|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Deviation Number** | **Participant Study Number,** *(if relevant)* | **Details of deviation** | **Date deviation was made** | **Date deviation identified** | **Staff member identifying deviation** | **How was deviation identified,**  *(e.g. monitoring visit, reported by nurse)* | **\*CAPA taken?**  *(if yes, give details)* | **Was this reported as a serious breach to MHRA?**  *(If yes, state outcome)* |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| \*CAPA-Corrective Actions/Preventative Actions  **FOR COMPLETION AT END OF STUDY:**  PI Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ PI Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_ \_\_ / \_\_ \_\_ \_\_ / \_\_ | | | | | | | | |