|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Form Title:** | Adverse Event Report Form | | | Lancaster University logo |
| **Form Ref.:** | HSCR-FORM006 | | |
| This form must be completed for adverse events occurring in research studies sponsored by Lancaster University. If the adverse event is deemed to be serious or related, please save and return this form to [sponsorship@lancaster.ac.uk](mailto:sponsorship@lancaster.ac.uk). The email should come from or be copied to the Chief Investigator’s work email address. If the event is deemed to be adverse, but not serious then please store the form in the Investigator Site File (ISF) or Trial Master File (TMF) and return to the sponsor when requested. | | | | |
| **Section 1 – Study and Adverse Event Details** | | | | |
| **Full title of research study** | |  | | |
| **IRAS ID** | |  | | |
| **Site ID or Name** | |  | | |
| **Principal Investigator Name** | |  | | |
| **Adverse Event ID** (SITEIDSA00X or SITEIDSAE00X) | |  | | |
| **Start date of Adverse Event** | | Click or tap to enter a date. | | |
| **Start time of Adverse Event** | |  | | |
| **End date of Adverse Event** | | Click or tap to enter a date. | | |
| **End time of Adverse Event** | |  | | |
| **Date of Form Completion** | | Click or tap to enter a date. | | |
| **Section 2 – Adverse Event Details** | | | | |
|  | | | | |
| **Section 3-Action Taken** | | | | |
|  | | | | |
| **Section 4-Principal Investigator Assessment of Seriousness (If identified by/at NHS site)** | | | | |
| **Serious Adverse Event?** | | Serious Adverse Event | | |
| Adverse Event | | |
| **Serious Adverse Event Criteria**  **(if applicable)** | | Death | | |
| Life Threatening | | |
| Hospitalisation or prolongation of existing hospitalisation | | |
| Persistent or significant disability or incapacity | | |
| Other (please specify) | | |
| **Section 5 – Principal Investigator Assessment of Expectedness and Relatedness (If identified by/at NHS site)** | | | | |
| **Expectedness** | | Expected | | |
| Unexpected\* | | |
| **Relatedness** | | Related \* | | |
| Unrelated | | |
| **\*Please note if your study had National Research Ethics Service favorable opinion, and the AE is serious, related and unexpected, then you will need to complete a non-CTIMP Safety Report to REC form, which can be found on the** [**HRA webpage**](https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/)**. If required, please ensure that this is included with the submission to the Clinical Research Governance team.** | | | | |
| **Section 6 – Principal Investigator Signature (If identified by/at NHS site)** | | | | |
| **Principle Investigator Signature** | |  | | |
| **Print Name** | |  | | |
| **Date** | | Click or tap to enter a date. | | |
| **Section 7-Chief Investigator Validation (If identified by/at NHS site)** | | | | |
| **I confirm I agree with the categorisation above and am happy with the actions taken by the PI.** (if selected you do not need to complete section 8 onwards. And should sign the declaration in section 7) | | | **I disagree with the categorisation above and would like to complete my own assessment.** (if selected, please proceed to section 8 onwards) | |
| **Chief Investigator Signature** | | |  | |
| **Print Name** | | |  | |
| **Date** | | | Click or tap to enter a date. | |

|  |  |  |
| --- | --- | --- |
| **Section 8-Chief Investigator Assessment of Seriousness** (if identified by the central research team/ if different from the PIs categorisation above) | | |
| **Serious Adverse Event?** | Serious Adverse Event | |
| Adverse Event | |
| **Serious Adverse Event Criteria**  **(if applicable)** | Death | |
| Life Threatening | |
| Hospitalisation or prolongation of existing hospitalisation | |
| Persistent or significant disability or incapacity | |
| Other (please specify) | |
| **Section 9 – Chief Investigator Assessment of Expectedness and Relatedness** (if identified by the central research team/ if different from the PIs categorisation above) | | |
| **Expectedness** | Expected | |
| Unexpected\* | |
| **Relatedness** | Related \* | |
| Unrelated | |
| **\*Please note if your study had National Research Ethics Service favorable opinion, and the AE is serious, related and unexpected, then you will need to complete a non-CTIMP Safety Report to REC form, which can be found on the** [**HRA webpage**](https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/)**. If required, please ensure that this is included with the submission to the Clinical Research Governance team.** | | |
| **Section 10– Chief Investigator Comments** (if identified by the central research team/ if different from the PIs categorisation above) | | |
| **This can include any comments about the SAE or any action you will or have taken. This could also include any requests for the research site PI to undertake any further action.** | | |
| **Section 11-Chief Investigator Signature** | | |
| **Chief Investigator Signature** |  | |
| **Print Name** |  | |
| **Date** | Click or tap to enter a date. | |
| **FOR SPONSOR OFFICE USE ONLY** | | |
| **Received by** | |  |
| **Date received** | |  |
| **Date sent to sponsorship committee** | |  |
| **Feedback from committee** | |  |