**Protocol/ Clinical Investigation Plan (CIP) Deviation Tracking Log**

|  |  |  |
| --- | --- | --- |
| Study Title: | Study Number: (EDGE ID) | IRAS Number |
| Principal Investigator: | Site: | |

**Protocol/ CIP Deviation: A protocol/ CIP deviation is any un-intended departure from the protocol/ CIP, e.g. a protocol/ CIP visit date deviation, which does not result in harm to the trial subjects or significantly affect the scientific value of the trial. These do not need to be reported to the Sponsor but must be documented in the CRF and Trial Site/Master. Appropriate corrective and preventative action must be taken**

**\*If the deviation has an impact on patient safety or study outcomes this may constitute a serious breach and should be reported to the sponsor as per SOP S-1013 UHL.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Event  No. | Event Date | Participant  ID/Initials | Description of Deviation | Deviation  Code | Corrective /Preventative Action taken to avoid recurrence  e.g. protocol amendment |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

Investigator Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Deviation Codes: A. Consent procedure. B. Inclusion/Exclusion criteria, C. Serious Adverse event reporting/Unanticipated adverse device effect

D. Randomization Procedures/study drug dosing E. Study Procedures F. Laboratory assessments/procedures G. Visit schedule/Interval H. Other

**Protocol/ Clinical Investigation Plan Deviation Tracking Log - Tool guidance document**

**Purpose of this document:**

To record all protocol/ CIP deviations that occurs at a study site.

This tracking log should provide a comprehensive list of all protocol deviations that occur at a study site. It is required for both observational and interventional clinical research studies

**The tool is complementary to, and does not replace, the requirement to report potential serious breaches of the Protocol to the Sponsor and Regulatory Authorities as per SOP S-1013 UHL**.

**Completion of the log:**

* Ensure Study Title/Study Number/ Sponsor/PI and site details are completed on all forms
* Record protocol/ CIP deviations in the tracking log as they occur, to ensure completeness and accuracy of data.
* The site PI should sign each form after it has been completed.
* The Deviations should be reviewed and corrective preventive action completed and recorded. (i.e. amendment to the Protocol).
* Events should be numbered sequentially, commencing with no 1.
* The log should be filed in the Essential Documents Folder (i.e. Trial Master File/Site File) in either a specific labelled section (Protocol/ CIP Deviations) or with the trial protocol.
* Pages should be filed in reverse chronological order, with the newest pages of the log placed at the front of the section.
* At the conclusion of the study, ensure all forms are complete and signed by the Principal Investigator.