

Witness Name: Sandra

Elizabeth Carman

Statement No.: WITN3425013

Exhibits: WITN3425014 - WITN3425030

Dated: 23 October 2020

INFECTED BLOOD INQUIRY

FIFTH WRITTEN STATEMENT OF SANDRA ELIZABETH CARMAN ON BEHALF OF SHEFFIELD TEACHING HOSPITALS NHS FOUNDATION TRUST

I provide this statement in response to a request for the production of documents and information under Rule 9(1), 9(2) and 9(4) of the Inquiry Rules 2006, in relation to the Trust as a whole, dated 21 August 2019.

I, Sandra Elizabeth Carman, will say as follows: -

Introduction

1. My name is Sandra Elizabeth Carman and my professional address is Sheffield Teaching Hospitals NHS Foundation Trust, 8 Beech Hill Road, Sheffield, S10 2SB. My date of birth is GRO-C 1969 and my professional qualifications are: BSc in Occupational Therapy, MSc Healthcare Practice, IoD Diploma in Company Direction, Diploma in Human Resource Management, Nye Bevan Executive Healthcare Leadership Award.

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2. My current role at Sheffield Teaching Hospitals NHS Foundation Trust is that of Assistant Chief Executive. My responsibilities include Corporate Governance and incorporate the role of Trust Secretary for the organisation.

Request for the production of documents and information under Rule 9(2) of the Inquiry Rules 2006, in relation to the Trust as a whole, dated 21 August 2019:

Documents and information connected to the Trust's Haematology and Infectious Diseases and Tropical Medicines Department.

3. Following the 21 August 2019 request our response to the request provided a summary of the August 2018 searches of the Trust's Haematology and Infectious Diseases and Tropical Medicines Department.
4. Following discussions with the Inquiry team this search was broadened to the whole organisation on the 14 February 2020. All Clinical Directorates were requested to undertake a physical search of all documentation such as notes, briefings, reviews, minutes of meetings etc. that they hold, compared against the search terms list provided **WITN3425014** – Search Terms List provided by the Inquiry January 2020).
5. The results of this search have been collated and prepared for submission to the Inquiry.
6. Physical documentation returned by the Clinical Directorates has being collated and detailed in **WITN3425015** – Collation of Clinical Directorate returns February 2020.
7. In addition **WITN3425015** includes a summary of any electronic materials that were deemed relevant to the inquiry by the Clinical Directorates.
8. All of the above documentation can be provided to the Inquiry.

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9. Typically the Board of Directors meets monthly. Sheffield Teaching Hospitals NHS Foundation Trust and predecessor organisations have electronic board papers dated from 1997 and the earliest paper copies archived from 1991, all available documents have now been scanned and are detailed in the schedule provided at [WITN3425016](#) – Collation of Board of Directors documentation.

10. All of the above documentation can be provided to the Inquiry.

All documents and information pertaining to all clinical trials and research conducted by the Trust

11. The earlier response was interpreted as relating to only those documents held in the Trust's Haematology and Infectious Diseases and Tropical Medicines Departments. A schedule is provided of all research studies recorded by the Sheffield Teaching Hospitals NHS Foundation Trust Clinical Research and Innovation Office that align with the search terms detailed in [WITN3425014](#) and is included at [WITN3425017](#) – Collation of Research Studies. The studies that are highlighted in blue are those that began/ended before national and local research governance requirements were implemented and as such were not authorised (have an authorisation date) by the Research Office.

12. Following a further request from the Infected Blood Inquiry team additional information was sought on 18 studies deemed relevant to the Inquiry (listed in [WITN3425030](#)).

13. These Research and Development files included study documentation approved by the Ethics Committee and any other applicable regulatory body, contracts, local approvals, Investigator Site Files (ISF): study documentation including patient data/information.

14. For all the studies listed in [WITN3425030](#) except for numbers 16 and 17, the Trust held minimal information as these studies were pre research governance, before the

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Research and Development Office was put in place and national requirements implemented. The Trust also considered whether the Investigators are still employed by the Trust, whom would be expected to retain the Investigator Site Files. No further information has been sourced. But in line with Good Clinical Practice 2006, which specify documents are retained for a minimum of five years after the study has ended (dependent on the nature of the study) the documents have now been destroyed.

15. For studies 16 and 17 the Trust held Research and Development Files. For studies 2, 7, 16 and 17 the Trust was able to facilitate provision of the ISF including patient data/information.

