**DIRECTORATE OF RESEARCH AND INNOVATION**

**Deviation/Event Reporting to R&D**

**Guidance Notes**

This form should be used to report significant deviations/events to the R&D office for all research Sponsored or Co-Sponsored by Great Ormond Street Hospital for Children (GOSH) or UCL Great Ormond Street Institute of Child Health (ICH). It may also be used to report significant deviations/events to the R&D office (and Sponsor) for research not Sponsored or Co-Sponsored by GOSH or ICH if the study Sponsor has not provided a suitable form.

The study procedures, departmental procedures and Trust Incident Reporting and Management Policy (e.g. completing a Datix incident) must also be followed.

SAEs, pregnancies and Important Medical Events (IMEs) should not be reported using this form (they should be reported using GOSH/ICH/FRM/R/003 or the study specific form).

Please see SOP/R/005 - Reporting and Escalation for Research for further details

**Examples of deviations/events** (to be used as a guide only and is not exhaustive).

* Protocol or GCP violation / deviation
* Violation of approval and/or approval conditions
* Research misconduct
* Confirmed research fraud
* An increase in the rate of occurrence of an expected (serious) adverse reaction, which is judged to be clinically important;
* A new event relating to the development of an intervention likely to affect the safety of the study participants e.g. a safety finding from a newly completed animal study or from another site or publication.

Significant deviations/events are those that are likely to have a significant impact on participant safety (including confidentiality) or the scientific value of the study.

**R&D Office contact is:** [**Research.Governance@gosh.nhs.uk**](mailto:Research.Governance@gosh.nhs.uk)

**Form to be sent to:** [**CTIMP.safety@gosh.nhs.uk**](mailto:CTIMP.safety@gosh.nhs.uk)

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| --- | --- |
| **Name of Reporter:** |  |
| **Telephone/Bleep:** |  |
| **Email:** |  |
| **Date report submitted:** | DD-MMM-YYYY |

| **Study number:** | **R&D number:** | ***Sponsor number:*** *(if different)* |
| --- | --- | --- |
| **EudraCT number:** | If applicable | |
| **Principal Investigator (PI):** |  | |
| **Site name/number:** |  | |
| **Short Study Title:** |  | |
| **Protocol Version:** |  | |
| **Sponsor:** |  | |

|  |  |
| --- | --- |
| **Date of Deviation/Event:** |  |
| **Date Study Team Aware:** |  |
| **Impact of Deviation/Event:** | Tick all that apply:  likely to have a significant impact on participant safety  likely to have a significant impact on participant confidentiality  likely to have a significant impact on the scientific value of the study  likely to impact the benefit:risk ratio of the study  If none of these apply then please contact R&D as you may not need to complete this form. |
| **Description:**   * *Be clear, concise, concrete, correct, considered, complete, courteous and consistent.* * *The SBARD (Situation, Background, Assessment and Actions, Recommendation, Decision) format can be helpful.* | **Participant ID Number (if applicable)**:  **Summary**:  **Explanation / description**: |
| **Action(s) Required:** | **Corrective action(s)**:  **Preventative action(s)**: |
| **Submissions Required:** | Are any of the following planned due to the deviation?  Urgent Safety Measure  Amendment  Halt to study or to recruitment (temporary or permanent)  No submission planned |

**For R&D office use only:**

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| --- | --- |
| Are GOSH/ICH Sponsor? | Yes  No |
| Date Received by R&D: |  |
| Date Assessed by R&D: |  |
| Assessment Outcome: | Minor Deviation/Event  Significant Deviation/Event  Serious Breach  Urgent Safety Measure  Other, Specify:  **Rationale for assessment outcome:** |
| Actions Required | No further action required  Triggered monitoring visit/audit  Further reporting (tick all that apply)  MHRA – Date Reported: DD-MMM-YYYY  REC – Date Reported: DD-MMM-YYYY  CI – Date Reported: DD-MMM-YYYY  PI {SITE} – Date Reported: DD-MMM-YYYY (add additional rows as required)  Other, Specify: |

**R&D Assessor**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Job Title** | **Signature** | **Date**  **(DD-MMM-YYYY)** |
|  |  |  |  |