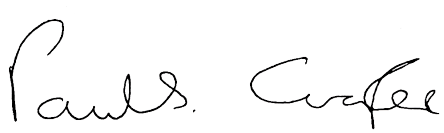
Regulation 28: REPORT TO PREVENT FUTURE DEATHS

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

	REGULATION 28 REPORT TO PREVENT DEATHS **THIS REPORT IS BEING SENT TO:** **1 [redacted] United Lincolnshire Hospital**
1	**CORONER** I am Paul COOPER, HM Assistant Coroner for the coroner area of Lincolnshire
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 02 September 2019 I commenced an investigation into the death of Michael James Robert ROLFE aged 72. The investigation concluded at the end of the inquest on 07 September 2022. The conclusion of the inquest was that: The deceased presented on 23rd August 2019 to A& E at the Pilgrim Hospital, Boston. A CT scan disclosed an intercranial bleed. He was not a candidate for surgery. Anti coagulants had already been stopped. He declined and died.
4	**CIRCUMSTANCES OF THE DEATH** Referral from [redacted] Integrated Assessment Centre, Pilgrim hospital [redacted] Due to death within 24hrs of admission. Mr Rolfe is a 72 yr old man admitted on 23/8/19 at 1627hrs with decreasing consciousness. He had a heache one day prior to admission. CT scan showed left cerebellar haemorrhage with intraventricular extension, compression of fourth ventricle and brainstem and obstructive hydrocephalus. ITU team initially intubated and ventilated him. However after discussion with QMC Neurosurgery, who were of the opinion that the position was not treatable. Discussion was had with family. He was extubated at 2350hrs the same day and transferred to the Stroke ward for EOLC. He passed away at 0930hrs on 24/8/19. PMH: TYPE 2 Diabetes mellitus, hypertension, non alcoholic steato hepatitis, hepatic encephalopathy, monoclonal gammopathy of undetermined significance, recent deep vein thrombosis started on Rivoroxaban, recent rectal bleeding. Spoke to [redacted] who is of the opinion that the Rivaroxaban most likely played a part in the bleed/death. He will liaise with his Consultant [redacted] (F) as to who will complete the Coroner's report. Decision taken for Consultant [redacted] to complete circumstances of death with CoD.
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)

	With reference to cause of death at 1b. The deceased had liver impairment due to cirrhosis. He was prescribed the anticoagulant Rivaroxaban for presumed deep vein thrombosis. Within 48 hours he developed rectal bleeding. During his admission to hospital his INR was 1.8 indicating blood was thin. Renal function impaired with a GFR of 39 - baseline 46. Rivaroxaban is contradicted in liver impairment, low platelets and severe renal impairment .(Documented in the product literature and British National Formulary). Consequently, it is represented that the deceased should not have been prescribed Rivaroxaban due to the bleeding risk. Administration of Rivaroxaban to someone with impaired clotting and low platelets would exaggerate the anticoagulant effect and be responsible for the rectal bleed and cerebral haemorrhage that resulted. If accepted the potential inappropriate administration may have led to the cause of death and this has important safety implications that are in the public interest. An action plan to prevent future deaths may be needed.
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 November 02, 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] I have also sent it to [redacted] who may find it useful or of interest. 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: 07/09/2022**  **Paul COOPER** **HM Assistant Coroner for Lincolnshire**