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 documentation 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
    f. IRB and any other applicable regulatory and contractual requirements
    g. Protocol amendments
    h. Changes to the Manual of Operating Procedures (MOP)

Retention and Distribution

1. All NTFs should be
    a. Kept on file in the site regulatory file
    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. NTFs should **not** be submitted via the NIAID Clinical Research Management System (N-CRMS) Site Essential Regulatory Document (SERD) portal, or to the Monitoring group for review.

3. Please send a signed and dated NTF as a PDF, attached to an email to the following groups;
    a. DMID Clinical Project Manager/point of contact for the clinical research study,
    b. DMID 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.

> ***Please note**, if the NTF is electronically signed, the signature should be a certified signature (or certificate-based signature). If this is not available within your institution, please provide a wet signature to the NTF and submit a scanned PDF.*

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Format and Content

The NTF should be written on institutional letterhead and include the following elements. Refer to the sample Template, following the Format and Content guidance, below.

Element	Element Description
Date:	Enter the date the NTF was written (format DD/MMM/YYYY):
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", "20-0013B"), if there is no other reference to the study arm/phase within the body of the NTF
From:	Name and title of the person writing the NTF, and their institutional affiliation / site name
Principal Investigator:	Enter the Principal Investigator's name
Subject:	Briefly describe 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 NTFs, when reviewing/reconciling study records. **IMPORTANT**: NTFs should **NEVER** contain any information that could potentially identify the subject (protected/personal health information – PHI) or unblind subjects and study team members.
Issue:	The 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. Remove any PHI, unblinding information.
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 implemented
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 of signature.

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NOTE TO THE STUDY FILE TEMPLATE

<Institutional Letterhead>

Date (DD/MMM/YYYY):

To:

From:

Principal Investigator:

DMID Protocol Number:

Subject:

Issue:

Resolution:

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

Comments:

Signature	**Date**