DMID NOTES TO THE STUDY FILE GUIDELINE AND TEMPLATE

Purpose

1. Notes to the Study File (NTF) are written to
    a. Clarify or add information regarding site specific regulatory file requirements and source document standards;
    b. Document and address any issue that is protocol and/or site specific that cannot be resolved without a change from previously approved procedures;
    c. Describe the immediate *and* preventative corrective action(s) taken, to resolve the issue;
    d. Explain a site-specific process that is not documented in any previously approved procedures.

2. NTFs are **NEVER** written as an exemption from:
    a. Protocol eligibility criteria,
    b. Protocol deviation reporting,
    c. Serious Adverse Event reporting,
    d. Adequate source documentation,
    e. ICH/GCP compliance, and
    f. IRB and any other applicable regulatory and contractual requirements

Retention and Distribution

1. All NTFs should be
    a. Kept on file in the site regulatory file and
    b. Made available to the clinical site monitors reviewing the site's documents and procedures.
    c. Submitted to the IRB, per the site IRB guidelines.

2. Please send a scanned PDF (or electronically signed pdf) of all NTFs as an email attachment, to:
    a. DMID Clinical Project Manager/point of contact for the clinical research study,
    b. Office of Clinical Research Affairs (OCRA) (email address: OCRAOps@mail.nih.gov), and
    c. If an issue relates to the study product, the DMID Product Support Team (email address: DMIDProductSupportTeam@mail.nih.gov).
    d. The protocol-specific Data Coordinating Center, as applicable.

3. The DMID-CROMS clinical site monitor will retrieve a copy of the memo as needed based on the significance of issues addressed in the Note to File.

Format and Content

The Note to the Study File should be written on institutional letterhead and include the following elements. Refer to the sample Template, following format guidance.

Element	Element Description
Date the NTF was written:	Date that the NTF was written
To:	DMID Protocol number followed by "Study File". **Note**: for protocol titles or numbers followed by an extended number or letter please provide the full set of characters (i.e., "ACTT 4"), if there is no other reference to the ACTT within the body of the NTF
From:	Name and title of the person writing the Note to the Study File, and their institutional affiliation
Subject:	DMID Protocol number [XX-XXXX] and site name. Include a brief note of the overall topic/content, in addition to the protocol and site name (i.e. DMID Protocol 20-0006; <site name>; *eGFR calculation*). This will help to identify Notes to File, when reviewing/reconciling study records. NTFs addressing study product should **NEVER** contain any information that could potentially unblind study team members.
Issue:	Body of the NTF should *clearly* describe the issue, topic, process and/or problem in a brief paragraph or bulleted outline form. Ensure temporal order to clearly construct events. Please see the **Purpose** section in this guideline regarding content.
Resolution:	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 the status of reports, records, or data will remain incomplete or unavailable, make a statement regarding failed attempts, or describe when and how the records will be retrieved or completed. If training is provided, explain the documents used to train, who was trained, and by whom and the date they were trained.
Effective date of the resolution:	Add an effective date for corrective actions taken

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Comments:	(*Optional*) Enter any additional comments or information not noted above including what changes will be made; for example, to site processes, or Quality Management/Quality Assurance plans, to assure future issues will be minimized or eliminated.
Signature block	Signature of person completing the NTF, and date.
Distribution	NTFs should **not** be submitted via Site Essential Regulatory Document (SERD) portal, or to the Site Monitoring group for review. The completed and signed NTFs **must** be submitted following the distribution noted in **Section 2 of this guideline**.

NOTE TO THE STUDY FILE TEMPLATE ON THE FOLLOWING PAGE

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NOTE TO THE STUDY FILE TEMPLATE

<Institutional Letterhead>

Date (DD/MMM/YYYY):

To:

From:

Subject:

Issue:

Resolution:

Effect date of Resolution (DD/MMM/YYYY):

Comments:

Signature	**Date**