Witness Name: Dr Ian Richard Starkey

Statement No.: WITN7006001

Exhibits: WITN7006002 - WITN7006005

Dated:

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR IAN RICHARD STARKEY

I provide this statement in response to a request under Rule 9 Request of the Inquiry Rules 2006 dated 8 November 2021

I, Dr Ian Richard Starkey, will say as follows: -

Section 1: Introduction

1. ***Please set out your name, address, date of birth and professional qualifications.***

1. Name: Ian Richard Starkey

Date of Birth: GRO-C 1951

Address: GRO-C EDINBURGH GRO-C

Professional Qualifications:

BSc (Hons) 1972

MB ChB (Hons) 1975

MRCP 1977

FRCP (Ed) 1989

2. ***Please set out your employment history including the various roles and responsibilities that you have held throughout your career, as well as the dates.***

2. Employment History:

August 1975 – January 1976: House Officer, General Medicine, Milesmark Hospital, Dunfermline, Fife

February 1976 – July 1976: House Officer, General and Vascular Surgery, Wards 13-14, Royal Infirmary of Edinburgh

August 1976 – March 1977: Senior House Officer in General Medicine, Wards 32-33, Royal Infirmary of Edinburgh

April 1977 – July 1977: Senior House Officer in Coronary Care, Ward 31a (CCU), Royal Infirmary of Edinburgh

August 1977 – July 1978: Registrar in General Medicine, Milesmark Hospital, Dunfermline, Fife

August 1978 – January 1979: Registrar in Neurology, Northern General Hospital, Edinburgh

February 1979 – January 1982: Registrar in Cardiology, Royal Infirmary of Edinburgh

February 1982 – November 1984: British Heart Foundation Research Fellow, Departments of Clinical Neurology, Radcliffe Infirmary, and Cardiology, John Radcliffe Hospital, Oxford

December 1984 – February 1987: Senior Registrar in Cardiology, Sheffield Hospitals (based at Northern General Hospital, Sheffield)

March 1987 – March 2010: Consultant Cardiologist, Lothian University Hospitals NHS Trust (based at Western General Hospital, Edinburgh)

April 2010 onwards: Retired from Clinical Practice.

3. ***Please set out your membership, past or present, of any committees, associations, parties, societies or groups relevant to the Inquiry's Terms***

of Reference, including the dates of your membership and the nature of your involvement.

3. I was a member, and subsequently Chair, of the Medicine/Clinical Oncology Research Ethics Sub-committee of Lothian University Hospitals NHS Trust, which became part of NHS Lothian in 2001.

4. I do not know the dates of my membership and chairmanship of this sub-committee: I have not retained documents relating to this. I have contacted the Manager of the South East Scotland Research Ethics Committees to determine whether records of the membership of this Sub-committee are still available. To date none have been found but I understand that a search of archived records is still ongoing.

4. Could you please confirm whether you have provided evidence to, or have been involved in, any other investigations, criminal or civil litigation in relation to human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products. Please provide details of your involvement and copies of any statements or reports which you provided.

5. I have not provided evidence to, or been involved in, any other investigations, criminal or civil litigation in relation to HIV, HBV. HCV infections and/or vCJD in blood and/or blood products.

Section 2: The Medicine/Clinical Oncology Research Ethics Sub-committee at NHS Lothian

5. ***Please explain:***

a) The role of the Medicine/Clinical Oncology Research Ethics Sub-committee at NHS Lothian.

6. The sub-committee considered applications made to it from hospital-based doctors and other healthcare professionals wishing to undertake research on or involving patients in Clinical Oncology or Clinical Medicine, including its various sub-specialties (Cardiology, Gastro-enterology, Clinical Neurology, etc). Those wishing to undertake such research were obliged to seek approval of the Ethics Sub-committee before the commencement of the project. They did so by sending a protocol of the proposed study along with a completed Ethics Sub-committee application form.

b) How the committee fitted within the structure of NHS Lothian.

