GUIDELINES FOR WRITING NOTES TO THE STUDY FILE

Notes to the Study File are written to:

- Clarify or add information regarding site specific regulatory file requirements,
- Clarify or add information regarding source document standards,
- Document and address any issue that is protocol and/or site specific that cannot be resolved without a change from previously approved procedures,
- Describe the immediate and preventative corrective actions taken,
- Explain a site specific process that is not documented in any previously approved procedures.

A Note to the Study File is NEVER written as an exemption from:

- Protocol eligibility criteria
- Protocol deviation reporting
- Serious Adverse Event reporting
- Adequate source documentation
- ICH/GCP compliance
- Institutional Review Board and any other applicable regulatory/contractual requirements

Note to the Study File should be printed on institutional letterhead and include:

- ☑ Date written
- ☑ Name, title, affiliation of the author
- ☑ Subject line with DMID protocol #, site name, topic or issue addressed
- ☑ A brief description or outline of the topic/process/problem being documented. It is acceptable to format as a paragraph, numbered list or bulleted items.
- ☑ A statement regarding failed attempts or when the records will be retrieved, if the status of reports, records, or data will remain incomplete or unavailable.
- ☑ A description of the resolution or pending corrections by the site personnel, if applicable.
- ☑ An effective date for corrective action, if different from the date in the memo header.
- ☑ A description, in "Comments", of what actions the site will perform to avoid similar issues in the future.

Retention and Distribution

All Notes to the Study File should be signed by the author, kept on file in the site regulatory file and made available to the clinical site monitors reviewing the site's documents and procedures. In addition, Notes to the Study File should be submitted to the site IRB, per its IRB guidelines.

Please send a scanned PDF of all Notes to the Study File, as an email attachment, to the DMID Clinical Project Manager/point of contact for the clinical research study, the Office of Clinical Research Affairs (OCRA) (email address: OCRAOps@mail.nih.gov), and if an issue relates to the study product, the DMID Product Support Team (email address: DMIDProductSupportTeam@mail.nih.gov). The DMID-CROMS clinical site monitor will retrieve a copy of the memo as needed based on the significance of issues addressed in the memo.

Please forward a copy to the protocol-specific data coordinating center, as well.

GUIDELINES FOR WRITING NOTES TO THE STUDY FILE

①

Date: ②

To: ③

From: ④

Re: ⑤

Issue: ⑥

Resolution: ⑦

Effective date of resolution: ⑧

Comments: ⑨

① This Note to the Study File should be printed on the site's letterhead

② Date that the Note to the Study File was written

③ Enter the DMID Protocol number followed by "Study File"

④ Enter the name, title, and the site or institutional affiliation of the person authoring the Note to the Study File. This individual should also sign the Note to the Study File in this area.

⑤ Subject line to include DMID Protocol number [XX-XXXX] and site name.

⑥ Body of the note should clearly define the issue. Include a brief description or outline of the topic/process/problem being documented. The format can include a paragraph, numbered list, or bulleted items.

Topic Examples:

- Clarify or add information regarding site specific regulatory file requirements
- Clarify or add information regarding source document standards
- Document and address any issue that is protocol and/or site specific that cannot be resolved without a change from previously approved procedures
- Describe the immediate and preventative corrective actions taken
- Explain a site specific process that is not documented in any previously approved procedures

⑦ Describe the resolution or pending corrections by the site personnel. Clarify what the site has been instructed to do by whom and as of what date. Include immediate corrective actions, actions taken to prevent reoccurrences, and how the site will monitor this issue. If status of reports, records, or data will remain incomplete or unavailable, make a statement regarding failed attempts, or describe when/how the records will be retrieved or completed.

⑧ Add an effective date for corrective action if the date is different from the date in the memo header, otherwise, enter N/A.

⑨ Enter any additional comments or information not noted above including what changes will be made to the Quality Management / Quality Assurance plans to assure future issues will be avoided.