16. All information is held in paper version.

A list of all the archives/places of deposit at which the Trust has deposited or stored documents and information.

A schedule of all documents and information on the Infection Control Accreditation Database and on the Infectious Diseases Archived Records that may be relevant to our Terms of Reference.

17. A search has been undertaken of the information contained in the Infection Control Accreditation Database and no information matches the search terms list provided in January 2020: WITN3425014.

18. Infectious Diseases Archived Records have been searched as a result of the original requests made in August 2018 and subsequent searches using the search terms list presented. Information sourced is detailed in the schedules outlined in this statement and previously provided.

A schedule of all document and information held by the Trust.

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19. The Trust has undertaken an electronic search of all pre 2000 electronic departmental folders and personal folders using the Inquiry's search term list (WITN3425014) the results of which are provided in the schedules listed below.

- (WITN3425018) – Schedule of pre 2000 departmental electronic folders
- (WITN3425019) – Schedule of pre 2000 personal electronic folders

20. All of the above documentation can be provided to the Inquiry.

Request for a written statement and the production of documents and information under Rule 9(1), 9(2) and 9(4) of the Inquiry Rules 2006, in relation to the Trust as a whole, dated 21 August 2019:

Please provide an account of the Trust's archiving system such as the process of transferring data/material to an archive.

21. A complete account of the Trust's archiving system for clinical records, (whether considered relevant to the Inquiry's Terms of Reference or not) is included at (WITN3425020) – Complete Account of the Trust's Archiving System.

22. An Electronic Document Management System (EDMS) is used as the current archiving system for Sheffield Teaching Hospital's clinical records and is also used by three areas within the Trust as part of the patient record. EDMS holds all documentation which would be filed within the clinical paper record and then scanned into the system. EDMS holds scanned patient case notes only. This comprises of:

- Emergency Department attendance cards
- Archiving process for case notes includes the following information:-
 - Do not attempt cardiopulmonary resuscitation (DNACPR) record

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- Case note front sheet
- Inter-Professional problem sheet (PD5630)
- Advance directive (living will) as appropriate
- Clinical Record
- Clinical Patient related Correspondence
- Investigations
- Anaesthetics
- Drug Records
- Other charts and forms
- Nursing records
- Loose documentation for patients that do not have a case note folder

23. For the three areas that use EDMS as part of the patient record (Hand Centre, Spinal Injuries and Infectious Diseases) all documentation relating to current inpatient and outpatient activity on discharge is scanned into EDMS.

24. *DocuShare* is a previous archive system used by Sheffield Teaching Hospitals where archived case notes and culled information were scanned and stored. This includes all medical documentation relating to inpatient and outpatient activity, correspondence, investigations, anaesthetic documents, drug cards and all nursing documents.

A list of all the Trust's repositories, including those storing documents and information in hard copy, electronic format, and any other form (whether the documents and information stored within the repositories are considered relevant to the Inquiry's Terms of Reference or not), together with an indication of the quantity of documents and information stored at each facility.

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25. Sheffield Teaching Hospitals NHS Foundation Trust uses a wide range of systems which contain patient information both in paper and electronic formats. The Trust has the following Medical Records libraries:

Library	Quantity as of 1 July 2020	Notes in EDMS (archive) 1 July 2020
RHH Main Library	168,588	557,420
NGH Main Library	62,438	347,808
Orthopaedic Library (NGH)	18,144	121,764
Spinal Injuries Unit (EDMS)		21,795
Renal Unit	8,742	25,723
Cardiology Library (NGH)	30,366	
Plastics/Hand Centre (EDMS)		115,354
Infectious Diseases (EDMS)		40,931
Weston Park Cancer Centre	53,520	58,694
Charles Clifford Dental Services	61,716	53,905
Neurosurgery (RHH)	13,556	15,596
Stereotactic Radiosurgery (RHH)	9,205	6,324
Secondary Storage (NGH)	125,940	

26. Clinical Records are also held in the Haemophilia Centre as they hold notes of patients with bleeding disorders both current and historic.

27. The Trust has a number of electronic systems, which hold patient data, much of this information will not be relevant to the Inquiry's Terms of Reference. The list of systems is included at [WITN3425021](#) – Electronic Systems that hold patient data.

28. All of the documentation referenced (patient and non-patient related) are held in hard copy or electronic format. The hard copy documents are kept in the libraries detailed in [WITN3425020](#) - Complete account of the Trust's archiving system, and the

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electronic documents are stored in the systems detailed in WITN3425021 – Electronic systems that hold patient data.

