

|  |  |  |
| --- | --- | --- |
| **Form Title:** | ICH GCP & Protocol Non-compliance Report Form  |  |
| **Form Ref.:** | HSCRS-FORM007  |  |
| This form is intended to be used for projects sponsored by Lancaster University that have discovered an incidence of GCP or Protocol non-compliance. It will be used in accordance with the procedure outlined in the accompanying document (GCP and Protocol Breach Process). This should be completed fully and accurately, in order for the sponsor to review all breaches. Please send all forms to the Clinical Research Governance Officers (CRGOs) via email to **Sponsorship@lancaster.ac.uk** with high importance and noting ‘Non-compliance report form for review’ and the study name in the subject line.  |
| **Details**  |
| **Study Title** |  |
| **Chief Investigator Name**  |  |
| **Site where the breach occurred** (Please state Lancaster University if the breach is a study wide breach) |  |
| **Site Principle Investigator Name** (if a site issue) |  |
| **Date Non-compliance occurred**  | Click or tap to enter a date. |
| **Date Non-compliance Identified**  | Click or tap to enter a date. |
| **Name and Position of Person Completing Form** |  |
| **Date Form Completed** | Click or tap to enter a date. |
| **Participants Affected** |
| **Single Participant** | **Multiple Participants**  | **All Participants**  | **None/Not Known** |
| [ ]  | **Participant ID number** |  |[ ] [ ] [ ]
|  | **Initials**  |  |  |  |  |

|  |
| --- |
| **Description** (Be as specific as possible about the deviation/breach, and include any references to GCP or protocol where necessary) |
|  |
| **Does the PI or CI (If a study wide issue) think this is likely to affect to a significant degree any of the following:**  |
| **Scientific value of the study**  | [ ]  |
| **Safety, physical or mental integrity of the participant(s)** |[ ]
| **None of the above** |[ ]
| **Corrective and Preventative Actions** Taken (please outline any actions you have undertaken to correct the breach or deviation, and any long-term actions to be undertaken to prevent this happening in the future)**:** |
|  |

|  |
| --- |
| **PI/CI Signatures (Please ensure the PI signs this if the issue is a single site issue, the CI should sign if this is a study wide or researcher issue)**  |
| **PI or CI Name**  |  |
| **Signature**  |  |
| **Date** (DD/MM/YYYY) |  |

|  |
| --- |
| **For Internal Use Only** (to be completed by the CRGOs upon receipt of the form) |
| **Name and Position**  |  |
| **Date Received** (DD/MM/YYYY) |  |
| **Date Completed** (DD/MM/YYYY) |  |
| **Category**  | **(A) Serious** |[ ]
|  | **(B) Major**  |[ ]
|  | **(C) Minor**  |[ ]
| **Initial Action Taken**  | **No further action, CAPA outlined is satisfactory**  | [ ]  |
|  | **Further action required, discussed CAPA with CI/PI** |[ ]
|  | **Escalated to CRSC/Sponsor Rep** |[ ]
|  | **Other** (please outline)  | [ ]  |