|  |  |  |  |
| --- | --- | --- | --- |
| Form number | **51.009A** | Version | **1.0** |
| Title | **Record of Breach Assessment Group** | | |

|  |  |
| --- | --- |
| NC Reference Number (ID from log) |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Trial ID |  | Trial Title |  |
| EudraCT ref |  | CTA Ref |  |

|  |  |
| --- | --- |
| Date reported to Sponsor |  |

|  |  |
| --- | --- |
| Date of Breach Assessment Group |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Date Reported to REC |  | Date Reported to MHRA |  |

|  |  |
| --- | --- |
| Chair |  |

**n.b. chair act as co-ordinator of meeting which is presented by lead of Serious Breach.**

|  |  |
| --- | --- |
| Potential Serious Breach Presented By |  |

|  |
| --- |
| Documents Considered |
| (Enter description of any documents presented or reference Numbers) |

|  |
| --- |
| Attendees |
| |  |  | | --- | --- | | Name | Role | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |  |  | |

|  |
| --- |
| Summary of discussion |
| (Please add a summary and reason why the issue is to be reported or NOT reported as a serious breach) |

\*\*Definitions and Guidance available in SOP 51.009.

|  |  |
| --- | --- |
| Is this a Breach of GCP, the Protocol or Both | |
| GCP | Protocol |
|  |  |

|  |  |
| --- | --- |
| Was the Breach Serious? |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| If Yes, was the impact to the safety or physical or mental integrity of the subjects of the trial, the scientific value of the trial, or both | | | | |
| Subject | Safety |  | Scientific Value of Trial |  |
| Physical Integrity |  |
| Mental Integrity |  |

|  |  |
| --- | --- |
| Confirmed as Serious Breach and Report to MHRA |  |
| Not confirmed as Serious Breach and not to be reported |  |

Approved on Behalf of Committee by Lead

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Lead Name |  | Title |  | Date |  |

**Form signatories**

|  |  |  |  |
| --- | --- | --- | --- |
| Prepared by | Caroline Watson | | |
| Signature |  | Date |  |
| Approved by | Chloë Cowan | | |
| Signature |  | Date |  |

**Document history**

|  |  |  |
| --- | --- | --- |
| **Version** | **Date** | **Description** |
| 1.0 |  | First Release |

|  |
| --- |
| This Form is a controlled document. The current version can be viewed on the GCTU website.  Any copy reproduced from the website may not, at time of reading, be the current version. |