The Royal College of Pathologists
Pathology: the science behind the cure

IBMS Institute of Biomedical Science

# Best practice recommendations

# The retention and storage of pathological records and specimens

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# Foreword

Best practice recommendations (BPRs) published by the Royal College of Pathologists should assist pathologists in providing a high standard of care for patients. BPRs are systematically developed statements intended to assist the decisions and approach of practitioners and patients about appropriate actions for specific clinical circumstances. They are based on the best available evidence at the time the document was prepared. It may be necessary or even desirable to depart from the advice in the interests of specific patients and special circumstances. The clinical risk of departing from the BPR should be assessed and documented.

A formal revision cycle for all BPRs takes place every 5 years. The College will ask the authors of the BPR to consider whether or not the recommendations need to be revised. A review may be required sooner if new developments arise or changes in practice necessitate an update. A full consultation process will be undertaken if major revisions are required. If minor revisions or changes are required, a short note of the proposed changes will be placed on the College website for 2 weeks for members' attention. If members do not object to the changes, a short notice of change will be incorporated into the document and the full revised version will replace the previous version on the College website.

This BPR has been reviewed by the Professional Guidelines team. It will be placed on the College website for consultation with the membership from 31 October to 28 November. All comments received from the membership will be addressed by the authors to the satisfaction of the Clinical Director of Quality and Safety.

This BPR was developed without external funding to the writing group. The College requires the authors of BPRs to provide a list of potential conflicts of interest. These are monitored by the College's Professional Guidelines team and are available on request. The authors of this document have declared that there are no conflicts of interest.

# 1 General principles of record and specimen retention

| Record/specimen type | Recommended retention period |
|---|---|
| Primary copy of record in patient's paper or electronic medical record | 20 years from last entry, or 30 years from last entry if cancer diagnosis.<br>Retention of hospital records after death – check local Trust policy; for GP records held in primary care – 10 years after death (3 years in Scotland) |
| Records (paper or electronic) and permanent specimens, such as tissue blocks, held in the laboratory that may also be regarded as primary components of the patient's medical record | 30 years, since it is largely unfeasible to maintain parallel processes for variation for cancer/non-cancer diagnoses or have knowledge of a patient's date of death. |
| Records specifically relating to cells and tissue used for transplantation, including transfusion | Lifetime of recipient |
| Records and serum samples used for microbiological investigations in preparation for transplantation | Lifetime (recipient)<br>At least 10 years (donor) |
| Antenatal serum samples from first booking visit | 2 years |
| Serum obtained following needlestick or hazardous exposure | 2 years |
| Tissue sections and other permanent microscopy preparations including digital images used for diagnosis and replaceable from a primary specimen such as a tissue block | Minimum of 8 years<br>If from a child, until they reach the age of 25 |
| Non-permanent specimens, empty specimen containers and sampled material surplus to testing requirements | Until verification of completed report; an additional margin may be advisable, depending on specimen type and feasibility. This is particularly relevant for specimens included in multidisciplinary team (MDT) review processes and/or referred externally for additional assessment, which will require longer retention periods to ensure all such processes are complete and have been reported upon before disposal. |
| Working records (paper or electronic) relating to laboratory processes, needed for laboratory accreditation | Minimum of 1 UKAS accreditation cycle plus a margin of 1 year. This will typically be 5 years in total for a fully accredited service, extended (until full accreditation is |

| | |
|---|---|
| | achieved for the relevant service) if accreditation is not awarded or is conditional. |
| Instrument and equipment performance logs | In general, lifetime of instrument/equipment plus minimum of 4 years (i.e. lifetime plus 1 accreditation cycle).<br>15 years for blood transfusion service refrigerator and freezer temperature logs |
| Records of specimens stored with consent for research/biobanking | Lifetime of specimen in storage |
| Records of archival 'surplus' diagnostic samples released for research | 5 years from closure of study, or as determined by study sponsor(s) |
| Records of disposal (includes medical and laboratory records, equipment and specimens that are discarded) | The laboratory should maintain an auditable record of disposed items, including details of the material/items discarded, method and date of disposal, with data available for at least 5 years (1 full UKAS accreditation cycle plus a 1-year margin) |

Please refer to Appendices 1 (records) and 2 (specimens and derived preparations) for more detailed information.

