ANNEX A

REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)

*NOTE: This form is to be used **after** an inquest.*

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** 1. [redacted] 2. [redacted] **and** [redacted] 3. **Sheffield Children's NHS Foundation Trust (Chair – Nicholas Jeffrey) Sheffield Children's Hospital, Western Bank, Sheffield, S10 2TH** 4. **Leeds Teaching Hospitals NHS Trust, Chief Executive, Mr Julian Hartley, NHS Improving Quality, 1 Whitehall Quay, Leeds, LS1 4HR** 5. **Dr Ieuan Davies, Chair – Endoscopy Working Group for the British Society of Paediatric Gastroenterology, Hepatology and Nutrition, University of Wales Hospital, Heath Park, Cardiff, CF14 4XW**
1	**CORONER** I am Melanie Jane Williamson, Assistant Coroner, for the coroner area of West Yorkshire (Eastern)
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013.
3	**INVESTIGATION and INQUEST** On 2nd July 2013 I commenced an investigation into the death of Lexie Louise Harrison, aged 2½ years. The investigation concluded at the end of the inquest on 26th January 2015. The conclusion of the inquest was a Narrative Conclusion (annexed hereto) and the medical cause of death was:- 1(a) Liver failure 1(b) Infantile Refsum Disease
4	**CIRCUMSTANCES OF THE DEATH** In 2011 Lexie Louise Harrison ("Lexie") was diagnosed as suffering from Infantile Refsum Disease. In or around March 2013 Lexie was placed on a programme for the banding of oesophageal varices, which procedure is performed endoscopically under general anaesthetic. On the 30th May 2013 Lexie underwent such a procedure at Sheffield Children's Hospital. The Consultant performing the procedure on that occasion attempted to band a varix but was unsuccessful in so doing. The size of the said varix was such that it was too small to be banded. The aforesaid procedure caused trauma to the varix and extensive bleeding therefrom, which bleeding gave rise to the decompensation of Lexie's liver. Lexie's

	condition continued to deteriorate. At 10:30 am on the 18th June 2013 Lexie died at her home address.
5	**CORONER'S CONCERNS** During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you. The **MATTERS OF CONCERN** are as follows. – (1) Birmingham Children's Hospital NHS Foundation Trust has a policy in place and/or guidelines dealing with paediatric endoscopy procedures for the banding of an oesophageal varix/oesophageal varices ("the procedure"). Neither Sheffield Children's NHS Foundation Trust nor Leeds Teaching Hospitals NHS Trust has such a policy and/or guidelines. Both of the latter Trusts have undertaken the said procedure for many years. (2) There is no standardisation of practices (either locally or nationally) adopted by Consultants when undertaking the said procedure, by reason predominantly of there being no national policy and/or guidelines in relation thereto. Such a national policy and/or guidelines should address the following:- (a) Precise definitions of the grades of oesophageal varices; (b) Which grades of varices should be subject to banding and which should not; (c) Those patients who are to be deemed suitable for placing on a banding programme and those who are not; (d) Once a patient is placed on a banding programme, the assessment process to be adopted prior to the said patient undergoing each procedure; (e) Post endoscopy care, for example, the administration of sucralfate, frequency of basic observations; (f) The steps to be taken to properly assess for and manage variceal bleeding, for example, the immediate use of antibiotics; (g) The circumstances in which a Consultant is deemed to be competent to undertake the procedure alone or with supervision.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you have the power to take such action.
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by Friday 17th April 2015. I, the coroner, may extend the period. Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.

8	**COPIES and PUBLICATION** I have sent a copy of my report to the **Chief Coroner** and to the following Interested Persons:- [redacted] Mr Nicholas Jeffrey – Sheffield Children's NHS Foundation Trust, Mr Julian Hartley - Leeds Teaching Hospitals NHS Trust and [redacted] – British Society of Paediatric Gastroenterology, Hepatology and Nutrition [and to the LOCAL SAFEGUARDING BOARD (where the deceased was under 18)]. I am also under a duty to send the Chief Coroner a copy of your response. The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.
9	**20th February 2015** [redacted] **Melanie J Williamson** **Assistant Coroner** **West Yorkshire (Eastern)**