29. Electronic documents held on the Trust Electronic Document Management System (EDMS) are scanned and stored using rigorous quality assurance processes. This work follows a standard operating procedure and the outcomes are reported to the Information Governance Committee. Once scanned onto the EDMS system hard copies are not retained and are destroyed in line with the Trust policy.

30. Given the nature of the information stored on the EDMS system there may be clinical records stored that could be potentially relevant to the Inquiry's Terms of Reference. These have not been searched as the review of clinical records is outside the scope of the Inquiry request at this time.

31. We have no records of any of the documents referred to in this statement being shared with any organisations (for example, UKHDO and /or NHS Digital).

An account of the process for archiving the Trust's documents and information at The National Archives and all other places of deposit. To include, but not limited to, the following information: the criteria for the transfer of Trust documents and information to an archive or place of deposit; whether original documents are transferred and if so whether the Trust retains copies; whether as part of the archiving process hard copy material is transferred to electronic format and if so whether the hard copy material is retained.

32. The Trust holds no paper records of any information submitted to the National Archives.

33. However it has come to light (letter received 31 October 2019 by Sandi Carman, Assistant Chief Executive from Sheffield City Archives) that historically the Trust has submitted documents to the Sheffield City Archives. Following a visit to the Sheffield

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City Archives on the 28 February 2020 it is considered that some of these documents may be relevant to the Inquiry.

34. A number of requests for access to material held at Sheffield City Archives, has already been made directly by the Inquiry team namely:

- Sheffield Regional Hospital Board, 1936-1986 (NHS27)
- Sheffield No 3 Hospital Management Committee, 1916-1974 (NHS37)
- Trent Regional Health Authority, 1938-1996 (NHS 32)
- Sheffield Area Health Authority (Teaching), 1957-1983 (NHS31)

35. It is understood from the Sheffield City Archives Team that Infected Blood Inquiry Team members have already visited and reviewed a significant amount of the documentation stored.

36. The Senior Archivist from the Sheffield City Archives reports that the Department of Health (DoH) now has ownership of the information contained in these records so liaison has taken place between the Inquiry solicitor and the DoH to gain permission to access restricted files.

A list and summary of all organisations and agencies that processed information (together with current contact details which may be provided separately) for which the Trust had or has any control, responsibility.

37. All documents and records from legacy organisations are covered in the summary of archives above. It is understood that this also includes Lodge Moor Hospital documentation and that all records transferred with the speciality and followed archive processes. To assist the Inquiry a Sheffield City Council document entitled Sheffield Hospitals has been attached as WITN3425022 - Sheffield Hospitals.

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A detailed account of the searches undertaken in response to the Inquiry's Rule 9(2) request dated 15 August 2018. This must include the search terms used, repositories checked and documents uncovered (whether considered relevant to the Inquiry's Terms of Reference or not).

38. Clerical and clinical staff carried out an extensive physical search of all rooms within the Haemophilia Centre at Royal Hallamshire Hospital, as well as the Anti-Coagulation Clinic, also Royal Hallamshire Hospital. In line with the request this search did not include review of clinical records (case notes).

39. Archiving systems that the Trust uses to store documents are detailed in WITN3425020 – Complete Account of the Trust's Archiving System. In response to the Inquiry's Rule 9(2) request of August 2018 physical searches were carried out as detailed in the paragraph above. Any EDMS scanned clinical records that related to Haematology which had not been destroyed were requested to be retained and the originals are in storage (one box). These are clinical records (case notes) and therefore not within the original scope of the request, but are available should they be required.

40. Documentation sourced at the time was provided in response to the request received from the Solicitor to the Inquiry dated 15 August 2018. Reference was made to the contents of this request letter to inform the search. This letter did not include a list of search terms.

41. The documents provided to the Inquiry as a result of the August 2018 searches and provided in 2019 were miscellaneous documents that included some internal meeting notes, some national and international meeting/ conference notes, and research papers. Presentations by nurse specialists. Lists of monitoring blood tests for HTLV3/ HIV/Hepatitis C. Counselling notes by haemophilia nurse specialist. Patient information leaflets. Letters regarding funding of services, electronic copies

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of the 'bibles' (books that document and concentrate administered from the Haemophilia Centre) and copies of the home treatment cards.

An account of all the Trust's retention and destruction policies, both past and present, together with an account of any material known to have been destroyed with potential relevance to the Inquiry's Terms of Reference and/or List of Issues. Please also provide copies of all destruction policies, past and present, as exhibits to the written statement.