7. NHS Lothian was formed in 2001; before that, the Medicine/Clinical Oncology Research Ethics Sub-committee was part of the structure of Lothian University Hospitals NHS Trust. As far as I can recall, there were a number of Sub-committees (Medicine/Clinical Oncology, Surgery, Paediatrics, possibly others) of the Research Ethics Committee. I am unsure of how this "fitted within the structure" of either the Trust or NHS Lothian.

c) What your role as Chair of the Medicine/Clinical Oncology Research Ethics Sub-committee at NHS Lothian involved.

8. As Chair of the Sub-committee, I chaired its meetings, at which all applications for ethical approval were considered and discussed. After this meeting, the Secretary of the Sub-

committee contacted the applicants to inform them of the decision of the Sub-committee. My recollection is that there were several possible outcomes of this discussion:

- The proposed research study was granted approval without amendment.
- It was requested that amendments should be made to the study protocol (these were often amendments to the 'Patient Information Sheet' or Consent Form) before approval could be granted. If the applicant made such amendments timeously and completely, the amended documents were often sent to the Chair for approval, without the need for the study to be discussed again at a meeting of the full Sub-committee.
- If necessary, the applicant was asked to attend the next meeting of the Sub-committee to explain certain aspects of the proposed study to its members.
- The proposed research study was rejected as being unethical.

9. In addition to my regular chairing of the meetings of the Sub-committee, I was frequently contacted by the Sub-committee Secretary or applicants who were seeking clarification of the Sub-committee's decisions or other "Chairman's actions".

d) What training and/or experience did you have in ethics prior to taking up the role?

10. I do not recall any specific training being offered to me prior to joining the Research Ethics Sob-committee. From memory, I was a member of the Sub-committee for some time (perhaps two years; I cannot recall exactly) before I became its Chair.

e) The ethical principles that guided the committee's decision making on applications.

11. In the absence of a detailed knowledge of the context of the proposed research study (previous published work on the subject, etc), the Sub-committee members were often in a position of having to accept the applicant's assurance that the proposed study would be worthwhile. The Committee (and especially its lay representatives) saw itself as the patients' advocate, keen to ensure that patients were exposed to neither unnecessary risk nor discomfort; that the purpose and exact nature of the study was explained to patients in a way that they could understand; that patients were given adequate time and opportunity to ask questions; and that patients were asked to consent to every aspect of the study that involved them – if necessary, the consent form could have multiple parts, each requiring a signature, so that patients could consent to involvement in some parts of the research study, but not others.

f) Which organisations could apply to the Committee for ethical approval.

12. See para 6.

g) How frequently the committee met.

13. The Sub-committee met between four and eight times per year (i.e. approximately every two months).

h) What the usual process for making applications was, and the usual process for determining such applications.

14. See paras. 6, 8, and 9.

Section 3: Notification Exercises

The Inquiry has heard evidence of the experiences of a number of infected and affected individuals who were notified of their 'at risk' status of vCJD. The Inquiry seeks to gain an understanding of the rationale behind policy decisions made in relation to notifying at risk individuals and how this changed over time.

6. The Inquiry understands that the Medicine/Clinical Oncology Research Ethics Sub-committee at NHS Lothian received an application from the National Creutzfeldt-Jakob Disease Surveillance Unit in Edinburgh in 1997 for approval of a Look back study involving the examination of CJD Surveillance Register and National Blood Transfusion Service records to establish whether (i) anyone suffering from CJD had ever given a blood donation, and if so whether the recipient of that donation had contracted CJD and (ii) whether anyone with CJD had received a blood transfusion and if so whether any of the donors were known to have CJD. As to this:

a) Were you a member of the ethics committee when this application was made?

