**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](mailto:sponsor@liverpool.ac.uk) along with all supporting documentation.

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

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

# PART A: Trial and Breach Details

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| --- | --- |
| **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 |

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

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| **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: |  | |
| No  Provide reasons why no intention to inform: |  | |

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| **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

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| **Impact Of Breach** | | | | |
| Potential Impact  Did 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 Impact  Did 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 | | | |

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

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| **Corrective and Preventative Actions (CAPA)** | | | | | | |
| CORRECTIVE ACTIONS  Provide brief summary of how the breach will be / has been corrected and how its impact will be / has been limited | |  | | | | |
| PREVENTATIVE ACTIONS  Provide 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** |
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# Part C: Sponsor Decision

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| 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:** | |

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| **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

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

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| **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)