

Note-To-File Template

A note to file should:

- Be generated on a case-by-case basis
- Include the subject and protocol it refers to
- Be signed and dated by the individual who is writing it
- Be legible if handwritten
- Explain clearly and *specifically* the reason for the error/omission/discrepancy or process/policy it aims to address; avoid using “one-size-fits-all” notes when providing details; overuse of a blanket statement will take away from the value of a note to file
- Be “one-size-fits-all” only when the error/omission/discrepancy is the result of a single, re-occurring oversight/erroneous practice (e.g. failure to provide subject with a signed/dated copy of the consent form) or when it refers to a general practice such as the filing of regulatory documents in alternate locations/electronically
- Should include any corrective action or follow-up when applicable
- Be filed with the document, subject file or behind the study binder tab to which it applies

Sample Note To File:

PROTOCOL #: DMS1001

TITLE: The Evaluation of Efficacy and Safety of "Investigational Drug Q"
 on recurrence of "Disease"

From: Joe Brown, research coordinator
 [Insert staff name, include role on study]

To: Subject File

Re: Subject# 11202-02
 [insert subject identification]

Date: March 31, 2010

This subject was consented by Dr. Smith on March 31, 2010. Dr. Smith, in error dated the consent form March 30, 2010. The dating discrepancy is not representative of an inappropriate consent process, but the result of a typographical error. Dr. Smith has been reminded to confirm the correct date in the future.

Signature: _____ Date: _____