Protocol Deviation Tracking Log – Guidance Page

This guidance page does not require filing.

A protocol deviation* is any un-intended departure from the study protocol which does not result in harm to the study subjects or significantly affect the scientific value of the study e.g. a clinic visits occurring outside of a specified window. These do not need to be reported to the Sponsor but must be recorded on a Protocol Deviation Tracking Log/CRF and in the Trial Master File/Investigator Site File as applicable. Where further documentation of a deviation is required, additional details should be recorded in a Site File Note and, where required, a Corrective and Preventative Action plan must be created in accordance with SOP S-1012 in order to avoid reoccurrence of the deviation.
*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.

Purpose of this document:

- To record 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 the Sponsor Reference Number/Study Title/Site and Principal Investigator (PI) details are added to the header of the document and are repeated across all pages.
- Record protocol deviations in the tracking log as they occur, to ensure completeness and accuracy of data.
- The site PI review and sign the form at regular intervals.
- The deviations should be reviewed and where necessary corrective and preventive action completed and recorded (refer to CAPA SOP (S-1012)
- Events should be numbered sequentially, commencing with no. 1.

The log should be filed in the relevant section of the Trial Master File/Investigator Site File)

Sponsor Reference Number:	
Study Title:	
Site:	
Principal Investigator:	

Protocol Deviation Tracking Log

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

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 (Please specify)

Principal Investigator Signature:	
Date	