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| **Study Stage:** Conduct, Termination |



**Purpose:** To document the reason for missing, delayed or erroneous documents, procedures, etc., in the regulatory binder, essential documents, or in participant data. This template will assist in explaining protocol deviations or investigator site practices that differ from the norm or from what is described in the protocol.

**Useful to:** Any study team documenting an error/omission/discrepancy or process/policy for a participant file. FDA Regulated Studies- information in a note-to-file can explain variation from a protocol and thus can help to prevent a finding of noncompliance.

**Instructions:**

* Complete this template on a case-by-case basis for a research participant or study administrative procedure.
* Be sure to include the participant identifier (if applicable) and protocol to which the note-to-file is referring.
* The template will be signed and dated by the individual who is completing the note-to-file.
* Explain clearly and specifically the reason for the error/omission/discrepancy or study standard operating procedure (SOP) deviation.
* Include any corrective action or follow-up when applicable.
* Make certain the note to file is maintained in permanent study records so that it is not misplaced and can be linked to the original document to which it refers.

**Best Practice Recommendation:**

* If a sponsor provides a note-to-file template, complete as instructed. Otherwise, adapt the Note-to-File template to study specific documentation requirements.
* Store in an area with limited access to prevent a possible HIPAA breach of confidentiality or other study-related confidential information.

**Template History:**

**Last updated:** 6/07/2022

**Reference(s):** IRBMED Adverse events and ORIOs:

<https://az.research.umich.edu/medschool/guidance/adverse-events-aes-other-reportable-information-and-occurrences-orios-other>

**Version:** 2.4

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| **Study Name:** | **IRB HUM #:** |
| **Principal Investigator:** |  |

**Date\_\_\_\_\_\_\_\_\_\_\_\_ Participant ID (if applicable) \_\_\_\_\_\_\_\_\_\_\_\_ Protocol Version \_\_\_\_\_\_\_\_\_\_**

**Description of Issue/Problem/Finding/Event: (Include any explanations, special circumstances, mitigating factors or clinical rationales that are applicable.)**

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**Corrective Action / Preventive Action (if applicable):**

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**Is the information documented in this note considered an adverse event or unanticipated problem? (View link in Guidance Reference section of instructional page.) Y N**

**Is this information reportable to the IRB and/or other regulatory agency (ies)? Y N**

**Note IRB submission and/or agency (ies) notified and date:**

**Form Completed by: (print name and sign) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**PI Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**