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. NHS England** **2. The Rt Honourable Steve Barclay MP, Secretary of State for Health and Social Care** **3. The Royal College of Pathologists** **4. The General Medical Council**
1	**CORONER** I am Carly Elizabeth Henley, Assistant Coroner, for the coroner areas of Newcastle upon Tyne and North Tyneside.
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 26th April 2022 the Senior Coroner opened an inquest into the death of Tyler Jay Ryan. On 17th October 2023 I resumed and concluded the inquest.
4	**CIRCUMSTANCES OF THE DEATH** Tyler Jay Ryan (born 02.09.2009) died at the Royal Victoria Infirmary, Newcastle upon Tyne on 12.02.2021 aged 11 years old. Tyler had been found in his bedroom at his home address in a collapsed state by his mother on the morning of 12th February 2021. Police, Paramedics and the Great North Air Ambulance Service attended at the home address and attempted to resuscitate him. He remained asystole. He was conveyed to the RVI, Newcastle by Air Ambulance. Sadly, his death was pronounced after prolonged attempts to resuscitate him. Post Mortem examination was carried out by [redacted], Consultant Perinatal and Paediatric Pathologist at the RVI on 17th February 2021. His report was filed on 20th December 2021, over 10 months later. He concluded

	that the death was due to 1a) Acute Anaphylactic Shock. The family did not accept this conclusion on the basis that Tyler had no known medical history of allergies and no agent was identified to have triggered this reaction. The family contended that there must have been an undiagnosed and potentially hereditary underlying condition. Tyler had four surviving siblings and the family were concerned that they too may be at risk of sudden fatal collapse. HM Senior Coroner for Newcastle instructed [redacted], Consultant Paediatric Histopathologist to report as an independent expert. Her report is dated 15th August 2022. In her opinion, Tyler died of Sudden Unexpected Death in Childhood. She recommended that an analysis of Tyler's tissue samples should be conducted to explore whether Tyler had an underlying genetic condition which may have caused an arrhythmia. Genetic testing, via molecular autopsy, subsequently confirmed that Tyler had two variants in the gene RYR2. The scientific evidence strongly suggests that these variants are pathogenic and therefore expected to cause human disease. The RYR2 gene is known to be associated with a rare genetic condition, type 1 catecholaminergic polymorphic ventricular tachycardia "CPVT". This condition can lead to the development of a potentially dangerous heart rhythm disturbance called Ventricular Tachycardia "VT", usually when exercising or under conditions of stress or emotional arousal. VT can degenerate to Ventricular Fibrillation "VF". VF is lethal if it is not corrected by defibrillation. CPVT is a cause of sudden death in children and young adults with a mortality rate of up to 50% by the age of 30 years old if left undiagnosed and untreated. It is possible that Tyler's siblings may have inherited this condition. Having heard the evidence, I concluded that Tyler died of Sudden Unexpected Death in Childhood.
5	**CORONER'S CONCERNS** During 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. [redacted] and [redacted] each gave evidence that the delay in Paediatric Pathology reports is due to a chronic shortage in recruitment and retention of Paediatric Pathologists in the UK. This shortage is systemic. Currently only 50 out of 80 national vacancies for Paediatric Pathologists are filled. Coronial and Forensic work is undertaken by these Pathologists on a private basis, in addition to their NHS work. This provides insufficient time to carry out this work in a timely fashion. There is an acute shortage of Subspeciality

	Paediatric Pathologists, with just one Paediatric Orthopedic Pathologist undertaking Forensic and Coronial work in the UK. 2. The delay in Paediatric Pathology Reports results in the delayed detection of the need for genetic testing amongst surviving siblings of children who die of Sudden Death in Childhood. Currently, it is not until the Pathologist provides a report that the need for genetic testing is identified. Reports can take up to two years to be filed. 3. [redacted] and [redacted] gave evidence that more widespread use of molecular autopsy would assist in detecting genetic abnormalities in children who have died suddenly, leading to greater opportunities to prevent future deaths within their families and in other families. 4. [redacted], Consultant Clinical Geneticist gave evidence that Tyler is, to date, the only human in history to have been found to have these two RYR2 variants which is significant to his family and to the wider scientific community. Greater use of molecular autopsy would save lives within families and in other families. The detection of these variants is directly relevant to others and the prevention of future deaths. 5. [redacted] gave evidence that the development of the use of molecular autopsy calls for a revision of the SUDIC Protocol also known as the Kennedy Protocol.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe your organisation has 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 12th December 2023. 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: Tyler's family 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	**17.10.2023** **C E HENLEY**