**Clinical Directorate Clinical Research Governance Team**

**FORM001 Serious Breach Reporting Proforma**

This form is to be completed as required in line with SOP017 - Identification and Notification of Serious Breaches. Once completed send to sponsor@liverpool.ac.uk along with all supporting documentation.

|  |
| --- |
| **To be completed by Sponsor** |
| **Unique Breach Number:** |       |
| **Initial Report?** |       | **Follow-Up Report** |       |
| **Attachments:** |       |

|  |
| --- |
| **Reporter details** |
| **Organisation:** |       |
| **Person reporting:** |       |
| **Email address:** |       | **Tel No:** |       |

# PART A: Trial and Breach Details

|  |
| --- |
| **Trial details** |
| Trial Acronym |       |
| Full Study Title |       |
| Chief Investigator Name |       |
| Current Protocol Version Number and Date |       |
| Protocol registrations (ISRCTN, etc.) |       |
| Research Ethics Committee (REC) Name |       |
| REC Number |       |
| EudraCT Number |       |
| University of Liverpool Sponsor Reference | UoL00      |

|  |
| --- |
| **Studies With Co-Sponsors[[1]](#footnote-1)** |
| Co-Sponsor Organisation Name |       |
| Co-Sponsor Contact Details |       |
| Co-Sponsor Reference |       |

|  |
| --- |
| **Breach Overview** |
| Date(s) breach occurred |       |
| Date reporter first aware |       |
| Were any external parties involved? | [ ]  Yes | [ ]  No |
| Details of external parties involved (name of individual/organisation, contact details, role in study) |      [ ]  N/A |
| Were any individual sites involved? | [ ]  Yes | [ ]  No |
| Details of Sites Involved (site name, site code and Principal Investigator name) |      [ ]  N/A |
| Were any individual participants affected? | [ ]  Yes | [ ]  No |
| Participant Study Numbers |      [ ]  N/A |
| Have the above participants experienced any SAEs/SARs/SUSARs linked to this incident? |      [ ]  N/A |
| If participants affected, will they be informed?  | [ ]  N/A |
| [ ]  Yes Provide date(s) participants informed: |       |
| [ ]  NoProvide reasons why no intention to inform: |       |

|  |
| --- |
| **Breach Summary (Who, When, Where, What)** |
| Provide a narrative of the incident (when and where it occurred, who was involved, what happened) |       |
| Provide brief summary of the outcome of the breach |       |

# Part B: Sponsor Assessment

|  |
| --- |
| **Impact Of Breach** |
| Potential ImpactDid the breach have the potential to affect any of the following: | **Participant physical safety:**  | [ ]  Yes | [ ]  No |
| **Participant rights (e.g. confidentiality):** | [ ]  Yes | [ ]  No |
| **Participant well-being / mental integrity:** | [ ]  Yes | [ ]  No |
| **Data Integrity / Scientific Value:** | [ ]  Yes | [ ]  No |
| **Approval Issues:** | [ ]  Yes | [ ]  No |
| **IMP:** | [ ]  Yes | [ ]  No |
| **Other non-compliances:** | [ ]  Yes | [ ]  No |
| Provide details of potential impact |      [ ]  N/A |
| Actual ImpactDid the breach actually affect any of the following: | **Participant physical safety:**  | [ ]  Yes | [ ]  No |
| **Participant rights (e.g. confidentiality):** | [ ]  Yes | [ ]  No |
| **Participant well-being / mental integrity:** | [ ]  Yes | [ ]  No |
| **Data Integrity / Scientific Value:** | [ ]  Yes | [ ]  No |
| **Approval Issues:** | [ ]  Yes | [ ]  No |
| **IMP:** | [ ]  Yes | [ ]  No |
| **Other non-compliances:** | [ ]  Yes | [ ]  No |
| Provide details of actual impact |      [ ]  N/A |

|  |
| --- |
| **Root Cause Analysis (RCA)** |
| Root cause analysis  |       |

|  |
| --- |
| **Corrective and Preventative Actions (CAPA)** |
| CORRECTIVE ACTIONSProvide brief summary of how the breach will be / has been corrected and how its impact will be / has been limited |       |
| PREVENTATIVE ACTIONSProvide brief summary of what measures have been taken to prevent the Root Cause (and any other contributing factors) resulting in any further breaches |       |
| **CAPA TRACKING** |
| **C or P?** | **Action** | **Responsible party** | **Deadline** | **Date of Completion** | **Location of Evidence** |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |

