|  |  |  |
| --- | --- | --- |
| Name of person reporting Breach**:** | Contact Details: | Date Breach Identified: |
| Study Number : IRAS Number: EudraCT Number:Study Title: | Principal Investigator: |

**Serious Breach Notification Form**

Include details of the breach; include the rationale (e.g. patient safety/data integrity issue and relevant legislation if known).

|  |  |
| --- | --- |
| Details of Breach | Action Taken |
|  |  |

CI/PI Name: …………………………………… CI/PI Signature …………………………………. Date ……………………………………