|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | | **PROTOCOL DEVIATION LOG - Category 1 & 2 only**  **Trial Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Site Name/No:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | |
| **Patient Trial ID** | **Date of Deviation** | **Description of Deviation (for example, missed visit, visit out of window, blood test missing, etc.)** | | **Category**  **1 or 2** |
|  |  |  | |  |
|  |  |  | |  |
|  |  |  | |  |
|  |  |  | |  |
|  |  |  | |  |
|  |  |  | |  |
|  |  |  | |  |
|  |  |  | |  |
|  |  |  | |  |

**By signing you confirm that you have reviewed the recorded Category 1 & 2 Protocol deviations. If any series of Protocol Deviations form a trend which warrant classification as a Category 3 or 4 deviation or any individual Protocol Deviation should be re-categorised to Category 3 or 4 please complete Form 51.008A and notify the Research Governance Manager or Lead Clinical Trials Pharmacist.**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | |  | | --- | |  | |  |  |  | |  |  | | | |
| **PI Sign Off Quarterly:** |  | |  |  |  | | |  |
|  | Print Name |  | Signature Date |  |  | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | |  | | --- | |  | |  |  |  | |  |  | | | |
| **Monitor Sign Off Quarterly:** |  | |  |  |  | | |  |
|  | Print Name |  | Signature Date |  |  | | | | |