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. Sheffield Children's Hospital**
1	**CORONER** I am Abigail Combes, assistant coroner, for the coroner area of South Yorkshire (West District)
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 27 October 2022 I commenced an investigation into the death of Kyra Ali Aslam born on 21 March 2022. The investigation concluded at the end of the inquest on 6 July 2023. The conclusion of the inquest was:- Kyra Ali Aslam was admitted to Sheffield Children's Hospital on 11 August 2022 for a planned procedure to reverse a stoma which had been created in March 2022. Kyra did not recover from the surgical intervention deteriorating relatively rapidly over the course of 2 days. She died at Sheffield Children's Hospital on 13 August 2022. The medical cause of death was: 1a: Faecal peritonitis, bowel infarction and sepsis 1b: Leaking of anastomosis 1c: Closure of colostomy
4	1. The consent process for Kyra's planned surgery in August 2021 did not amount to fully informed consent on the part of Kyra's parents. It is clear that a decision had been made about the course of action to be pursued and this was put to the parents without description of the risks. The option to delay the surgery until after Kyra was 12 months old which was suggested as a possible consideration with the SI report, was not in accordance with the clinical view of the consultant responsible for Kyra's care. Having heard evidence from both Kyra's mother that she was informed this was a much more straight forward surgery than the original surgery which Kyra had and the evidence of the consultant that he could not recall exactly what was discussed with Kyra's family but he would not have offered them clinically unsuitable options (ie waiting until after Kyra was 1 year old) The risks of the procedure were not adequately explained to Kyra's parents at the time of the procedure by the consultant. The consent for the procedure was in effect done twice, there was no evidence either way of what risks were described to Kyra's family by the anaesthetic consultant who also sought consent for the procedure.

2. Notwithstanding my finding above, it is clear that it would never have been a clinical option open to Kyra's family to simply wait until after Kyra was older than 12 months for the procedure. That does not negate the fact that informed consent requires adequate explanation of the risks involved in the procedure being undertaken (including in this case the 1-2% risk of anastomosis). On the balance of probabilities that the finding that fully informed consent was not provided by Kyra's family on the basis of the evidence from Kyra's mother that the impression she was left with was that this was a much less risky procedure this does not change the evidence of the consultant that this surgery was a necessary surgery and it was the only clinically suitable option for Kyra. Therefore even in the context of full disclosure of the data of all of the risks, on the balance of probabilities the surgery would have proceeded and therefore the outcome for Kyra would have been the same.

3. On the basis of the evidence available it was not evident to the consultant or his colleagues, during the procedure, that there was any interruption to the blood supply to Kyra or that there was any issue with the suturing and sealing of the bowel. It was not obvious to the consultant or his colleagues that there was likely to be future issues with the blood supply to the bowel or anastomosis.

4. Kyra was unwell after the surgery and her mother was identifying that she was not behaving either how she normally would or how she had after her earlier surgery which Kyra's mother had been led to believe was a much more significant surgery. Kyra mother's concerns were explained by the medical team as matters which were normal within the context of pain, anaesthetic response and surgery. On the balance of probabilities I find that insufficient weight was placed on Kyra's mothers concerns. These ought to have been more clearly explored with her to understand whether there was anything in 'mother's intuition' that ought to lead medics to consider alternative causes for Kyra's presentation. However, in the circumstances the explanations preferred by the medical teams were within the context of reasonable medical opinion and therefore I am satisfied that on 11 August 2021 the insufficient weight placed on Kyra's mother's observations did not make a difference to the outcome for Kyra.

5. On 12 August 2021 Kyra began vomiting. This was a concern for the nursing staff, along with the temperature and the fact that her heart rate was elevated. It was on the 12 August 2021 that I heard evidence the nursing staff were thinking Kyra may have sepsis. Kyra was prescribed antibiotics and was given IV fluid to try and support her.

6. The nursing staff had significant concerns about Kyra and raised those concerns with medical staff as frequently as they felt able to do. I am satisfied on the basis of the evidence which I have heard, that the nursing staff supporting Kyra raised the concerns as soon as they were able to do so and as regularly as required to safeguard Kyra.

7. It is apparent that anastomosis within 48 hours of the procedure is a rare condition. The result of that is that it was not something which was high on the list of differential diagnosis the medics were considering and instead the medics formed the view that ileus was the most likely cause of the deterioration.

8. This was a possible diagnosis that all of the medics were working towards and that none of the medics considered that escalation to intensive care was required. I also heard evidence from the Consultant that even if he had been considering sepsis he would not have escalated care to intensive care as Kyra's management was suitable for ward level management.

9. On the balance of probabilities, that insufficient weight was placed on the nursing concerns about Kyra. The nursing staff were the best placed to identify the overall holistic view of Kyra's condition and they had significant concerns

	about her deterioration. 10. The medics appeared to place little weight on the observations and concerns instead placing significant weight on their own observations and the lack of expected signs of anastomosis and/or peritonitis. 11. That said, the diagnosis which the medics were considering the most likely was within the range of possible reasonable diagnosis which applied to Kyra's presentation. On the balance of probabilities that the medics had not ruled out sepsis or other conditions for Kyra but that they incorrectly worked on the basis of what they believed the most likely diagnosis. The findings cannot be made with the benefit of hindsight, clearly their diagnosis was the wrong one and this was apparent during the surgery on the 13 August 2021. However the working diagnosis was within the spectrum of reasonable possible diagnosis and the treatment the medics provided was appropriate for that diagnosis.
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 could 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. Whether there is a culture which prevents medics from taking account of the views of parents or nursing staff when considering the overall presentation of patients 2. Where a junior doctor is over ruled by a Consultant, is that learning adequately explained to that junior doctor to learn for next time?
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe your organisation 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 30 January 2024. 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: Kyra's family. I am also under a duty to send a copy of your response to the Chief Coroner and all interested persons who in my opinion should receive it. I may also send a copy of your response to any other person who I believe may find it useful or of interest 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.
9	**5th December 2023** **Abigail Combes**