

# Instruction for Use

## NOTE TO FILE / DEVIATION LOG

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Template	
<b>Purpose</b>	To keep a comprehensive record of all written Notes to File and Deviations
<b>Use</b>	Study coordinator, Principal investigator, other site staff, Monitor, Sponsor
<b>Details</b>	This log should provide an overview and location of all written Notes to File and deviations.
<b>Best Practice Recommendations</b>	<ul style="list-style-type: none"> <li>To be used in electronic format</li> <li>In the upper part of the page identifying the study, delete (Local) if the study is monocentric, and ( ) if the study is multicentric,</li> <li>First indicate via the drop-down menu if it's a deviation or not,</li> <li>Then determine the Type of Note to File/Deviation: Clarification, Decision, Documentation, Other (specify in the below row), via the drop-down menu,</li> <li>Next enter the location of the note to file/deviation form: TMF, ISF, Participant file, Pharmacy binder, Other, via the dropdown menu,</li> <li>Copy-paste the first sheet into the second and select only the deviations, or use the filter to isolate them,</li> <li>Send this table to the Sponsor and Monitor on a regular basis.</li> </ul>

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