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 the  Protocol  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: | |