

### Protocol Deviation Tracking Log

Study Title:	UoL Ref Number:	Sponsor
Principal Investigator:	Site:	

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

**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 UoL.**

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

## **Protocol Deviation Tracking Log- Tool guidance document**

### **Purpose of this document:**

To record all protocol 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 UoL.**

### **Completion of the log:**

- Ensure Study Title/Sponsor reference number/ Sponsor/PI and site details are completed on all forms.
- Record protocol 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/Investigator Site File) in either a specific labelled section (Protocol 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.