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.** The Right Honourable Jeremy Hunt, Secretary of State for Health, Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS
1	**CORONER** I am Alan Peter Walsh, HM Area Coroner for the Coroner Area of Manchester West.
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 the 16th June 2016 I commenced an investigation into the death of Karen Ann Thorne, 44 years, born 31st March 1972. The investigation concluded at the end of the Inquest on 24th October 2016. The medical cause of death was:- 1a Bronchopneumonia 1b Progressive Multifocal Leukoencephalopathy – Immune Reconstitution Inflammatory Syndrome 1c Natalizumab Treated Multiple Sclerosis The conclusion of the Inquest was Karen Ann Thorne died as a consequence of recognised complications of Natalizumab treatment for Multiple Sclerosis and subsequent Plasma Exchange treatment where Progressive Multifocal Leukoencephalopathy identifiable from a Scan conducted in October 2015 was not identified and diagnosed until February 2016 and the delay led to an adverse effect on her response to treatment and prognosis.
	CIRCUMSTANCES OF THE DEATH 1. Karen Ann Thorne (hereinafter referred to as "the Deceased") died at Salford Royal Hospital, Eccles Old Road, Salford on the 13th June 2016. 2. In 2005 the Deceased was diagnosed with Multiple Sclerosis and she had two relapses in 2010, which fulfilled the clinical criteria for rapidly evolving severe Multiple Sclerosis, and in December 2010 she attended Salford Royal

NHS Foundation Trust to discuss treatment options for her Multiple Sclerosis with the Neurology Consultant.

3. In April 2011, the treatment for rapidly evolving severe Multiple Sclerosis commenced with Natalizumab, which is a drug given every 28 days by infusion.

   The Deceased was advised that the drug carried a small risk of a serious condition called Progressive Multifocal Leukoencephalopathy (hereinafter referred to as PML), which is a potentially life-threatening progressive viral disease that affects the brain, and the Deceased was monitored for the potential effects of PML using annual Magnetic Resinance Scans (hereinafter referred to as MR Scans) of the brain with an annual Neurology clinic review.

4. The MR Scans and the annual clinic reviews continued until May 2015 when the annual Scan was changed to a four monthly MR Scan following a re-assessment of the risk of PML.

   A MR Scan was conducted on the 20th May 2015 and the Scan showed subtle changes consistent with PML but the subtle changes were not identified by the radiology report at the time. The radiology report was not received for a period of 50 days following the Scan on the 20th May 2015 and during that time the Natalizumab infusions continued every 28 days.

5. The next MR Scan was conducted on the 10th October 2015, which showed clear evidence of PML on the Scan but the report of the Scan did not identify PML and the Deceased continued to receive infusions of Natalizumab every 28 days. The report of the Scan was not received for 65 days following the Scan, during which time the infusion of Natalizumab continued.

6. The Deceased deteriorated in December 2016 and a further MR Scan was conducted on the 8th February 2016 which identified PML and which was reported as PML.

   At that time the Natalizumab was stopped and on the 18th February 2016 Plasma Exchange treatment was commenced. The appropriate treatment for PML is to stop the Natalizumab infusion and commence Plasma Exchange treatment.

7. The Deceased developed immune reconstitution inflammatory syndrome, which is a recognised complication of Plasma Exchange treatment, following the commencement of Plasma Exchange treatment and she subsequently died on the 13th June 2016 as a consequence of a recognised complication of PML and a recognised complication of plasma exchange treatment.

8. It was accepted by the Salford Royal NHS Foundation Trust that the delay in the diagnosis of PML together with the delay in treatment for PML led to an adverse effect on the Deceased's response to treatment and the prognosis.

	9. The Trust also accepted that the delay in reporting the Scans for a period of 50 days in May 2015 and a delay of 65 days in October 2015, together with the fact that PML was not reported, led to additional infusions of Natalizumab, which would have been stopped if the Scan had been reported within a reasonable period and the reporting of the Scan had identified PML, bearing in mind the infusion was given every 28 days. It was accepted that the Scans should be reported before the next infusion of Natalizumab, which would avoid inappropriate additional infusions after the available diagnosis of PML and which would improve a patient's response to Plasma Exchange treatment and the prognosis.
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. During the Inquest evidence was heard that:- i. There are delays in reporting neuroradiology within the Salford Royal NHS Foundation Trust and at the present time the longest wait is 60 days, which is a slight improvement from the end of 2015 when the Scan conducted on the Deceased was not reported for 65 days but a delay of 60 days is still unacceptable. ii. There is an increasing demand for neuroradiology, and radiology in general, and there is a national shortage of Radiologists. iii. The delay in reporting radiology is of greater concern in cases where a patient is receiving treatment on a regular basis, namely every 28 days in the case of the Deceased, and the Scans are not reported for a period in excess of 60 working days, during which time the Deceased received 2 or 3 additional Natalizumab infusions, which would have been stopped had the Scan been reported and identified PML before the next infusion. iv. Evidence was given at the Inquest, on the basis of information received from the Royal College of Radiologists, that the national shortage of Radiologists was due to the fact that there are a fixed number of training positions for Radiologists each year and the number is insufficient to produce the number of Radiologists required to give an appropriate service and to report radiology within a reasonable, necessary and expected time period. The information referred to the fact that there was no shortage of clinicians prepared to train as Radiologists and that there were more applicants than training positions.

	The evidence given to the Inquest was that an increase in the number of training positions would increase the number of Radiologists to address the national shortage of Radiologists, which is creating the delays in reporting radiology and delays in the diagnosis of conditions requiring either immediate treatment or the cessation of treatment with recognised complications. 2. I request you to consider the above concerns in relation to a national shortage of Radiologists and to review the number of training positions to address the national shortage of Radiologists and to address delays in the reporting of radiology and the diagnosis of disease, either requiring treatment or the cessation of treatment.
6	**ACTION SHOULD BE TAKEN** In my opinion urgent action should be taken to prevent future deaths and I believe that you 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 Friday 6th January 2017. 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:- 1. [redacted] Mrs Thorne's husband 2. The Chief Executive, Salford Royal NHS Foundation Trust, Stott Lane, Salford M6 8HD 3. The President of the Royal College of Radiologists, 63 Lincoln's Inn Fields, London WC2A 3JW 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	**Dated** **11th November, 2016** **Signed**  **Alan P Walsh, Area Coroner**