Guidance for Creating a Note to File

This guidance provides a description of a Note to File, when they should be used as a documentation practice during the conduct of human subjects research. A template for a standard Note to File is also provided, though alternate formats can be used.

1. What is a Note to File?

A Note to File provides way to describe and document deviations, problems, or events occurring during the conduct of research which cannot be documented in a standard case report (CRF) form or research record. A Note to File can also be used to document specific regulatory requirements for a study, document receipt of new information about an intervention, or catalog site-specific protocol requirements. A Note to File essentially provides a way for a researcher or research team to document information which does not easily fit into other standardized forms.

2. When should a Note to File be used?

A Note to File should be used in the following examples, though it also useful for other events which may occur during the research process:

- When the research team deviates in any way from the IRB approved protocol. For example:
  - A participant neglected to date a Consent Form. In this case a NTF would be completed describing the deviation and how the deviation will be corrected by having the participant sign a new Consent Form at the next visit.
  - A participant was not able to make it to Study Visit 3, which according to the protocol must be completed within 10 days of Visit 1. A replacement visit is schedule at a later time, and a NTF is completed to document the deviation.
- When a research participant contacts the researcher or research team with questions or concerns about a study in which they are enrolled. A NTF would be created to summarize the communication for future reference.
- When research is being conducted as part of a multi-site trial and the coordinating center has specific requirements for study conduct, such as specific file-labeling protocols. A NTF would be created to document these specific requirements for the research team.
- When New Information is encountered by a researcher or research team which may affect the ethics and safety of a research design, or the accuracy of risk information presented in a consent form (e.g. a journal article or conference presentation more clearly defining the risks of a given procedure, drug, or device). A NTF would describe this New Information and any Corrective Action Plan (CAP) undertaken in response.

3. Who should complete a Note to File?

A Note to File can be completed by any designated member of the study team. In some cases, the Principle Investigator will also need to sign the Note to File to document their awareness of the information provided in the NTF. Any NTF should be retained as part of the research record.

Office of Institutional Review Board
IRB Policy & Guidance
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Note To File

Date:

Principle Investigator:

IRB ID#:

Written By:

Subject: <e.g. Protocol Deviation, Participant Communication, New Information, etc…>

Pertains to: <e.g. participant ID#, when applicable>

Explanation of Event/Issue:

Description of the event or issue being documented including: how, when, and by whom the event or issue was identified, cause of issue, and any preventative action or corrective action plan undertaken in response to the event or issue.

Related Forms and Documents:

When applicable, what other documentation in the research record has been completed relative to the event or issue

Author's Signature: _____ Date _____

PI's Signature _____ Date _____