15. I cannot remember whether or not I was a member of the Medicine/Clinical Oncology Research Ethics Sub-committee when the application was received in 1996/1997. Incidentally, there is a discrepancy between the information given to me in the Inquiry's request for a written statement and production of documents, in which it is stated that the application was received in 1997, and Professor Will's letter to Dr K Palmer (subsequently forwarded to me), dated 22 November 1999 [WITN7006002], in which it is stated that Ethical Committee approval had been received in 1996. I do not have any records from this time: I have contacted the Manager of the South East Scotland Research Ethics Committees, who has been able to confirm only that I became the Chair of the Sub-committee on or before 25 February 1999; I have been given no information

as to when I became a member of the Sub-committee. I am told that the organisation's electronic records go back only as far as 1999, but that NHS Lothian archives may have records from further back. I have been informed that, if the inquiry wishes to access these archives, it would need to contact Helen Newbery (Scientific Officer, NHS Lothian: Helen.Newbery@ GRO-C) and Heather Charles (Head of Research Governance, NHS Lothian: Heather.Charles@ GRO-C).

b) If so, what was the basis upon which ethical approval was given for this study? In particular, why was the decision not to inform any of the recipients of blood from patients infected with CJD, that they were at risk of developing CJD, given ethical approval?

16. As my answer to a. suggests, I do not know the basis upon which ethical approval was given for the study.

c) If not, do you have any knowledge of why ethical approval was given for the study and in particular the decision not to inform any of the recipients of blood from patients infected with CJD, that they were at risk of developing CJD.

17. See my answer to b.

7. The Inquiry understands that a further application for ethical approval for a further look back exercise was brought by the National Creutzfeldt-Jakob Disease Surveillance Unit in Edinburgh in 1999/2000, by which time you were chair of the Ethics Committee. As to this application:

a) Who was sitting on the committee at this time?

18. I have no information of the composition of the Medicine/Clinical Oncology Research Ethics Sub-committee in 1999-2000. I have been informed that this information may be made available to the Inquiry, but that the inquiry would need to contact Helen Newbery and Heather Charles, NHS Lothian – see 6a.

b) Were decisions made jointly by the committee (and if so how), or could they be made by you alone, as the Chairman?

19. Every new application for ethical approval was considered by the committee, with several different outcomes possible – see 5c. Amendments to the study protocol that had been requested by the Sub-Committee were usually approved by the Chair alone, although on occasions, I recall the study being discussed by the entire Sub-committee again, before a final decision was made. As Chair, I was sometimes contacted directly by members of a Research Team, to discuss an amendment to the study (for instance, an extension to the length of the study; or an unforeseen problem that had arisen) – in that instance, a decision could be made by me alone as the Chair.

c) The Inquiry understands that initially you refused ethical approval for the study. Please explain why. You may find NHBT0004364_004 to be of assistance.

20. It is incorrect to state that "a further application for ethical approval for a further look back exercise" was brought by the National Creutzfeldt-Jakob Disease Surveillance Unit in Edinburgh in 1999/2000. In fact, Professor Will's letter to Dr Palmer, subsequently forwarded to me and referred to above

(6a) [WITN7006002] stated that the already approved study was "ongoing" – he asked whether or not he should apply for "renewal of Ethical Approval" for this study or whether this (renewal of Ethical Approval) could "be carried out with chairman's action". However, he also described he and his team as being "in a dilemma", as the study protocol (which stated that recipients of blood donated from individuals who subsequently developed CJD or vCJD would not be notified) was now at odds with a procedure proposed by Dr P Hewitt (Lead Consultant in Transfusion Microbiology, National Blood Service), following a recommendation from MSBT (Microbiological Safety of Blood and Tissues), discussed at a meeting held at the Department of Health in early-October 1999, between the NBA (National Blood Authority – now closed) and the Department, along with their respective legal advisers. The proposed procedure was described in a letter from Dr Hewitt to Professor Will, dated 12th October 1999 [WITN7006003], a copy of which had been sent to Dr Palmer (forwarded to me) in November 1999. It had been agreed that an individual presenting as a blood donor, who was known to have received blood from a donor who later developed vCJD, should be contacted to be informed, at a face-to-face interview, that the donated blood could not be used and the reason for that decision. A letter from Professor Len Doyal (Professor of Medical Ethics, St Bartholomew's and the Royal London School of Medicine and Dentistry) to Dr Hewitt, dated 20th December 1999 (shown to me by Professor Will) [WITN7006004], stated that it would be "immoral and illegal" to act otherwise, despite his assertion that his understanding at that time was that there was "very little sound evidence that vCJD can be transmitted by blood".

