Guidelines for Writing a Note-to- File for Research Studies

Why a Note-to-File

A Note-to-File gives explanation to the conduct within a research trial. It is used to clarify an error, omission or discrepancy or to document a problem or corrective action. For example, a Note-to-File may be appropriate to:

- Clarify why a protocol procedure was missed or completed out of sequence
- Clarify or add information regarding site specific document location

A Note-to-File may be utilized if there is something that affects the entire study. This type of note-to-file should be placed in the study regulatory binder.

A Note-to-File may be utilized to explain something that happens to a particular subject(s). In this case, the note-to-file should be filed in the subject research records.

When utilizing a Note-to-File, one must document not only the event itself, but also proactive steps to prevent the incident from happening again. Once a Note-to-File is created, it become part of the permanent study record.

A word of caution; a "Note-to-File" is not a panacea for all things that have gone wrong, nor a replacement for a reportable violation. A large number of notes/memos to file can be a "red flag" to an auditor or reviewer. The Note-to-File is not a replacement or substitute for notifying the IRB.

How to create a Note-to-File

When creating a Note-to-File the content should be clear and concise. Any current and future study staff (as well auditor or reviewer) should be able to readily identify what occurred, why and applicable corrective action.

The note should describe the specific issue including date issue occurred. A Note-to-File should be printed on institution letterhead (need not be in color) and should be signed and dated by the individual or organization responsible for its content, as follows:

- If the issue relates to site performance, the appropriate credentialed individual from the site should write and sign the note to file.
- If the issue relates to principal investigator (PI) responsibilities (e.g., human subject protection, data integrity at the site), the PI should write and sign the note to file.

- If the issue relates to actions taken by the sponsor or monitor (e.g., clarification of a protocol section), an appropriate credentialed individual from the sponsor should write and sign the note to file.

Sample Template attached

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Note-To-File

Date: Date Note to File written

IRB Protocol #: xxxx-xxxxx

Study Title: Include Sponsor, if applicable

From: Staff name, include role in study

RE: Topic and specific subject identifier, if applicable

In this section include description and corrective action(s)

_____ _____

Signature, title Date