

## Notes to File

A Note To File (NTF) may be written by any member of the study team to provide additional information or clarification when other documentation is unavailable or inadequate elsewhere in the research records.

A Note to File (NTF) may be used to:

- Explain the location of a study document when it is not filed in the expected location;
- Explain a discrepancy, the action taken in response, and the method adopted to prevent similar discrepancies;
- Clarify an instruction or direction regarding some activity that is required by the protocol but is not clearly explained in the protocol.

Notes to File *must not* be used in place of the [Unanticipated Problem Report](#) to notify the IRB of a protocol deviation or unanticipated event.

Study personnel should create a NTF *only* if an action, clarification, plan or discrepancy is not addressed fully in other study documents. It should never be used as a substitute for good, prospective, and complete source documents or Good Clinical Practice (GCP). The presence of too many Notes To File can raise the concerns of auditors and regulatory inspectors over why there are so many issues with study procedures or study documentation.

At a minimum, the following information should be recorded on the Note To File:

- Study Name and IRB #
- Subject ID (if applicable)
- Purpose of the Note to File
- Explanation, clarification, and/or description of corrective action
- Author's (and/or Principal Investigator's) Dated Signature

A Note to File is considered source documentation and must be signed and dated by either the person making the entry or the person reviewing and/or validating information the document contains. NTFs can be retained with the essential regulatory documents or in a subject's research chart as appropriate. Ideally, they should reside near the study document that is addressed or explained by the note.

### References:

1. *Good Clinical Practice: A Question & Answer Guide*, Barnett Educational Services, May 2013.
2. ["Use, Abuse and Misuse of Notes to File"](#), *Perspectives in Clinical Research*, 2011 Jan-Mar; 2(1):38-40.
3. [Guidelines for the Planning and Conduct of VA Cooperative Studies](#), VA Office of Research & Development, 2013.