CELLULAR PATHOLOGY RECORDS AND SPECIMENS RETENTION, STORAGE AND DISPOSAL POLICY

POLICY

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Approving Body	Histopathology Clinical Governance Committee
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Target Audience	Staff who work in the Department of Cellular Pathology
Review Date	August 2022
Sponsor (Position)	Medical Director
Author (Position & Name)	Consultant Histopathologist and Head of Service for Cellular Pathology: Dr Shafiq Gill
Lead Division/ Directorate	Diagnostics and Outpatients
Lead Specialty/ Service/ Department	Cellular Pathology
Position of Person able to provide Further Guidance/Information	Cellular Pathology Manager

Associated Documents/ Information	**Date Associated Documents/ Information was reviewed**
Not Applicable	Not Applicable

CONTENTS

1.0 INTRODUCTION

This document has been produced to take account of modifications in practice required to comply with Human Tissue Act 2004 and to update our current practice in accordance with most recent RCPath and IBMS guidelines on retention and storage of pathological records and specimens. Most of the guidelines used in this document have been taken from RCpath Publication "The retention and storage of pathological records and specimens (4th edition, 2009)"

In most cases, records and archived specimens are held primarily to benefit the medical care of the patient concerned, as part of that patient's medical record. Under the Human Tissue Act 2004, consent is not needed for retention and use of tissue from living individuals for this purpose. However, consent from a relative (or other appropriate third party) or the authorisation of a Coroner is required for retention of all tissue obtained at post-mortem examination. In relation to data protection law, it is reasonable to infer that the information held in pathological records was generated legitimately in the first instance and that patients are aware of its continued existence within the confidential archives of the hospital. Indeed, patients would have legitimate grounds for complaint if their future healthcare was compromised because technical details of their previous investigations had been erased without their knowledge. We can therefore assume that pathologists have legitimate authority to retain records and archives for the benefit of individual patients, relying only on the consent that was a clinical requirement for their original generation.

This policy is issued and maintained by the Executive Medical Director (the sponsor) on behalf of the trust, at the issue defined on the front sheet, which supersedes and replaces all previous versions.

2.0 POLICY STATEMENT

This policy outlines the procedure to be followed when making decisions about retention, storage and disposal of cellular pathology records and specimens.

This policy applies to:

Staff group(s)

- Staff who work in the department of Cellular Pathology

Clinical area(s)

- Department of Cellular Pathology

3.0 DEFINITIONS/ ABBREVIATIONS

Trust:	Sherwood Forest Hospitals NHS Foundation Trust
RCPath:	Royal College of Pathologists
IBMS:	Institute of Biomedical Sciences
HTA:	Human Tissue Authority

4.0 ROLES AND RESPONSIBILITIES

HTA Designated Individual is responsible for:

- providing direction and guidance regarding storage, retention, and disposal of records and specimens

Cellular Pathology Head of Service and Medical consultants are responsible for:

- supporting the HTA Designated Individual and cellular pathology laboratory staff in implementation of this policy document

Cellular Pathology Laboratory Manager is responsible for:

- ensuring that records and tissues are stored in accordance with this policy document
- ensuring that records and tissues are disposed of in accordance with this policy document
- ensuring that chain of custody is not broken when material is referred between hospitals
- ensure that systems are regularly audited and audit findings are discussed in regular departmental meetings.

Pathology Service Manager &Service Director are responsible for:

- supporting the cellular pathology department in ensuring that adequate facilities are maintained for storage, retention and disposal of records and tissues as per this policy document

5.0 APPROVAL

Cellular Pathology Clinical Governance Group

Trust HTA Management Group

Pathology Clinical Governance Group

6.0 DOCUMENT REQUIREMENTS (NARRATIVE)

The scope and nature of pathology records

Clinical and diagnostic records and reports

These are hard copy or electronic records of the results of pathological investigation(s) sent or made available to the requesting clinicians, with the expectation that they will be stored within the patient's individual clinical record. With respect to computer-generated, electronic records, the same criteria that cover conventional records apply, unless they have been converted to hard copy records and preserved as such.

