ANNEX A

REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

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

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** 1. **Will Hancock, Chief Executive** **South Central Ambulance Service** **Northern House** **7-8 Talisman Business Centre** **Talisman Road** **Bicester OX26 6HR** 2. [redacted] **Warwick Medical School** **Warwick University** **Coventry CV4 7AL**
1	**CORONER** I am David Clark Horsley, senior Coroner for the Coroner area of Portsmouth and South East Hampshire.
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 28th January 2016 I commenced an investigation into the death of Samantha Ann Hopkins, aged 29. The investigation concluded at the end of the inquest on 30th August 2016. The conclusion of the inquest was: At about 06.10 hours on 12th October 2015, Samantha Ann Hopkins was found on the floor of her living room in a collapsed state. She had fallen earlier and had struck her head on the floor. Paramedics were called and resuscitation was commenced and continued as she was taken to Queen Alexandra Hospital by ambulance. Resuscitation was continued at the hospital but to no avail and she was pronounced deceased at 07.16 hours that day. At the time of her death, Mrs Hopkins was 36 weeks pregnant. The medical cause of her death was subdural haematoma. I concluded that she had died due to an accident.
4	**CIRCUMSTANCES OF THE DEATH** The paramedics, who attended Ms Hopkins' home, initiated the PARAMEDIC 2 Trial on the basis that she was in cardiac arrest. In the heat of the moment, they forgot that pregnant women are excluded from the trial. She was administered one dose of the trial drug before a paramedic team leader arrived and realised what had happened. Ms Hopkins was thereafter given adrenaline.

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: Although the SCAS staff participating in the PARAMEDIC 2 Trial had been instructed as to the classes of patients to be excluded in the trial and information was provided inside the trial drug packet about the exclusions, they overlooked that pregnant women were expressly excluded and the exclusion warning inside the packet was also overlooked. If the exclusions had been prominently listed on the outside of the packet, this oversight might have been avoided. I was also told in evidence that Warwick Medical School (which is responsible for the PARAMEDIC 2 trial) had given the participating ambulance services no guidance on how the exclusions were to be highlighted to trial participants and that this had been left to the ambulance services themselves. I am concerned that exclusions should be prominently highlighted on the outside of the trial drug packet. As there are only four categories of exclusion, this should be easily achievable.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths as suggested in my concerns and I believe 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 1st November 2016. 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 Ms Hopkins' relatives. 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	**06 September 2016** **[SIGNED BY CORONER]** **David Clark Horsley**