Dear Sir/Madam

I would like to report fraud that has been identified in a trial sponsored or co-sponsored by NHS Greater Glasgow and Clyde (NHSGGC) and is not categorised as a serious breach of GCP.

**NOTE: This FORM should only be completed when the fraud identified does not impact on patient safety or the quality of the data and therefore does not constitute a serious breach of GCP. If a serious breach of GCP is identified the MHRA processes of reporting these should be followed. Refer to SOP 51.009**

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| --- | --- | --- | --- |
| **Name and Contact Details of Reporter** |  | | |
| **Organisation of Reporter** |  | | |
| **Details of Individual or Organisation committing fraud** |  | | |
| **Confirm if the Individual or Organisation committing fraud have been made aware** | Yes | **☐** | |
| No | **☐** | |
| **Contact details for Individual/Organisation committing fraud** (if different from the above): |  | | |
| **Clinical trial details**  (for each trial include as a minimum; EudraCT number, CTA number, IRAS number, study title, Sponsor, UK Chief Investigator name and REC name) |  | | |
|  | Commercial | | **☐** |
| Non-Commercial | | **☐** |
| **Confirm which other parties have been notified and when e.g. other competent authorities, EMA, CQC, HRA, REC, other GxPs etc** |  | | |
| **Date Fraud Identified by Sponsor** |  | | |
| **Date Fraud Notified to MHRA** |  | | |

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| **Please give details of the fraud** |
| **Fraud summary** *(provide a brief top-level summary of the fraud):* |
| ***Incident information:***  . |
| ***Other relevant information:***  *(i.e. study status, site(s), ethics,.)* |
| **Please give details of the action taken:** |
| ***Impact Assessment****:*  *What is the extent of the issue and the impact? This should be investigated and reported. The issue may need to be reviewed across sites, trials, sponsors, electronic systems etc to determine the extent of the issue and impact. Provide full details of the impact assessment, include what has been looked at and how this has been done i.e. methodology should also be included here. If this is not known at the time of report provide details of when this will be available and submitted as a follow-up report. If identity fraud has been raised describe impact on trial, impact on data collected and impact on individual(s) affected.* |
| ***Root Cause Investigation:***  *The root cause investigation by your organisation should be explained including details of investigations by other organisations (e.g. CRO/ethics/trust), the results and outcomes of the investigations. If this is not known at the time of report provide details of when this will be available and submitted as a follow-up report* |
| ***Corrective & Preventative Action (CAPA) Plan:***  *Provide a clear measurable CAPA plan including any actions already taken/implemented. Include details of which organisation is responsible for each action (e.g. Sponsor, CRO, CRA, site etc) and a timeline. Also include how the incident will be transparently reported in the final report/publication and how this incident will be documented in the TMF for future inspection. If this is not known at the time of report provide details of when this will be available and submitted as a follow-up report.*  *If identity fraud has been raised describe the measures taken to notify the individual(s) affected and the methods of removal of the data from the trial and the individuals medical history.*  ***NOTE: false data should be removed/deleted from the trial but the information should not be destroyed. This includes falsification of trial data and data relating to identity fraud. The false trial data and an audit trail of the process followed may be required by Regulators.*** |

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