# 1 Introduction

This is an update of the advice of The Royal College of Pathologists and Institute of Biomedical Science on *The retention and storage of pathological records and specimens*.

## 1.1 Key updates and additions in this edition

- Updated general guidance on retention of healthcare records distilled from the *Records Management Code of Practice 2023* – a guide to the management of health and adult care records in the NHS in England.
- Updated advice for point-of-care testing (POCT).
- Adjusted document retention times reflecting transition to ISO 15189:2022, which acknowledges the different purposes of clinical records and those kept for technical quality assurance and incorporates the POCT standard ISO 22870. This transition is well advanced at the time of publication of this update in 2024.

- Updated guidance on storing digital records; in particular, digital images used for histopathological diagnosis and laboratory information management systems (LIMS) configuration data essential for organisational resilience in case of accidental or malicious IT system failure.
- Adjusted histological tissue section retention time (new minimum recommended retention time of 8 years) to align with diagnostic digital image retention.
- Consideration of the sustainability, financial and environmental impacts of retaining and, ultimately, disposing of records (both physical and electronic) and specimens.

## 1.2 Terms of reference, history, development and legislative framework of the guidelines

The original working party for this guidance was appointed in 1994 by the Council of The Royal College of Pathologists, with the following terms of reference: “To make recommendations on minimum retention times for pathology records, tissues and semi-permanent or permanent pathological preparations, including those required for operational use, for education, teaching, training and general scholarship, for research per se, for historical purposes and against the possibility of future litigation, audit or allegations of scientific fraud and to report to Council”.

Following publication of the first version in that year, a second edition in 1999 additionally considered ethical and practical implications relevant to genetic testing, especially those services offered directly to the public, and the use of stored archives (specimens and records) in research, education, audit and quality control. In 2005 and 2009, further editions included implications of the Data Protection Act 1998, the Human Tissue Act 2004 and the Human Tissue Act (Scotland) 2006, the increasing use of electronic records and molecular diagnostic tests for acquired disease, and the requirements arising from participation in external quality assurance schemes. Transition to laboratory oversight by the United Kingdom Accreditation Service (UKAS) with accreditation against the ISO15189 standard, increasing use of POCT and genome-wide sequencing technologies, and biobanking of clinical samples for research were the major topics for updating in 2015.

In the current revision, implications of the Data Protection Act (2018), that includes the UK General Data Protection Regulation post-Brexit, and the Privacy and Electronic Communications Regulation (PECR; updated in 2019) are considered. General principles arising from Article 8 of the Human Rights Act (1998) continue to apply.

## 1.3 Contributors

The names of the coordinators and the large number of individuals who have assisted with the production of the original 1994 document and its revisions in 1999, 2005, 2009 and 2015 can be found within the text of the relevant versions. This revision builds upon their work.

Stakeholders contributing to writing the 2024 revision are:

- The Royal College of Pathologists (Dr Bridget Wilkins, Chairs and members of all of the Specialty Advisory Committees)
- Institute of Biomedical Sciences (Mr David Wells)
- Human Tissue Authority (HTA; Dr Caroline Beckett)
- UKAS (Ms Lorraine Turner)
- UK NEQAS (Mr Liam Whitby)
- other members of the Pathology Alliance (including Association of Clinical Biochemistry (ACB), British Society for Haematology, British Infection Association).

Thanks also to Dr Katie Heaney (Chief Healthcare Scientist and POCT Specialty Lead, Frimley Health NHS foundation Trust) for her specific input relating to POCT.

## 1.4 Scope and principles of the guidance

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,[1] 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), the authorisation of a Coroner (a Procurator Fiscal in Scotland) or the police (Police and Criminal Evidence Act, 1984) is required for retention of tissue obtained at post-mortem examination.[2]

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.

Individuals and organisations nonetheless have responsibility, under current data protection law, to only retain the data that is needed for ongoing patient care or justifiable wider public health concerns. Increasingly, technological advances make retaining data and preparations derived from clinical specimens more possible. As laboratory clinicians and scientists in this fast-changing environment, we need to challenge the rationale for what we keep and why; we should intelligently risk assess different specimen types and clinical contexts to inform what we actually retain. For example, long-term storage of nucleic acids, sera and microbiological isolates at ultra-low temperature (ULT), with minimal loss of analytical quality, is increasingly possible with improvements in freezing technology.