21. Professor Will and I discussed this dilemma: my letter to him dated 30 January 2000 suggests that we were both uncertain as to whether it was ethically appropriate to tell someone that, during receipt of a blood transfusion, they may have been donated a virus, which might or might not be responsible for causing a lethal disease after an uncertain and undeterminable time interval. Notwithstanding my personal reservations, however, I concluded that a proposed National Policy, agreed by the Department of Health, should be adhered to. That is the reason that I refused ethical approval for continuation of a study, the protocol of which stated specifically that the investigators would not notify recipients of blood donated by individuals who subsequently developed CJD or vCJD.

d) The Inquiry further understands that you subsequently granted ethical approval of the study. Please explain why. You may find NCRU0000112_068 and NCRU0000112_069 to be of assistance.

22. Professor Will requested a discussion with me in May 2000 and we subsequently corresponded with each other (letters dated 23rd May 2000 and 31st May 2000 respectively). In his letter, Professor Will reiterated that "there is no evidence that CJD has been transmitted through blood or blood products" and that the "risk remains theoretical". He states that he enclosed a letter, dated 6th February 1998, from Dr G Winyard, Director of Health Services for the NHS Executive, although I have been unable to procure a copy of this letter, even from the staff of the National Creutzfeldt-Jakob Disease Surveillance Unit. Professor Will's view was that this letter stated the opposite ethical view to that expressed by Professor Doyal (7c), namely that informing patients that they had received blood donated by someone who subsequently developed vCJD

might cause unjustified worry and create "a permanent blight on their lives, for example to obtaining life or health insurance".

23. Professor Will stated that it was his view, and that of representatives of the Department of Health and the NBA, that it would be unethical not to continue the lookback study, as this might be the only mechanism by which transmission of vCJD through blood or blood products could be identified. He gave two further re-assurances:
    - That if any change in the ability to diagnose vCJD in its incubation period or any intervention became available, the ethical position regarding notification of recipients would be reconsidered immediately.
    - That the Department of Health was proposing the setting up of an "Expert Group on the Management of CJD Incidents"; amongst other things, this group would consider incidents, including blood donors who had previously received blood from individuals who had subsequently developed CJD/vCJD, on a case by case basis. This was described in a letter from Dr Mike McGovern (Health Services Directorate) to Dr Robinson (Medical Director, National Blood Authority) dated 12 January 2000 [WITN7006005], made available to me by Professor Will. It was Professor Will's view that these policy decisions were "quite separate from the ethical issues relating to the lookback study itself"

24. Faced with the lack of credible evidence that CJD/vCJD has actually been transmitted via infected blood or blood products, coupled with the reassurances detailed above, I decided to reinstate ethical approval for the lookback study.

8. What if any steps did the Ethics Committee take to ensure that patients identified as being at risk of CJD through the look back programme were appropriately notified by The Expert Group on the Management of CJD Incidents?

25. I am not aware of any steps taken by the Medicine/Clinical Oncology Research Ethics Sub-committee to ensure that patients identified as being at risk of CJD through the look back programme were notified to the Expert Group on the Management of CJD Incidents.

Statement of Truth

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

Signed GRO-C Ian Richard Starkey

Dated 10 February 2022

Exhibits referred to in my statement (electronic copies attached)

URN	Description	Date
WITN7006002	Letter from Professor Will to Dr K Palmer, relating to renewal of ethical approval for the lookback study	22/11/1999
WITN7006003	Letter from Dr P Hewitt to Professor Will regarding recipients of blood donations from individuals who themselves later develop vCJD	12/10/1999
WITN7006004	Letter from Professor Len Doyal to Dr Hewitt regarding the ethics of telling/not telling recipients or donors who are linked to vCJD	20/12/1999
WITN7006005	Letter from Dr M McGovern to Dr E Robinson regarding the setting up of the "Expert Group on the Management of CJD Incidents"	12/01/2000