Electronic records now take many forms and are used for a wide variety of purposes. Mostly, these parallel the functions of paper records so that retention times can be deduced from those suggested for equivalent physical records. However, their ease of access and dissemination necessitates even more stringent security arrangements such as encryption and password protection. They also carry different risks of corruption or loss than do hard-

copy records and arrangements for regular, accurate back-up are essential. The speed of change in IT provision for health services makes it essential to ensure that such records remain accessible for the full period of their retention and possible use. Laboratory professionals should ensure that electronic record-keeping and transfer are encompassed by, and compliant with, their organisations' overall IT security policies, including the safe-keeping and regular updating of passwords and encryption keys.

Laboratory working records: reports and documentation for internal use

These include:

- request forms
- protocols of procedures
- day books
- worksheets
- batch records (of reagent batches linked to series of specimens; also specimens analysed as cohorts on automated instruments)
- graphic output from instruments
- photographic records
- catalogues of the pathological archive or museum
- bound copies of reports and records
- correspondence
- records of telephoned, faxed and e-mailed reports
- equipment maintenance logs
- quality control and quality assurance records
- standard operating procedures
- accreditation documents
- records of inspections

Where these items are held in electronic form, often as digital image files, the same criteria that cover conventional records apply. However, extra care is needed to ensure data security and prevent corruption or deterioration of data. Suitable back-up systems should be employed and, as equipment becomes obsolete, re-recording or the production of durable hard copy may become necessary to maintain access.

Use of a robust document management system is recommended, capable of providing a secure repository for paper and electronic records with tracking of updates for procedural documents such as standard operating procedures.

Specimens

These include:

- stored human biological specimens such as blood, serum, urine, faeces, cells and tissue (including part or whole body organs)
- tissue blocks
- wet preparations including fixed tissue samples of any size
- stained slides or other permanent or semi-permanent preparations
- museum specimens

When the term "tissue" is used in this document, it is used broadly in parallel with the definition of "relevant material" in the Human Tissue Act 2004, i.e. material that consists of or includes human cells. However, this document is not limited to such material, as it includes reference to human biological material that is regarded by the Human Tissue Authority as

acellular (such as serum and plasma) and derived materials such as nucleic acids. In general, such material is not covered by the Human Tissue Act 2004, although there are caveats in the Human Tissue Authority's guidance regarding plasma and serum. The professional requirement to adhere to relevant ethical standards should be regarded as binding for all human tissue and derived materials. Further advice concerning the definition of relevant material within the Act can be found at:
www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm

The management of records and specimen archives: general comments

Diagnostic records are properly retained in individual patient notes or in electronic form. The safe keeping of these records is primarily the responsibility of hospital records departments or recipient general practitioners or private practitioners, once the pathologist has issued the report. The primary purpose of diagnostic records retention by laboratories is for internal use; correlation with results from previous and subsequent specimens, responding to queries from other healthcare professionals, audit and quality assurance. In addition archived materials can be used for properly approved and consented research.

The statutory role of Designated Individuals in supervising suitable practices under the authority of HTA licences is also crucial in relation to the above, as it is to all scheduled purposes licensed by the HTA. Indeed, many areas of the guidance in this document align with the HTA standards for such suitable practices. Designated Individuals can provide a valuable source of additional information regarding acceptable conditions for storage and use of human cells and tissues, from living or deceased individuals, regulated under the Act.

There are reasons why individual pathologists or heads of departments may wish to retain documents or materials for periods that are longer than the minimum times recommended here. The following reasons for retention of tissue obtained from living individuals are legally permissible without patient consent, largely because they are regarded as a necessary part of the process of providing healthcare:

- Further diagnosis, or ongoing clinical management.
- Clinical audit.
- Quality control.
- Teaching and training healthcare staff.
- Epidemiology.
- Analysis of data (such as case mix) for administrative or other purposes.
- Direct evidence in litigation.
- Individual, active research studies for which data or samples are suitably anonymised and current approval is in place for the purpose, given by a recognised Research Ethics Committee (REC).

