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| **GENERAL INSTRUCTIONS** – delete this box from the completed form. Red text represents instructions to you – to be deleted from the final version.**NOTE: This form is designed to be a starting point on a Note to File. Update it as necessary for your specific study.** 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
* 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 File should be retained, stored, and kept on file in the study records and made available to monitors.  |

**Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Participant ID:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Research Staff Completing Note-to-File Printed Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Principal Investigator Printed Name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_