# Part C: Sponsor Decision

|  |  |
| --- | --- |
| Sponsor Name |       |
| Does this breach meet the definition of a “Serious Breach” and require reporting to regulatory bodies? | [ ]  Yes | [ ]  No |
| **Provide explanation if required:**      |
| Does the Sponsor require any additional CAPA to be taken in addition to those listed above? | [ ]  Yes | [ ]  No |
| **Provide details:**      |
| Does the Sponsor require any of the following actions to be taken in response to this breach? | **Amendment to Study Documents / Design / Management?** |
| [ ]  Yes | [ ]  No |
| **Provide details:**      |
| **Urgent Safety Measure?** |
| [ ]  Yes | [ ]  No |
| **Provide details:**      |
| **Permanent Halt to the Study?** |
| [ ]  Yes | [ ]  No |
| **Provide details:**      |
| **Studies With Co-Sponsors Only[[2]](#footnote-2)** |
| Does the study have a co-Sponsor which jointly assesses breaches?*If yes, the second Sponsor should complete the following rows* | [ ]  Yes | [ ]  No |
| Co-Sponsor Name |       |
| Does this breach meet the definition of a “Serious Breach” and require reporting to regulatory bodies? | [ ]  Yes | [ ]  No |
| **Provide explanation if required:**      |
| Does the Sponsor require any additional CAPA to be taken in addition to those listed above? | [ ]  Yes | [ ]  No |
| **Provide details:**      |
| Does the Sponsor require any of the following actions to be taken in response to this breach? | **Amendment to Study Documents / Design / Management?** |
| [ ]  Yes | [ ]  No |
| **Provide details:**      |
| **Urgent Safety Measure?** |
| [ ]  Yes | [ ]  No |
| **Provide details:**      |
| **Permanent Halt to the Study?** |
| [ ]  Yes | [ ]  No |
| **Provide details:**      |

|  |
| --- |
| **Sponsor Signatories**  |
| Sponsor Representative Name |       |
| Sponsor Representative Role |       |
| Sponsor Representative Signature and Date |       |
| **Studies With Co-Sponsors Only[[3]](#footnote-3)** |
| Does the study have a co-Sponsor which jointly assesses breaches?*If yes, the second Sponsor should complete the following rows* | [ ]  Yes | [ ]  No |
| Co-Sponsor Representative Name |       |
| Co-Sponsor Representative Role |       |
| Co-Sponsor Representative Signature and Date |       |

# Part D: Notification and Onward Reporting

|  |
| --- |
| **Sponsor Notification Details** |
| Date Initial Report submitted to Sponsor(s) |       |
| Date(s) Follow-up Reports submitted to Sponsor(s) |      [ ]  N/A |

|  |
| --- |
| **Regulatory Reporting Details** |
| Date Initial Report submitted to the study’s Research Ethics Committee (REC) |      [ ]  N/A |
| Date(s) Follow-up Reports submitted to the study’s REC |      [ ]  N/A |
| Date Initial Report submitted to the Competent Authority |      [ ]  N/A |
| Date(s) Follow-up Reports submitted to the Competent Authority |      [ ]  N/A |

1. Only complete for those where assessment of breaches is jointly performed by both Sponsors [↑](#footnote-ref-1)
2. Only complete for those where assessment of breaches is jointly performed by both Sponsors [↑](#footnote-ref-2)
3. Only complete for those where assessment of breaches is jointly performed by both Sponsors [↑](#footnote-ref-3)