Where specimens or permanent or semi-permanent preparations are kept, they should be adequately labelled, indexed and catalogued, so that the record remains accessible, usable and under professional control and guidance.

A-Documents, electronic and Paper Records

A1-Request Forms

- Request forms should be kept for 30 years
- Consideration should be given to scan request forms by using scanning equipment (as is the current practice in most departments). These forms can then be disposed of after 3months

A2-Daily Work logs (day book and electronic equivalents) and other records of specimens received by the laboratory
As these are the only available patient/tissue record, they must be stored as long as the wax blocks are stored i.e. 30 years. Items older than 30 years should be disposed of.

A3-Mortuary registers
Mortuary registers should be kept for 30 years and should be stored in the secure Mortuary Storeroom.

A4-Protocols of standard operating procedures
Both current and outdated protocols should be dated and kept in a catalogued, accessible format for at least 30 years. Use of a document management system capable of administering records in electronic and paper formats is strongly recommended, with maintained access to the legacy of previous versions.

A5-Records of telephoned or faxed reports
Retain for 30 years

A6-Reports and copies (physical or electronic)
Six months or as needed for operational purposes. Where copies represent a means of communication or aide memoire, for example at a multidisciplinary team meeting or case conference, they may be disposed of when that function is complete. Copies of reports sent by fax, with accompanying details of the date and time of transmission, and the intended recipient, should be retained in conjunction with the matching specimen reports stored long-term by the laboratory. Any such copies generated to substitute for an original report (e.g. if an original is misplaced) should be retained as for the original.

A7-Surgical (histological) reports
Electronic or hard copy to be kept for at least 30 years by the laboratory, with maintained accessibility of e-copies when laboratory computer systems are upgraded or replaced.

A8-Post-mortem reports
The report should be lodged in patient's record; in the case of Coroner's or Fiscal's reports, this is dependent on the Coroner's or Fiscal's approval. Electronic or hard copy should be kept for at least 30 years with maintained accessibility (see also RCPath document Section D). In addition to accessible indexing of paper copies, there must be continuation of access to e-copies when laboratory computer systems are upgraded or replaced. This guidance applies equally to rapid, short reports that may be prepared for the Coroner, summarising cause of death, and to the final reports of post-mortem examinations.

A9-Correspondence on patients
Retain for 30 years

Paper documents, once scanned, may be disposed of as long as security and accessibility of the derived electronic records are assured.

For issues regarding storing email correspondence please refer to RCPath document (Page 15, paragraph 44) for detailed advice.

A10-Photographic records
Where images represent a primary source of information for the diagnostic process, whether conventional photographs or digital images, they should be kept for at least 30 years. In

practice, these will represent material from which neither the primary tissue(s) nor subsequent tissue blocks, slides or cell suspensions have been stored and will include images from post-mortem examinations.

In some circumstances, images of pathological specimens may be produced as an alternative to storing the specimen itself. This should be done only where it is possible to be confident that the image contains all the diagnostic information in the original specimen, and that its storage will satisfy any possible future requirements, of a medico-legal as well as of a clinical nature. In such circumstances, the images should be stored for at least as long as is recommended for the specimens from which they are derived, with continued accessibility and assured storage conditions to avoid deterioration in quality over time.

Where images represent a means of communication or aide memoire, for example at a multidisciplinary meeting or case conference, they may be disposed of when that function is complete.

A11-Batch records
Retain for 10 years

A12-Internal quality control records
Retain for 10 years

A13-External quality assessment records
Retain for 5 years where no performance related issues have been raised

Retain for 10 years where there have been performance related issues

A14-Accreditation documents and records of inspections
Retain for 10 years, or until superseded

A15-Equipment maintenance logs
Lifetime of instrument/ equipment; plus a minimum of 4 years.

