ANNEX A

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. **Medical Director, LTHTR** 2. **Chief Executive, LTHTR**
1	**CORONER** I am Miss Claire Hammond, area coroner, for the coroner area of Preston and West Lancashire.
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. [HYPERLINKS]
3	**INVESTIGATION and INQUEST** On 18 August 2014 I commenced an investigation into the death of Mary Anne Gemma Hanson, 74 years of age. The investigation concluded at the end of the inquest on 15 April 2015. The conclusion of the inquest was that Mary Anne Gemma Hanson died as a result of rare but recognised complications of appropriate surgery, when she developed intraventricular haemorrhage due to postoperative apoplexy in brain invasive pituitary adenoma, which had been operated on by way of transphenoidal debulking surgery on 27 June 2014.
4	**CIRCUMSTANCES OF THE DEATH** Mary Hanson was admitted to Royal Preston Hospital 27 June 2014 for elective surgery to remove a large pituitary tumour. Although the procedure itself was routine, other than for a cerebrospinal fluid leak, which was repaired, she developed a bleed post-operatively, from which, despite the insertion of an external ventricular drain and a re-exploration of the tumour, she failed to recover and she died on 15 August 2014. Mary Hanson had been seen in combined pituitary clinic by [REDACTED] consultant neurosurgeon, and [REDACTED], consultant endocrinologist on 2 June 2014, following which a clinic letter was dictated by [REDACTED] At some point prior to surgery, a 'capacity assessment proforma' and 'best interest proforma' were filled in by Staff Nurse [REDACTED] by reason of the fact that it was considered Mary Hanson lacked capacity to make a decision about the need for surgery due to her inability to retain information. Following that assessment, consent was taken by [REDACTED], neurosurgical registrar, using a 'Consent Form 4' for adults who are unable to consent themselves.
5	**<u>CORONER'S CONCERNS</u>** 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) Mary Hanson had been seen in combined pituitary clinic by [REDACTED] consultant neurosurgeon, and [REDACTED] consultant endocrinologist on 2 June 2014. Although [REDACTED] evidence was that the risks of surgery would have been clearly explained to both Mary Hanson and her daughter [REDACTED] at that consultation, and that he would have stressed that the risk of serious harm and death is very small, [REDACTED] evidence was that they had not been advised of a risk of death by any clinician, and that her knowledge as to the risk of death was because of her own research carried out on the internet;

(2) There is no record in the medical records of that clinic appointment regarding what risks and benefits were discussed;

(3) There are no patient information leaflets for patients considering pituitary surgery to take home and digest, something [REDACTED] considered should be provided;

(4) The clinic letter sent to Mary Hanson's GP following the clinic does not detail the risks and benefits of surgery;

(5) The 'capacity assessment proforma' does not have a box to fill in the date, nor a box for the clinician's signature, or the signature of others consulted during the capacity assessment process;

(6) The 'best interests proforma' does not have a box to fill in the date, nor a box for the clinician's signature, or the signature of other consulted during the capacity assessment process;

(7) The best interests proforma' contains five boxes on the final page: "consideration of the person's beliefs and values that would have been likely to influence [their] decision if [they] had capacity; relevant circumstances [they] would take into account if they were making the decision themselves; the identified risks of the proposed treatment and any alternative treatments; the identified benefits of the proposed treatment and any alternative available treatments; the outcome of the best interest assessment, which should demonstrate the weighing of information, reasons for discounting a particular point of view or the manner in which weight has been applied to certain views. It should demonstrate your analysis and findings as the named decision maker." These questions are clearly central to the best interests assessment, yet they had not been completed by the Staff Nurse carrying out the assessment and were all left entirely blank;

(8) Given that GMC guidance on consent is that if a discussion regarding treatment is to be delegated, the person to whom that task is delegated must be suitably trained and qualified, have sufficient knowledge of the proposed treatment and understand the risks involved, it is doubtful whether a staff nurse is likely to be the appropriate person to complete the proforma and take such a decision;

(9) When [REDACTED] undertook the consent process on the day of surgery using Consent Form 4, he did not notice that the key boxes on the best interests proforma had not been completed;

(10) Consent Form 4 does not contain a section for the clinician to carry out the best interests assessment, and in particular does not have anywhere to list the risks and benefits of treatment, or the balancing of the two, something which both [REDACTED] and [REDACTED] thought it should.

6	**ACTION SHOULD BE TAKEN**

	In my opinion action should be taken to prevent future deaths and I believe 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 16 June 2015. I, the area 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 Mary Hanson's daughter, [redacted] 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]** 21 April 2015 **[SIGNED BY CORONER]** [redacted]