WITNESS STATEMENT OF DEBRA ANNE POLLARD

1. I, Debra Anne Pollard of the Royal Free London NHS Foundation Trust, Pond Street, London, NW3 2QG, will say as follows:

2. I am employed by the Royal Free London NHS Foundation Trust (the Trust) as a Lead Nurse Specialist within the Haemophilia & Thrombosis Centre. I have worked for the Trust as a Clinical Nurse Specialist since February 1992 and have been in my current role since May 2014.

3. The information provided within this witness statement is based upon facts within my knowledge, save for where I indicated the source of information or belief. Where matters are not directly within my knowledge, I believe them to be true.

4. I attach to this statement a bundle of supporting documents which are relevant to the comments in Ms Ryness-Hirsch's statement dated dated 8 February 2019. Page numbers referred to in this statement in the form **[WITN3094001/1 – 31]** are references to pages in that bundle.

5. As the Lead Nurse Specialist, my responsibilities include leading and managing a team of specialist nurses and allied health professionals. I am also responsible, together with the Centre Director, for the strategic development and management of the department.

6. Since my arrival at the Haemophilia & Thrombosis Centre in 1992, I have been responsible on a number of occasions for answering questions from the Infected Blood Inquiry (the Inquiry). As a result, I am aware of some of the issues surrounding the Inquiry and know how to investigate matters arising within our archives and systems.

Scope of this witness statement

7. I have been asked to write this witness statement on behalf of the Trust to respond to matters raised within the witness statement of Ms Della Ryness-Hirsch, dated 8 February 2019, specifically the section of the witness statement at paragraphs 54 to 70 in which Ms Ryness-Hirsch comments upon the period of time during which Mr Nicholas Hirsch ("Nick") was under the care of the Royal Free Hospital (the Hospital) between July 1985 and October 2009.

8. The Inquiry has requested that the Trust respond to Ms Ryness-Hirsch's statement that the Hospital refused to provide Nick with recombinant Factor VIII products between 1997 and 2003;

    a. Initially refusing because Nick was aged 18 years and 2 months, and
    b. Later claiming that there was a shortage of recombinant factor products.

Decision not to prescribe recombinant Factor VIII for patients over the age of 18 years

9. Ms Ryness-Hirsch is correct that Nick was not treated with recombinant Factor VIII between the period covered within paragraphs 54 and 77 of her witness statement; namely between 1996 and August 2003. As set out within Ms Ryness-Hirsch's witness statement, she wrote to Dr Lee in August 1996 regarding the Factor products that Nick was receiving. Dr Lee responded by letter dated 19 August 1996 [**WITN3094001/1**] advising that she "did not think it is of any advantage for Nicholas to move from one plasma-derived product to another at this stage but ultimately, I would hope that all our patients will be treated with recombinant factor VIII. At the present time, this is not possible but, it may become possible over the next years".

10. The statement that Dr Lee makes in relation to treatment with recombinant Factor VIII not being possible for Nick at that time refers to the fact that the Hospital was following the guidance issued by the Department of Health confirming that recombinant Factor VIII was only to be prescribed to newly diagnosed children

with haemophilia. It was not until 2003 that recombinant Factor VIII was funded for adults with haemophilia.

11. For completeness, I note that the timeline given at paragraph 56 of Ms Ryness-Hirsch's statement suggests that it was in or around August 1996 that the Government announced that treatment with recombinant Factor VIII would be provided to children under 18 years of age and that, at that time, Nick was 18 years and 2 months old. I believe that Ms Ryness-Hirsch is referring to the fact that the Hospital made the decision to switch previously treated patients under the age of 18 years to recombinant Factor VIII beginning with the first previously treated child to be switched in July 1996. Nick would have been 20 years and 2 months at the date that this first previously treated child received treatment. However, the formal Government announcement was made by Frank Dobson, Secretary of State for Health, in March 1998, at which time Nick was 21 years and 11 months old.

12. There is no documentation that I can find to explain how the decision was made in 1996 to switch those under 18 years old. I can only assume that there was a local agreement to support this financially, either by the Hospital or the relevant Commissioning authorities at the time. I do remember that this was not standard practice throughout the UK, and that many regions were unable to switch the children until the Government announcement in 1998.

Shortage of recombinant factor products

13. I note from the attached correspondence that Mrs Hirsch made several appeals via her local health authority for an Individual Funding Agreement, with the aim of ensuring that Nick was prescribed recombinant Factor VIII. Dr Lee liaised with the local health authority and Ms Ryness-Hirsch in relation to these requests **[WITN3094001/2–7, and 10-12]**.

14. Within the context of these correspondence, Dr Lee wrote to Mr Chambers, Commissioning Manager for South Barnet PCG Office, on 25 January 2001. At the conclusion of this letter, Dr Lee confirms that, should the Government recommend that hospitals treat all adults with recombinant Factor VIII, "there certainly would not be enough recombinant Factor VIII in the market place". This

statement is supported by the advice note issued by the UKHCDO Advisory Committee on 29 March 2001 **[WITN3094001/8]**. In this document, entitled "Managing Shortfall in Recombinant and Plasma Derived Factor VIII Products", the UKHCDO Advisory Committee recommends the development of various contingency plans for decreasing the use of recombinant Factor VIII whilst there was an identified shortfall in Factor VIII supplies. The UKHCDO Advisory Committee advice note was also provided to Nick by letter dated 5 April 2001**[WITN3094001/9]** .

15. Upon the basis of the above, we therefore agree with Ms Ryness-Hirsch's statement that she and Nick were advised that there was a shortage of recombinant factor products and that this would have been the main, if not sole, reason that Nick was not prescribed recombinant Factor VIII products until 2003.

Prescription of Recombinant Factor VIII

16. On 12 February 2003, there was a Department of Health announcement stating that funding would be made available to extend the introduction of recombinant clotting factor products to all patients **[WITN3094001/13 - 14]**. There was then a period of time during which consideration was given to how this funding would be introduced and how the process would be managed **[WITN3094001/17 - 26]**.

17. Nick was first treated with recombinant Factor VIII in August 2003, prior to a dental extraction **[WITN3094001/27 - 28]**. The individual treatment protocol was signed by Professor Christine Lee on that day. He was also given a supply of the products to take home to treat himself. This prescription was dispensed under protocol by Staff Nurse Gillian Pascoe and checked by Staff Nurse Rebecca Bell. According to the Hospital's records, Nick was not exposed to plasma-derived clotting factor after this time.

18. On 28 January 2004, Nick was sent a letter from the Trust's Haemophilia Centre **[WITN3094001/29]**. This letter was a local version of the one created by the UK Haemophilia Centre Doctor's Organisation. This letter explained about recombinant clotting factor concentrate, set out the National Guideline for the "roll-out" programme, and invited Nick to attend the Centre for a formal switch of products. I note that Nick had been receiving recombinant products for 5 months by the time of this correspondence.

19. On 19 February 2004, Nick attended the Hospital for the formal switching process, which included a consent form and a check list. Both of these documents were signed by him and by Staff Nurse Gillian Pascoe **[WITN3094001/30 - 31]**.

20. It is the Trust's position that the Hospital followed the relevant national guidelines for the prescribing of clotting factor concentrates for men over the age of 18 years with Haemophilia during the time period in question. From the records I have reviewed, I am satisfied that, as soon as it was possible, Nick was switched to the product of his choice.

I believe that the facts stated in this witness statement are true.

Signed: GRO-C

Debra Anne Pollard

Date 07 MAY 2019