DMID INFORMATION SHEET

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

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

1. Date written
2. Name, title, affiliation of the author
3. Subject line with DMID protocol #, site name, topic or issue addressed
4. 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.
5. 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.
6. A description of the resolution or pending corrections by the site personnel, if applicable.
7. An effective date for corrective action, if different from the date in the memo header.
8. 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:

- DMID Clinical Project Manager/point of contact for the clinical research study,
- 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.

Questions

Contact your DMID protocol-specific Point of Contact or email the DMID Office of Clinical Research Affairs, OCRA Help.