OR REPEATED PROTOCOL DEVIATION, THIS SECTION SHOULD BE INCLUDED:** |
| **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:** | <If applicable, effective date for corrective action (may be the same date as in the memo header)> |
| **Comments:** | <Any additional comments or information not noted above> |