# 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.
* 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 #: 2010-01000

TITLE: The Effect of ‘Investigational Product’ on XYZ Levels in Healthy Controls

From: research coordinator

[Insert staff name, include role on study}

To: Subject File

Re: Subject# 015-SAW

[insert subject identification ]

Date: October 31, 2011

Dr. Smith consented the subject on January 20, 2010. Dr. Smith, in error dated the consent form January 22, 2010. The dating discrepancy is not representative of an inappropriate consent process, but the result of a typo. Dr. Wolf has been reminded to confirm the correct date in the future.

Signature: