|  |  |
| --- | --- |
| **Date:**  | *[Insert date of the note to file (NTF)]*  |
| **Clinical Research Site Number:****Principal Investigator/Investigator of Record:** |  |
| **Protocol Number, Version and Date:**  |  |
| **RE:** [*insert a brief description of the subject of the NTF]*  |

***[NOTE:*** *Before creating an NTF, always ask: “Is this NTF useful to clarify what happened?”, “Does this NTF clarify what happened?”, “Is there another place where this information could be better documented via a late entry or clarification?”, “Who is the best individual to document the necessary details relating to this discrepancy?”.*

*The NTF can be used to explain situations such as:*

* *Location of a study document when it is not filed in the appropriate location*
* *Discrepancy between different versions of the same document, the action taken in response to said discrepancy, and the method adopted to prevent similar discrepancies moving forward*

*Include all pertinent details, such as date of occurrence and document version/date. The NTF must be created, signed, and dated by someone who was involved and/or who identified and could clearly document the discrepancy.*

***This should be used for clarification purposes only.***

***For any noncompliance, such as protocol deviations, a Corrective and Preventive Action process should be followed and documented.]***

\_\_\_\_\_\_\_ \_[signature and date]\_\_ \_\_\_\_\_\_\_

 [*Name*]

 [*Role*]