UNIVERSITY OF LEICESTER

Information requested	Response
Sponsor reference number:	
Study Title or acronym:	
Chief investigator:	
Principal investigator:	
Study centre:	

Serious Adverse Event Listing Table

Patient Study ID	**Date of SAE** *dd/mm/yyyy*	**Date Study Team Aware** (dd/mm/yyyy)	**Title of Event**	**Serious Criteria** (1-6)*	**Assessment of relationship to procedure/intervention/IMP** (Related/Unrelated)	**Outcome** (1-5)‡	**Date Initial Report sent to Sponsor** *dd/mm/yyyy*	**Date Follow up/final report sent to Sponsor** *dd/mm/yyyy*	**Date Sponsor confirmed SAE closed** *dd/mm/yyyy*

*1 – Resulted in death, 2 – Life threatening, 3 – Inpatient hospitalisation or prolongation of existing hospitalisation, 4 - Persistent or significant disability/incapacity, 5 - Congenital anomaly/birth defect, 6 - Other.
‡1 - Resolved, 2 - Resolved with sequelae, 3 - On-going, 4 - Unknown, 5 - Fatal.