

**ANNEX A**

**REGULATION 28: REPORT TO PREVENT FUTURE DEATHS (1)**

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

	<p><b>REGULATION 28 REPORT TO PREVENT FUTURE DEATHS</b></p> <p><b>THIS REPORT IS BEING SENT TO:</b></p> <p>1. Professor [REDACTED] Institute of Head and Neck Studies and Education University of Birmingham Birmingham B15 2TT</p>
1	<p><b>CORONER</b></p> <p>I am Kevin McLoughlin, Senior Coroner/Area Coroner/Assistant Coroner, for the Coroner area of West Yorkshire (East).</p>
2	<p><b>CORONER'S LEGAL POWERS</b></p> <p>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.</p>
3	<p><b>INVESTIGATION and INQUEST</b></p> <p>On 4 December 2018 I commenced an investigation into the death of Carl Anthony Schmidt, aged 51. The investigation concluded at the end of the Inquest on 5 September 2019. The conclusion of the Inquest was a narrative conclusion based upon a cause of death of</p> <p>1a Radiation-induced neuropathy 1b Radiotherapy for tonsillar squamous cell carcinoma 2 Ischaemic heart disease.</p> <p>Mr Schmidt had participated in a clinical trial known as 'Compare' in which he was <b>treated with an accelerated radiotherapy and chemotherapy in March/April 2018</b>. He developed neurological symptoms approximately six months later and died on 20 November 2018</p>
4	<p><b>CIRCUMSTANCES OF THE DEATH</b></p> <p>Mr Schmidt was a 51-year-old HGV driver. He was diagnosed with cancer of the tonsils in January 2018 and underwent tonsillectomy. He agreed to participate in a clinical trial involving accelerated radiotherapy and chemotherapy. The treatment programme was completed in April 2018. In October he developed neurological symptoms in the area near to the site of his radiotherapy. He was admitted to hospital on 8 November 2018. Post mortem investigations by a consultant neuropathologist and a consultant histopathologist concluded that, on the balance of probability, radiotherapy-induced nerve injury was the likely cause of his death.</p>

5	<p><b>CORONER'S CONCERNS</b></p> <p>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.</p> <p>The <b>MATTERS OF CONCERN</b> are as follows. –</p> <p>(1) The form of chemo radiotherapy provided in the clinical trial potentially exposes the patient to neurological damage.</p> <p>(2) The mechanism by which the radiotherapy/chemotherapy treatment probably causes injury needs to be further investigated to establish whether this occurs directly or indirectly by affecting the immune system.</p>
6	<p><b>ACTION SHOULD BE TAKEN</b></p> <p>In my opinion action should be taken to prevent future deaths and I believe your organisation at Birmingham University has the power to take such action.</p>
7	<p><b>YOUR RESPONSE</b></p> <p>You are under a duty to respond to this report within 56 days of the date of this report, namely by Thursday 7 November 2019. I, the Coroner, may extend the period.</p> <p>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.</p>
8	<p><b>COPIES and PUBLICATION</b></p> <p>I have sent a copy of my report to the Chief Coroner and to the following Interested Persons</p> <p>(1) [REDACTED]</p> <p>I have also sent it to (2) [REDACTED] Consultant Oncologist, St James' Institute of Oncology, Bexley Wing, Beckett Street, Leeds LS9 7TF, who may find it useful or of interest.</p> <p>I am also under a duty to send the Chief Coroner a copy of your response.</p> <p>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.</p>
9	<p>11 September 2019</p> <p><i>Kevin McLaughlin</i></p>