A16-Records of service inspections and instrument maintenance
Lifetime of instrument/ equipment; plus a minimum of 4 years.

B-Specimens and Preparations

B1-Frozen tissue for immediate histological assessment (frozen section)

Stained microscope slides should be kept as described below for sections from fixed specimens. Residual tissue should be processed as a normal, fixed specimen once the frozen section is complete.

B2-Paraffin Blocks
All paraffin blocks should be retained for 30 years.

B3-Wet tissue (representative portion or whole tissue or organ)
Surgical wet tissue from living patients should be kept for 4 weeks after issue of final report. After this period tissue should only be disposed of if final report has been issued. Cases in which a supplementary report is anticipated after additional tests (such as various molecular investigations or referral for expert opinion), which may occasionally exceed this period,

arrangements should exist to ensure that individual specimens are retained until the additional report has been finalised. Similarly, cases may be requested for 'keeping' by the reporting pathologists. Any further retention should be reviewed every 4 weeks.

B4-Microscopic slides
All microscopic slides should be stored for 20 years.

Disposal of human tissue
Disposal of human biological samples must be carried out in a respectful manner. Exactly what constitutes a respectful manner will vary with the specimen type. The Human Tissue Authority has issued Codes of Practice relevant to this subject, particularly Code 5; the current versions of the codes are available from the Authority's website https://www.hta.gov.uk/search?search_api_views_fulltext=codes+of+practice&sort_by=search_api_relevance&sort_by=search_api_relevance&=Apply

Disposal of liquid specimens is unlikely to cause concern as long as misuse of samples or residues is made impossible. Solid tissue samples from surgical or biopsy specimens can usually be incinerated, but the samples and the process of destruction should not be visible to the public and they should not be mixed with other forms of clinical or general waste. Disposal should be in keeping with requirements of the Environment Agency.

Where patients have indicated, within the normal time limits for retention of samples, a wish for the return of unprocessed or surplus material, such requests should be complied with. In such cases, the responsibility is on the laboratory to indicate any hazards that may be present in the returned material.

7.0 MONITORING COMPLIANCE AND EFFECTIVENESS

Cellular Pathology Laboratory manager will set up a system of regular audits to monitor compliance with this document. These audit findings will be shared at the departmental clinical governance and management meetings.

Minimum Requirement to be Monitored (WHAT – element of compliance or effectiveness within the document will be monitored)	Responsible Individual (WHO – is going to monitor this element)	Process for Monitoring e.g. Audit (HOW – will this element be monitored (method used))	Frequency of Monitoring (WHEN – will this element be monitored (frequency/ how often))	Responsible Individual or Committee/ Group for Review of Results (WHERE – Which individual/ committee or group will this be reported to, in what format (eg verbal, formal report etc) and by who)
Audit of compliance with policy	Cellular Pathology Manager	Audit of patient material and records	Annual	HTAMG; Departmental CGC meeting

8.0 TRAINING AND IMPLEMENTATION

No specific training is required for the application of this policy.

9.0 IMPACT ASSESSMENTS

- This document has been subject to an Equality Impact Assessment, see completed form at Appendix A
- This document has been subject to an Environmental Impact Assessment, see completed form at Appendix B

10.0 EVIDENCE BASE (Relevant Legislation/ National Guidance) AND RELATED SFHFT DOCUMENTS

Evidence Base:

1. The Royal College of Pathologists. The retention and storage of pathological records and specimens (5th edition, 2015). https://www.rcpath.org/search-results.html?q=retention

2. Human Tissue Authority. www.hta.gov.uk Codes of practice for consent, post-mortem examination, and removal, storage and disposal of human organs and tissue.

