Appendix 1

**Site File Note**

|  |  |
| --- | --- |
| Study Title |  |
| Study Number: | IRAS Number:  |
| Reason for File Note | Explanatory/Other [ ] Deviation [ ]  Serious Breach [ ] If deviation is this from theProtocol [ ] GCP [ ] SOP [ ] Other [ ] N/A [ ]   |
| Date of incident  |  |
| Details |  |
| Corrective Action(s) |  |
| Preventative Action(s) |  |
| Impact on Patient Safety |  |
| Impact on Research Integrity |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Title | Name | Signature | Date |
| Author |  |  |  |
| CI/PI |  |  |  |
| Sponsor informed: Yes [ ]  No [ ]  N/A [ ]  | Date sponsor informed: |