Karen Dilks
Senior Coroner for the City of Newcastle upon Tyne

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** 1. **Andrew Reed, Chief Executive for Royal College of Surgeons of England** **35-43 Lincoln's Inn Field** **London** **WC2A 3PE**
1	**CORONER** I am Karen L Dilks, Senior Coroner, for the Coroner area of Newcastle upon Tyne
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 6 March 2015 I commenced an investigation into the death of Stephen Pettitt. The investigation concluded at the end of the inquest between the 5 November and 8 November 2018. The conclusion of the inquest was a narrative conclusion: Died due to complications of an operation to treat Mitral Valve Disease and in part because the operation was undertaken with Robotic Assistance.
4	**CIRCUMSTANCES OF THE DEATH** Stephen Pettitt suffered from Severe Mitral Valve Disease. He became increasingly symptomatic and surgical repair of his Mitral Valve was advised.

The Consultant Surgeon responsible for his care offered Mr Pettitt a Robotically Assisted Operation.

He was informed that this would be the first such operation at the Freeman Hospital in Newcastle.

The Consultant Surgeon had some experience of Minimally Invasive Mitral Valve Repair Operations. He had not previously undertaken a Robotically Assisted Mitral Valve repair.

Prior to the operation the Consultant Surgeon spent an inderterminate period operating the Robotic equipment in order to familiarise himself with it.

He was not supervised or guided when doing so.

He also observed 4 Robotic Mitral Valve repair operations in the USA.

He personally arranged the attendance of Proctors at the operation.

The evidence clearly established the absence of any local or national guidelines in respect of the following:

1. Minimum training requirements for undertaking New Interventional Procedures

2. Minimum requirements for the recruitment and use of Proctors in New Interventional Procedures

3. The role of Proctors in any New Interventional Procedure

4. Guidance, information and advice to be provided to patients prior to formal consent to a New Interventional Procedure

Mr Pettitt underwent a Robotically Assisted Mitral Valve Operation on the 23 February 2015. The operation was the first undertaken at the Freeman Hospital and the first performed by the primary surgeon.

No plan was in place setting out maximum cross clamp time and/or circumstances in which conversion to a conventional operation should occur, prior to the operation.

A surgical and anaesthetic proctor, experienced in Robotic Heart surgery, were engaged to attend to advise and assist throughout the operation.

Complications occurred during the operation including Suture Misalignment, inability to sight Annuloplasty ring, bleeding and the unplanned and unexpected departure of the Proctors prior to the operations conclusion.

The operation was prolonged with a cross clamp time in excess of 6 hours.

	Mr Pettitt's death was the direct consequence of the operation and its complications.
5	**CORONER'S CONCERNS** Coroners Concerns are set out in the attached report to the Newcastle upon Tyne NHS Foundation Health Trust. The Coroner considers however there are wider national implications and that consideration to the creation of appropriate national guidelines in respect of the implementation of any New Interventional Procedure programme and the training required in respect thereof should be considered.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you Andrew Reed 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 22 March 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 the following Interested Persons • [redacted] • The Newcastle upon Tyne NHS Foundation Health Trust • The Secretary of State for Health and Social Care – Right Honourable Matt Hancock MP 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	**25 January 2019** ..... **HM Senior Coroner for the City of Newcastle upon Tyne**