REGULATION 28: REPORT TO PREVENT FUTURE DEATHS.

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** • Manchester University NHS Foundation Trust Copied for interest to: • Chief Coroner • Next of kin
1	**CORONER** I am Mr Zak Golombeck, Acting Area Coroner for Manchester (City) Area
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	**INQUEST** I concluded the inquest into the death of **David John Smith** on 12th February 2019 and recorded that he died from. 1a Multiple Organ Failure 1b CMV pneumonitis with pneumonia and acute respiratory distress syndrome 1c Renal transplant of a CMV positive kidney for fibrillary glomerulonephritis
4	**CIRCUMSTANCES OF THE DEATH** The deceased underwent a dual cadaveric renal transplant on 11 November 2016 following diagnosis of fibrillary glomerulonephritis The CMV status of the donor kidneys was listed as positive on the Electronic Offering System (EOS) form, however this information was never communicated to the deceased for him to consider the risks of proceeding with the transplantation. The plan for the deceased's surgery was communicated to the Renal transplant team in an email on the morning of 11 November 2016. This email did not, as it should have done, include reference to the donor's CMV status, nor did it attach, as it should have done the relevant EOS form The deceased proceeded to surgery, whereby he was operated on by the consultant surgeon and a clinical fellow. Both clinicians had the opportunity to consider the EOS form upon their respective authoring and checking of the operation note. The clinical fellow authored the operation note and erroneously entered the donor's CMV

	status as negative. The consultant did not review the operation note as he should have done and did not cross-check the donor's CMV status so to action post-operative care. Had the donor's CMV status been recorded correctly on the operation note, the deceased (who had a negative CMV status himself) should have received oral Valganciclovir by 13 November 2016 at the latest This was due to the deceased being a high risk as per the hospital trust's CMV policy. When the deceased was transferred to the ward, a flowsheet (as per the hospital trust's policy) was commenced. On the flowsheet both the donor's and the deceased's CMV statuses were recorded as negative, and together with the plan recorded on the operation note, no prophylaxis for CMV was commenced. The deceased was diagnosed with the CMV virus on 16 December 2016 and was admitted to the renal transplant unit and commenced treatment for CMV. The deceased was diagnosed with Ganciclovir resistance in March 2017 and in June 2017 the deceased commenced intravenous Foscarnet The deceased continued to deteriorate and died at the Manchester Royal Infirmary on 5 July 2017. There were numerous missed opportunities for the donor's CMV status to have been correctly recorded, and these missed opportunities were made more likely as a result of a system that was in place without the necessary checks and balances. One simple but fundamental error of a mis-recording led to the deceased not receiving the necessary medication, and this contributed to his death.
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 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. The consent process – I found that the CMV status of the donor's kidneys (listed as positive on the Electronic Offering System form) was never communicated to the Deceased for him to consider the risks of proceeding with the transplantation, and for him to provide informed consent. 2 Recording of the CMV status – When the plan for the deceased's surgery was communicated to the Renal transplant team in an email, this did not include reference to the donor's CMV status, nor did it attach the relevant EOS form. Consideration should be given to introducing a process in which the EOS form itself is sent onwards to the Renal transplant team to ensure important information such as the CMV status is not missed by the treating clinicians.

6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you and 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 Wednesday 9th October 2019**. 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 Interested Persons. I have also sent it to organisations 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:** **NAME OF CORONER:** **14th August 2019** **Zak Golombeck** HM Acting Area Coroner for Manchester City Area **Signed:**  .