Regulation 28: REPORT TO PREVENT FUTURE DEATHS

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

	REGULATION 28 REPORT TO PREVENT DEATHS **THIS REPORT IS BEING SENT TO:** **1 Medicines and Healthcare products Regulation Agency (MHRA)**
1	**CORONER** I am Sophie LOMAS, Assistant Coroner for the coroner area of Derby and Derbyshire
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 26 February 2020 I commenced an investigation into the death of Roy DRAPER aged 77. The investigation concluded at the end of the inquest on 18 July 2022.
4	**CIRCUMSTANCES OF THE DEATH** Roy Draper was diagnosed with mesothelioma in November 2019. He elected to participate in a clinical trial which consisted of first line chemotherapy drugs along with either a trial drug or a placebo. He received his first treatment in January 2020 and began to feel unwell shortly after. He was admitted to Royal Derby Hospital on 21st January 2020 with severe gastrointestinal symptoms which were consistent with an adverse drug reaction. Despite treatment he remained unwell and was effectively bedbound. He subsequently developed bronchopneumonia and on 6th February 2020 he suffered a massive stroke. He was recognised to be approaching the end of his life and sadly died on 13th February 2020 at Royal Derby Hospital. After his death it was confirmed that Mr Draper had received the placebo as part of the clinical trial and that the gastrointestinal symptoms were likely caused by a reaction to the chemotherapy drugs. The court heard evidence that Mr Draper's mesothelioma was extensive and would have placed him at risk of both having a stroke and developing pneumonia. The symptoms from the adverse reaction to chemotherapy would have tested his physiological reserves and placed further strain on his body. On balance, the root cause of Mr Drapers death was mesothelioma. For many years Mr Draper worked as a Coach Builder. During this work, he was exposed to asbestos. As a result of this occupational exposure, Mr Draper developed the mesothelioma which caused his death. The conclusion of the inquest was: Industrial disease
5	**CORONER'S CONCERNS** During the course of the investigation my inquiries 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:

	(brief summary of matters of concern) The matters of concern arise in the context of patients who are undergoing a clinical trial but who become acutely unwell and are admitted to another hospital for treatment. In such circumstances the treating hospital wishes to know further information about the trial as it may be relevant to treatment decisions. At inquest the evidence was unclear as to whom bears responsibility for initiating unblinding requests and what the process is. The evidence was conflicting in that the treating hospital understood that unblinding requests were considered by the clinical trials team once they were notified of a suspected adverse event whereas the clinical trial hospital believed that unblinding would only be considered once a formal request was made from the treating hospital. This evidence gives rise to the following matters of concern: 1. There is a lack of a clear system and protocol on whose responsibility it is to trigger consideration of the unblinding process and the correct procedure that should be followed by the treating hospital. If such a protocol in fact exists, then it does not appear to have been sufficiently disseminated. 2. There is no formal referral system for the treating hospital to use to report adverse events to the trials team and trigger consideration of the unblinding process. This means that conversations about the process between hospitals are not transparent.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you (and/or 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 September 29, 2022. 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] **University Hospitals of Leicester** **University Hospitals of Derby and Burton** 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 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 by the Chief Coroner.
9	**Dated: 04/08/2022**

	 **Sophie LOMAS** **Assistant Coroner for** **Derby and Derbyshire**