**NIMH Note to File (NTF) Template**

**Tool Summary** (*Remove Tool Summary before finalizing and distributing the document)*

***Purpose:*** *This template provides a recommended structure for documenting departures from research studies.*

***Audience/User:*** *Principal Investigators and study team members who document departures from research studies*

***How to Use This Template:*** *This template contains two types of text: instruction/explanatory and example text.****Instruction/explanatory text*** *are indicated by italics and should deleted. Footnotes to instructional text should also be deleted. This text provides information on the content that should be included.* ***Example text*** *is included to further aid in document development and should either be modified to suit the drug, biologic or device (study intervention), design, and conduct of the planned clinical trial or deleted. Example text is indicated in [brackets in regular font]. Within example text, a need for insertion of specific information is notated by <angle brackets>. Example text can be incorporated as written or tailored to a particular document. If it is not appropriate to the document, however, it too should be deleted.*

***Version control*** *is important to track document development, revisions, and amendments. It is also necessary to ensure that the correct version of this document is used by all staff conducting the study. With each revision, the version number and date located in the header of each page should be updated*

**NIMH Note to File (NTF) Template**

Study/Protocol ID: \_\_\_\_\_\_\_\_\_\_\_\_\_ Site Name/Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Subject ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Applicability:** *Include subject ID(s) if NTF pertains to a particular subject or subjects*

**RE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Written by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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

**Explanation of Event/Issue

*Description of the issue/process/problem being documented, including (if applicable) how, when, and by whom the issue was identified, cause of issue (if known), corrective and preventive actions taken (when and by whom).*

Description of related forms/documents *(if applicable)*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Author’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PI’s Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Note to File Guidance:*

*Notes to the Study File are written to acknowledge a discrepancy or problem with the study’s conduct, or for other administrative purposes (such as to document where study materials are stored). Notes to the Study File should be written by the individual responsible for its content, and the author should sign and date the note. If the Note to Study File pertains to an item for which the PI is responsible (subject protection, data integrity, etc.), the PI should co-sign and date the note to acknowledge his/her awareness of the issue. Notes to the Study File should be kept on file in the study records and made available to study monitors or auditors reviewing the site’s documents and procedures*