REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (2)

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

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** 1. The Minister for Health – [redacted]
1	**CORONER** I am Miss Lorraine Harris, Area Coroner, for the coroner area of East Riding of Yorkshire and City of Kingston Upon Hull.
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** On 2nd November 2023 I commenced an investigation into the death of James Arthur HOLGATE, aged 89 years. The investigation has not yet concluded, and the inquest has not yet been held. Mr HOLGATE's medical cause of death has been given as: *1a Traumatic Intracranial Haemorrhage* *1b Fall* *2 Mitral Valve replacement (on warfarin), Hypertension, Atrial Fibrillation, Frailty*
4	**CIRCUMSTANCES OF THE DEATH** On 30th October 2023 Mr HOLGATE age 89 years was admitted to Hull Royal Infirmary with recurrent falls, progressive confusion, slurred speech and progressive decline. While in the care of the Emergency Department Mr HOLGATE sustained a fall. A CT scan showed evidence of a traumatic head injury, Mr HOLGATE was deemed very unwell and not for surgical intervention. Mr HOLGATE deteriorated further and another CT scan showed an ongoing bleed with mass shift which had not been evident on the original CT. Mr HOLGATE was reviewed again and still deemed not fit for intervention and placed on a palliative care pathway. Mr HOLGATE died on 1st November 2023.
5	**CORONER'S CONCERNS**

The **MATTERS OF CONCERN** are as follows. –

This matter was referred to this court and is a case where it is entirely suitable to proceed to inquest without the need for a post mortem examination.
Evidence regarding the cause of death will be provided at inquest by way of a statement from the treating clinician with the CT scans showing the sequence of events.
The family indicated that it had been Mr HOLGATE's wishes, and indeed something that they supported, for his body to be donated for medical science/research.
This process has long been a way of researching illness and disease as well as assisting in the training of doctors. It is recognised as fundamentally important to progressing the understanding of medicine and treatment.

Each receiving medical research/training establishment have a criteria, one of which is that, unless there are exceptional circumstances, the deceased should not have undergone a post mortem examination. This is understandable, and exceptions allow in certain instances this to be waivered.

In Mr HOLGATE's case the local medical research/training establishment had full capacity and were unable to accept him. As is normal the family/Coroners Officer were referred to an alternative establishment at Nottingham.

Nottingham politely declined, they indicated that they were prevented from accepting due to what appears to be an anomaly in the law. As the matter was subject of a coronial inquest they could not accept the donation.

In non-inquest matters reported to the coroner, where post mortem examination is not required and the coroner is content there is no requirement to investigate further, a form A is signed to indicate this and the coroner is then able to return the deceased back in to the care of their family/personal representative/funeral director to allow funeral arrangements or body donation to proceed. In these instances medical research/training establishments are able to accept donation.

Where a coroner is likely to hold an inquest in a situation where a post mortem is not necessary as a cause of death statement can be obtained and the coroner is content that there is no further need to retain the deceased for any further examination, the coroner must also ensure that the deceased is returned back to the care of the family/personal representative/funeral director as soon as practicable. This normally allows for funeral arrangements to proceed.

In both instances the coroner authorises release of the deceased, in majority of cases the person is cremated ie they will not be available nor required for the coroner, even when the matter is proceeding to inquest. All relevant enquiries have to be made and sufficient evidence obtained before the release is authorised.

	It is surprising therefore that the medical research/training establishments are stating that they are prevented from accepting people that are to be the subject of an inquest due to the Human Tissue Act. I fully accept there may be some circumstances where it would be inappropriate however if the coroner has no reason to object then the fact that the death is the subject of an inquest should not prevent the donation. On reading the legislation, the establishments are either indicating an anomaly in the law or interpreting it incorrectly and guidance may be required. Human Tissue Act 2004 covers donation. Section 11 covers permission required from a coroner, it reads: **11 Coroners** *(1)Nothing in this Part applies to anything done for purposes of functions of a coroner or under the authority of a coroner.* *(2)Where a person knows, or has reason to believe, that—* *(a)the body of a deceased person, or* *(b)relevant material which has come from the body of a deceased person,* *is, or may be, required for purposes of functions of a coroner, he shall not act on authority under section 1 in relation to the body, or material, except with the consent of the coroner.* However the medical research/training establishments refer to section 1(3) of the act which explicitly states the body cannot be accepted unless the death has been registered. Section 1 Subsection (3) HTA states: **1 Authorisation of activities for scheduled purposes** *1(3)The use of the body of a deceased person for the purpose of anatomical examination shall be lawful if done—* *(a)with appropriate consent, and* *(b)after the death of the person has been registered—* *(i)under section 15 of the Births and Deaths Registration Act 1953, or* *(ii)under Article 21 of the Births and Deaths Registration (Northern Ireland) Order 1976.* Matters that proceed to inquest are not registered until the close of the inquest. Some inquests are dealt with in a very timely manner, however some may take some months to conclude. It appears that the consent in Section 11 may have the ability to override the consent required in Section 1(3), if it is then organisations are not interpreting it this way.
6	**ACTION SHOULD BE TAKEN** In my opinion urgent action should be taken to prevent future deaths and I believe you have the power to take such action. This may be by way of clarification or guidance if S11 overrides the need to register before acceptance. Donations of this kind further the advancement of medicine, treatments and training and as such prevent many deaths. It appears that those people who are subject of an inquest should not be prevented from donating their bodies

	when the coroner is content it is entirely appropriate to do so and it is the wishes of those making the arrangements.
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by 28th February 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 – the family of James Arthur HOLGATE. I have also sent it to The Royal College of Surgeons who may find it useful or of interest. 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	**[DATE] 3rd January 2024** **[SIGNED BY CORONER]** Lorraine Harris