**INSTRUCTIONS: NOTE TO FILE – MISC.**

**Purpose:** To document specific regulatory requirements for a study, document receipt of new information about an intervention, catalog site-specific protocol requirements, or other information which does not easily fit into other standardized forms.

**Useful to:** Any study team documenting information which does not easily fit into other forms.

**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 note to file.
* 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.

|  |  |
| --- | --- |
| **NOTE TO FILE** | |
| **PI:** Click or tap here to enter text. | **IRB #** Click or tap here to enter text. |
| **Study Title:** Click or tap here to enter text. | |
| **Protocol Version:** Click or tap here to enter text. | **Sponsor:** Click or tap here to enter text. |
| **Date:** Click or tap to enter a date. | **Participant ID** *(if applicable)***:** Click or tap here to enter text. |
| **Description/Purpose of the Note to File:**  Click or tap here to enter text. | |

|  |
| --- |
| **Signatures:** |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *Form Completed By (print name & sign)*  *Date* |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *PI Signature (optional)*  *Date* |
|  |