AUSTRALIAN ICH GCP (Including Teletrials) SOP 50 Appendix 1 Example Protocol Deviation Log

Purpose:
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.

This tool is complementary to, and does not replace, the form reporting individual protocol deviations to the Ethics Committee and others as required.

Definition:
A protocol deviation is a failure to conduct all aspects of the study as described in the approved study protocol and ICH GCP E6 R2. These may be the result of human error when the deviation is investigator or trial management related or they could be subject related, where subjects misunderstand or ignore guidance given to them whilst they are on study.

Reporting:

The Principal Investigator is responsible for the reporting of protocol deviations. Site staff or a study monitor may prepare a protocol deviation form, but this form should be signed by the PI. This form should be kept in the Trial Master File for the relevant site. Once signed by the PI a new form is required for any further breaches even if the previous form was filled to the end.

Protocol Deviation Codes:

A – Consent Procedures

B – Inclusion/Exclusion Criteria

C – Concomitant Medication/Therapy

D – Laboratory Assessments/Procedures

E – Study Procedures

F – Serious Adverse Event Reporting/Unanticipated Adverse Device Effect

G – Randomization Procedures/Study Drug Dosing

H – Visit Schedule/Interval

I – Efficacy Ratings

J – Other

Protocol Deviation Tracking Log (Can use Sponsors)

Page Number __

Please use one sheet per Site. If signed by the PI please file and use a new form even if all 6 rows are not completed

- *Each page should be separately numbered to allow cross-referencing (e.g., deviation #3 on page 9)*
- *Deviation Type: (A-J) See codes below—enter the appropriate deviation code from the list.*

Protocol Number:		**Primary Site Name/Number:**	
Protocol Title (Abbreviated):		**Principal Investigator:**	
		Satellite Site Name/Number (if applicable)	
		Sub- Investigator (if applicable)	

No.	Subject ID	Site No	Date of Deviation	Date Identified	Description	Type of Deviation See Codes	Resulted in AE?	Did Subject Continue in Study?	Ethics Reporting Req. (Yes/No)	Ethics Reporting Date
1										
2										
3										
4										

Investigator Signature: _____ **Date:** _____