|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **File note no.** |  | | **Version of NTF** |  |
| **PROTOCOL ID** | *22SM8039* | | **CHIEF INVESTIGATOR** | *Prof. Anthony Gordon* |
| **Site** |  | | **PRINCIPAL INVESTIGATOR** |  |
| **NTF Title** | *Summary of file note (ideally not exceeding 20 words)* | | | |
| **Details** | *Prepare a file note to explain any of the following:*   * *Additional details that clarify the issue* * *Where documents are filed (if the location is different to the usual practice)* | | | |
| **Reason** | *Please give a brief description of the reason (no more than 100 words where possible)* | | | |
| **Impact** | *Please give a brief description of the impact (no more than 100 words where possible)* | | | |
| **Protocol deviation or violation?** | No | Yes | | |

**Actions Taken:**

|  |  |
| --- | --- |
| **Actions Completed** | *Include details of what has been or will be done to address it (proceed as per SOP\_QA010)* |
| **Actions Planned** |  |

**Reported / Written by:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** |  | **Role on Study** |  |
| **Signature & Date** |  | | |

**Approved by:  
(authorised, knowledgeable member of staff e.g. Study Manager, Monitor, or Coordinator/Operations Manager or PI/CI of trial)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** |  | **Role** |  |
| **Signature & Date** |  | | |

**Instructions:**

**Please file this file note in the file note section of TMF/ISF/Pharmacy Site File (if applicable); also place a copy in relevant sections and/or patient’s notes if applicable; please forward copy to the Study Manager or Monitor.**

*Delete all instructions in blue italic text before finalising.*