Related SFHFT Documents:

- Hospital Post Mortem Policy

11.0 KEYWORDS

Archive; Human Tissue Authority; HTA

12.0 APPENDICES

Appendix A – Equality Impact Assessment
Appendix B – Environment Impact Assessment

APPENDIX A – EQUALITY IMPACT ASSESSMENT FORM (EQIA)

Name of service/policy/procedure being reviewed: Cellular Pathology Records and Specimens Retention, Storage and Disposal Policy			
New or existing service/policy/procedure: Existing			
Date of Assessment: 06/06/2019			
For the service/policy/procedure and its implementation answer the questions a – c below against each characteristic (if relevant consider breaking the policy or implementation down into areas)			
Protected Characteristic	**a) Using data and supporting information, what issues, needs or barriers could the protected characteristic groups' experience? For example, are there any known health inequality or access issues to consider?**	**b) What is already in place in the policy or its implementation to address any inequalities or barriers to access including under representation at clinics, screening?**	**c) Please state any barriers that still need to be addressed and any proposed actions to eliminate inequality**
The area of policy or its implementation being assessed: Cellular Pathology			
Race and Ethnicity	None	n/a	None
Gender	None	n/a	None
Age	None	n/a	None
Religion	None	n/a	None
Disability	None	n/a	None
Sexuality	None	n/a	None
Pregnancy and Maternity	None	n/a	None
Gender Reassignment	None	n/a	None
Marriage and Civil Partnership	None	n/a	None

Socio-Economic Factors (i.e. living in a poorer neighbourhood / social deprivation)	None	n/a	None

What consultation with protected characteristic groups including patient groups have you carried out?

-

What data or information did you use in support of this EqIA?

-

As far as you are aware are there any Human Rights issues be taken into account such as arising from surveys, questionnaires, comments, concerns, complaints or compliments?

- **None**

Level of impact

From the information provided above and following EQIA guidance document Guidance on how to complete an EIA (click here), please indicate the perceived level of impact:

~~High Level of Impact/Medium Level of Impact~~/Low Level of Impact *(Delete as appropriate)*

For high or medium levels of impact, please forward a copy of this form to the HR Secretaries for inclusion at the next Diversity and Inclusivity meeting.

Name of Responsible Person undertaking this assessment: Clair Sleney

Signature:

Date: 06/06/2019

APPENDIX B – ENVIRONMENTAL IMPACT ASSESSMENT

The purpose of an environmental impact assessment is to identify the environmental impact, assess the significance of the consequences and, if required, reduce and mitigate the effect by either, a) amend the policy b) implement mitigating actions.

Area of impact	Environmental Risk/Impacts to consider	Yes/No	Action Taken (where necessary)
Waste and materials	• Is the policy encouraging using more materials/supplies? • Is the policy likely to increase the waste produced? • Does the policy fail to utilise opportunities for introduction/replacement of materials that can be recycled?	No	
Soil/Land	• Is the policy likely to promote the use of substances dangerous to the land if released? (e.g. lubricants, liquid chemicals) • Does the policy fail to consider the need to provide adequate containment for these substances? (For example bunded containers, etc.)	No	
Water	• Is the policy likely to result in an increase of water usage? (estimate quantities) • Is the policy likely to result in water being polluted? (e.g. dangerous chemicals being introduced in the water) • Does the policy fail to include a mitigating procedure? (e.g. modify procedure to prevent water from being polluted; polluted water containment for adequate disposal)	No	
Air	• Is the policy likely to result in the introduction of procedures and equipment with resulting emissions to air? (For example use of a furnaces; combustion of fuels, emission or particles to the atmosphere, etc.) • Does the policy fail to include a procedure to mitigate the effects? • Does the policy fail to require compliance with the limits of emission imposed by the relevant regulations?	No	
Energy	• Does the policy result in an increase in energy consumption levels in the Trust? (estimate quantities)	No	
Nuisances	• Would the policy result in the creation of nuisances such as noise or odour (for staff, patients, visitors, neighbours and other relevant stakeholders)?	No	