**Incident Report**

|  |  |
| --- | --- |
| **Organisation name:** |  |
| **Trial(s) affected:** |  |

|  |  |  |
| --- | --- | --- |
| **Date identified** | |  |
| **Reported by**  *Name and role* | | **Name:**  **Role:** |
| **Start date and end date of incident**  *Start and end date may be the same* | | **Start date:**  **End date:** |
| **Trial number(s) of affected patients**  *if applicable* | |  |
| **Name of IMP(s) *involved***  *if applicable* | |  |
| **Is incident ‘Important’ as per CTC definition?**  *Any incident that has a significant or potential to have a significant adverse impact on the rights, safety or wellbeing of trial subjects and/or data integrity and/or has an impact on a trial site, organisation or department’s ability to conduct trials* | | **Yes**  **No** |
| **Incident details**  *Include how/when it was identified, why it occurred (focusing on processes)* |  | |
| **Site/Organisation Correction(s) & Corrective Action(s)**  *Detail measures that were or will be taken to correct the incident and/or minimise its impact. Include date(s) of implementation/planned implementation and person(s) responsible* |  | |
| **Site/Organisation Preventative Action(s)**  *Detail measures that have been or that will be implemented to prevent future occurrences. Include date(s) of implementation/planned implementation and person(s) responsible* |  | |
| **For all ‘important’ incidents (at a minimum)** | | |
| **Root Cause Analysis**  *A root cause analysis must be completed for all incidents defined as ‘important’ but may be conducted for all incidents.*  *Give details of investigations performed to determine the root cause of the incident. As part of the investigation, consider the following:*   * + *Is there a procedure in place? / Is the procedure clear?*   + *Was training provided?*   + *How were training and procedures communicated? Was communication clear?*   + *Has this process been used before? Is it a new process?*   *(Tools e.g. fishbone and 5 whys may be used to help determine root cause)* |  | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Form completed by:** | | | | | |
| **Name:** |  | **Role:** |  | **Date:** |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Form reviewed by** (*if different to completed by*)  *The form should be reviewed by a senior member of the team for ‘important’ incidents e.g. the Principal Investigator/Lab Manager/Pharmacy Lead etc.*  **Provide email evidence of review.** | | | | | |
| **Name:** |  | **Role:** |  | **Date:** |  |

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Please return 1 copy to UCL CTC for Trial Master File. File original in relevant file e.g. Investigator site file/pharmacy file/ATIMP Management/Central Lab File.***

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**CTC INCIDENT REVIEW (UCL CTC USE ONLY):**

**When reviewing the incident report, please ensure you review the following questions and add details to the incident database:**

* Is discussion/referral required with:
  + STC/TGL?
  + Trial statistician?
  + Regulatory team?
* Does incident fulfil the criteria of a:
  + ‘Important’ incident? (if decision does not match site/organisation’s assessment or the site/organisation has not completed this field on the report, please add/amend the report accordingly, initialling and dating the change/addition and provide the updated report to the site/organisation clarifying why the incident is/is not important).
  + Urgent Safety Measure?
  + Potential serious breach?
* Enter incident on incident log database and update entry throughout incident review process
* Refer to SOP T69 when necessary

|  |  |
| --- | --- |
| **Date received:** |  |
| **Reviewed by:** |  |
| **Incident Log ID:** |  |