Center for Clinical and Translational Science

NOTE TO FILE INSTRUCTIONS

PURPOSE

A Note to File is a memo written to identify and/or clarify a discrepancy or problem in the conduct of clinical research studies.

HOW TO USE

- Complete the form header by adding the date that the note to the study file is written, subject of the note to file, the Principal Investigator's name and credentials, the IRB study number and the study title.
- Describe the topic/process/problem being documented in the body of the memo, it can be formatted as a paragraph, numbered list, or bulleted items.

  Include the following, as appropriate:

  - Root Cause: The reason(s) that the issue arose
  - Corrective Actions: Description of the corrective actions taken or planned by the study personnel
  - Comments: Any additional comments or information not noted above
- Include the signee's name, job title/study responsibility and department in the section below the signature line
- Print the Note to File on institution/department letterhead
- Be sure to include the appropriate signature

GOOD PRACTICE RECOMMENDATIONS

- The Note to File should be signed and authored by the individual or organization responsible for it's content, as follows:
  - If the issue relates to site performance, the appropriate credentialed individual from the site should write and sign the note to file.
  - If the issue relates to principal investigator (PI) responsibilities (e.g., human subject protection, data integrity at the site), the PI should write and sign the note to file.
  - If the issue relates to actions taken by the sponsor or monitor (e.g., clarification of a protocol section), an appropriate credentialed individual from the sponsor should write and sign the note to file.
- Be sure to customize the template to make it study-specific.