**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](mailto: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: |