

Appendix 1: Log of Protocol Deviations

Breach Number	Date Breach Identified	Subject Identifier <i>(if applicable)</i>	Brief Description of Breach	Date Breach Reported to Sponsor
1	12/Dec/2013	AD0006 TD0007 DC0008	Three participants that were on active treatment had their treatment terminated early due to a lack of drug supply.	18/Dec/13
2	30/May/2013	RW0003	Clinical care blood results that were taken on 14/Jun/2012 and used to screen for study inclusion were outside of the defined time of 14 days as stated on the protocol.	11/Aug/2015
3	12/Oct/2015	N/A	Deviation to sponsor SOP-RES-019_Adverse Event Reporting in Clinical Trials of Investigational Medicinal Products, as adverse events have been logged within the CRF rather than the AE Record.	17/Nov/2015
4	17/Nov/2015	DC0012	SAE report 5000-09 was not submitted within 24 hrs of identification by the site	26/Nov/2015
5	21/Aug/2014	LH0015	Patient was consented to the study but did not commence treatment and was withdrawn from the study due to a lack of IMP.	26/Nov/2015
6	21/Aug/2014	AM0016	Patient was consented to the study but did not commence treatment and was withdrawn from the study due to a lack of IMP.	26/Nov/2015