42. All destruction of paper records have been managed by the Retention schedule which forms part of Records Management NHS Code of Practice. Destruction of archive clinical records took place in 2018 for Northern General Hospital case notes which were held in off-site storage and we have a full audit of those which were destroyed and those that were then sent to EDMS for scanning.

43. At the request of the Inquiry the schedule of the documents destroyed from 30 June 2017 and completed on 20 June 2018 for the Northern General Hospital case notes have been provided at WITN3425023 – Schedules of documents destroyed (1-40).

44. In response to further questions from the Inquiry team the following information is provided.

- The tab named N06LMISC on the attached is blank as we did not have any boxes in storage that related to this particular code. This was a standard template that was used and the off-site location log was referenced for confirmation.
- Some of the files are not destroyed and are returned this is because each box which was held off-site was audited against specific criteria e.g. dates of birth within the retention period, held maternity records are examples. These notes that did not meet the disposal criteria were returned to us from off-site and scanned into EDMS.

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- On the Exhibit there are some yellow and red colour coding (shading) on the documents. Those highlighted in yellow had either previously been returned to site on request or additional records held in the box being audited. This provided the Trust with additional assurance that the off-site storage team audited each box.
- With regards to the one box that we retrieved from disposal the Inquiry asked if the only include clinical patient information (i.e. not minutes of meetings or other documents). To confirm this box only includes patient case note folders retrieved from the off-site scanning company.

45. As covered in paragraph 39 on receipt of the Inquiry letter in August 2018 any Clinical Records not yet physically destroyed following scanning and that related to Haematology were recalled and are now securely stored. This relates to one box of records.

46. Royal Hallamshire Hospital had an onsite scanning bureau which scanned archived records after four years from the last activity. Scanning started at Royal Hallamshire in the early 1990's and these records can still be accessed via our *DocuShare* system on request.

47. Authority was given by the Medical Director in 2013 to destroy all Microfilms held within Medical Records. Evidence of this authorisation is included at WITN3425024 – Email authorising destruction. This action was in line with the Trust's Medical Records Management Policy.

Record	Date range of destroyed Microfilms
Northern General	1980's to 1984
Royal Hallamshire	1960's to early 1980's
Neurosurgery	1980's
Jessops	1970's to 1992

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48. See following appendices for Trust Policies relating to this:

- **WITN3425025** – Retention Schedule
- **WITN3425026** – Records Management Code of Practice for Health and Social Care 2016
- **WITN3425027** – Records Management Policy (v. 1)
- **WITN3425028** – Records Management Policy (v. 2)

49. With regard to the 'compost' elements of current health care records, our apologies, this is a typographical error. This should read 'composite' elements of current health records. The original email which identifies when the error occurred is included at **WITN3425029** – Email clarification (composite).

Statement of Truth

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

GRO-C

Signed _____

Dated 23 October 2020

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Table of exhibits:

Date	Notes/ Description	Exhibit number	Exhibit Inquiry Reference
	Search Terms List provided by the Inquiry January 2020	EXHIBIT A	WITN3425014
	Collation of Clinical Directorate returns February 2020	EXHIBIT B	WITN3425015
	Collation of Board of Directors documentation	EXHIBIT C	WITN3425016
	Collation of Research Studies	EXHIBIT D	WITN3425017
	Schedule of pre 2000 departmental electronic folders	EXHIBIT E	WITN3425018
	Schedule of pre 2000 personal electronic folder	EXHIBIT F	WITN3425019
	Complete account of the Trust's archiving system	EXHIBIT G	WITN3425020
	Electronic Systems that hold patient data	EXHIBIT H	WITN3425021
	Sheffield Hospitals	EXHIBIT I	WITN3425022
	Schedules of documents destroyed (1-40)	EXHIBIT J	WITN3425023
	Email to authorise destruction	EXHIBIT K	WITN3425024
	Retention Schedule	EXHIBIT L	WITN3425025
	Records Management Code of Practice for Health and Social Care 2016	EXHIBIT M	WITN3425026
	Records Management Policy v.1	EXHIBIT N	WITN3425027
	Records Management Policy v.2	EXHIBIT O	WITN3425028
	Email clarification (composite)	EXHIBIT P	WITN3425029
	Study File Data on Collation of Research Studies, annex to Exhibit D	EXHIBIT Q	WITN3425030

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