**NOTICE OF INCIDENT/DEVIATION/BREACH FORM**

|  |  |
| --- | --- |
| Study Title |  |
| REC reference: |  |
| Sponsor Ref Number: |  |
| Sponsor: |  |
| Chief Investigator: |  |
| Study Site: |  |
| Principal Investigator: |  |
| Type of Deviation reported (Tick all applicable options): | [ ]  Deviation from Protocol  | For JRES office use only : |
|  [ ]  Other (Minor) [ ]  Major  [ ]  Critical  |
| [ ]  Deviation from Documented procedure (e.g. Sponsor SOPs) |
| [ ]  Deviation or Non- compliance with GCP  |
| [ ]  Prospectively identified deviation |
| [ ]  Retrospectively identified deviation |
| Date Deviation identified: |  |
| Deviation number: |  |
| Initial or follow up report (circle): |  Initial Follow up |
| If follow up, date of follow up report: |  |
| Description of Deviation (Include subject numbers, how it was identified, who it was reported to): |  |
| Significance of Deviation to Subject Safety (as assessed by PI/CI or delegate): |  |
| Significance of Deviation to Integrity of Data (as assessed by PI/CI or delegate): |  |
| Corrective action (if applicable): |  |
| Preventative action: |  |

Reported by:

|  |  |
| --- | --- |
| Name: |  |
| Title: |  |
| Signature: |  |
| Date: |  |

Please submit completed form to the Sponsor: Joint Research & Enterprise Service.

Tel: 0208 725 5013 Email: adverseevents@sgul.ac.uk

File a copy of this completed form with the CRF and the Investigator Site File

Complete the Protocol Deviations Log JREOLOG0005

**For JRES Office Use only:**

Report reviewed by:

|  |  |
| --- | --- |
| Name: |  |
| Title: |  |
| Signature: |  |
| Date: |  |
| Comments: |  |
| Further reporting/escalation required: |  |
| Status: | [ ]  On-going  | Date of next review:  |
| [ ]  Closed  | Date: |