***TITLE: Note to File***

***SOP Version #*** RM XX.XX

***Author(s):***

 ***Approved by Date***

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***Approval:***

 ***Approved by Date***

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***Annual review of current version Review date Comment***

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**Instructions for modifying this template:**

1. This is a template and should be used as such. Please use this in the manner most appropriate for your research unit.
2. Anything in this template can and may be modified as appropriate for your area while accounting for your interpretation of the most current FDA Guidance.
3. After you have modified this SOP template, do not forget to remove the “**Instructions for modifying this template**” table.
4. Number the SOP using you own guidelines for numbering.

**I. SCOPE/PURPOSE**

The purpose for this SOP is to define the reason for crafting a Note to File (NTF) and provide a Note to Study File template

**II. ALLOWABLE EXCEPTIONS**

This SOP is to be followed without deviation.

**III. RELEVANT REGULATIONS/GCPS**

 None known

**IV. DEFINITIONS/ACRONYMS**

NTF – Note to File

**V. RESPONSIBLE PERSONNEL**

This SOP applies to the following – Study Investigators, Study Coordinators, Regulatory Affairs and sponsors.

**VI. DETAILS**

**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.
* Document and clarify subject related incidents that require further explanation.

A Note to the Study File **defines the issue and/or clarifies** what the site has been instructed to do, has done, or what the site has agreed to do. It should not merely list the issue but **must include** what was done or the immediate corrective actions taken to prevent reoccurrences, and how the site will monitor this issue. A Note to the Study File can be written stating that CV etc are kept in a separate location.

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

* Protocol eligibility criteria,
* Protocol deviation reporting,
* Serious Adverse Event reporting,
* Institutional Review Board and any other applicable regulatory/contractual requirements.

**Note should be printed on institutional letterhead and include:**

* Date written
* Name, title, affiliation of the author
* Subject line with protocol # (if available, protocol name with version number and date, site name, topic or issue addressed
* Brief description or outline of the topic/process/problem being documented
* May be written as a narrative, numbered list or bulleted items
* If status of reports, records or data will remain incomplete or unavailable, a statement regarding failed attempts or when the records will be retrieved
* If applicable, describe the resolution or pending corrections by the site personnel
* If different from the date in the memo header, an effective date for corrective action
* If applicable, document In “Comments” what actions the site will perform to avoid future similar issues

**Retention and Distribution**

All notes to the study file should be signed by the author, the original kept on file in the site regulatory file and made available to the clinical site monitors reviewing the site’s documents and procedures. The Notes to the Study File may need to be sent as an email, faxed or hard copy.

**VII. QA**

NA

**VIII. APPENDICES/ RESOURCES**

Appendix A: Template Note to File

**IX. RELATED SOPs**

NA

**Appendix A Template Note To File**

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|  |  |
| --- | --- |
| **Date:**  | ➁ |
|  |  |
| **To:**  | ➂  |
|  |  |
| **From:**  | ➃  |
|  |  |
| **Re:**  | ➄  |

|  |  |
| --- | --- |
| **Issue**: | ➅ |
|  |  |
| **Resolution**: | ➆ |
|  |  |
| **Effective date of resolution**: | ➇ |
|  |  |
| **Comments**: | ➈ |

➀ This Note to the Study File should be printed on your site’s letterhead

➁ Date the Note to the Study File the day was written. Use DD/MMM/YYYY format.

➂ List the Protocol number and IRB Protocol number followed by “Study File”;

➃ 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.

➄ List the Protocol number [XX-XXXX], the complete protocol title and version # and the IRB Protocol #. Add site name or to whom the Note to Study File applies (if different than the institution listed in #3)

➅ Body of the note should clearly define the issue. Include a brief description or outline of the topic/process/problem being documented. Maybe formatted as 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.

➆ Describe the resolution or pending corrections by the site personnel, otherwise enter N/A. Clarify if the site has been instructed to do an action and by whom and as of what date. Include what action has been taken or the 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 your failed attempts or describe when/how the records will be retrieved or completed.

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

➈ Enter any additional comments or information not noted above including what changes to the QA/QM plans may be necessary to assure future issues will be avoided.