# Note-To-File Template

A note-to-file should:

* Be legible if handwritten.
* Be generated on a case-by-case basis.
* Include the subject and protocol to which it refers.
* Be signed and dated by the individual who is writing it.
* 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:**

IRB #:

TITLE:

From: Ann Smith, research coordinator

[Insert staff name, include role on study}

To: Subject File

Re: Subject#

[insert subject identification]

Date:

This subject was consented by Dr. Lewis on March 31, 2010. Dr. Lewis, 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. Lewis has been reminded to confirm the correct date in the future.

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