Another very relevant example is that digital imaging offers the potential to easily create permanent preparations from previously non-permanent or semi-permanent pathology samples (e.g. immunofluorescent preparations). Should we now keep all such preparations for 30 years, as permanent specimens, even though historically nothing has been kept long-term and the clinical ‘product’ is the report in a patient’s record, not the preparation that was interpreted to provide that report?

Storage and linkage of data by electronic means is also increasingly possible, influencing what clinical records and technical laboratory data we can easily retain. Obviously, where there is significant added clinical value, the case can be made for retention; but retention should never just be ‘because we can’ now that a new category of product has been created. There are also environmental and financial costs to retaining physical materials and electronic records. While financial pressures should not be primary concerns, neither should they be ignored; laboratories have a responsibility to use their NHS funding responsibly. With the advantage of being able to influence new workstreams for electronic record keeping, we also need to keep in mind the environmental impact of running highly energy-consuming electronic equipment such as ULT freezers and data storage servers.

Previous updates of this guidance have dealt in depth with altered consent and licensing requirements relating to retention specifically for purposes other than the direct benefit of the patient concerned, in response to initial implementation of the Human Tissue Act 2004[1] and the Human Tissue Act (Scotland) 2006.[3] The principles of patient autonomy and consent are fundamental to these Acts; it follows that patients ought to know what data

and samples are held. In the unlikely event of a patient insisting on the destruction or return of a sample, the pathologist should make all reasonable attempts to ensure that the patient understands the possible adverse consequences of destruction. Laboratories should have established procedures for informing patients of such consequences, and of the potential health hazards associated with handling and storing human tissue samples. However, if a patient so informed still insists on destruction or return, consent has explicitly been withdrawn and laboratories must comply with the patient's request.

The situation in Scotland relating to tissue blocks and slides is different. The Scottish legal position is that the blocks and slides become the property of the hospital, on the basis that they form part of the individual's medical record.

It must be emphasised that this document is concerned with the retention and storage of pathological records and archived specimens, not their use.

Detailed guidance regarding the physical conditions (including security) of storage are also not within the remit of this guidance, other than the general proviso that stored records and specimens should remain intact and accessible for the full term of their retention. A few points of principle are included relating to tissue storage conditions to optimise long-term specimen integrity for biobanking purposes and for future molecular genetic testing. There is also brief reference to security in relation to storage of hazardous pathogens, chemicals and radioisotopes.

This document does not cover material stored for therapeutic uses, such as transfusion or transplantation, although the retention of laboratory records concerning such activities is included.

The fact that material has been retained for the benefit of the patient does not imply that other uses are necessarily either legitimate or illegitimate. When using archives of specimens and records for any other purpose, including the benefit of other patients, pathologists must consider whether their actions are ethical and legal. In respect of research, the opinion of an appropriate research ethics committee must be sought. Further information, contacts for local committees and procedural details can be found on the Health Research Authority website (www.hra.nhs.uk), with the Integrated Research Application System accessible directly at www.myresearchproject.org.uk. In respect of data, the hospital's 'Caldicott guardian' and/or data protection officer should be able to advise. The establishment of clinical ethics committees in many UK hospitals is welcomed as a further potential source of advice. In difficult cases, it may be necessary to seek

advice from the Information Commissioner's Office (www.ico.org.uk) in respect of data, or the HTA (www.hta.gov.uk) in respect of human biological samples.

Whenever such advice is sought, the presence and nature of consent, even if implied rather than explicitly obtained consent, is likely to be important in whether the proposed use is regarded as ethical or not. It is, therefore, hoped that hospitals will implement procedures to ascertain and record the wishes of all patients in this regard. Current progress towards implementing such procedures is highly variable across the NHS and remains incomplete. It is incumbent on laboratory staff to be fully aware of the local arrangements in place in their hospitals and in other units (such as general practitioner [GP] and dental surgeries) from which specimens may be received. A requirement to re-contact patients for consent long after a clinical event is rarely practical or ethical. Consequently, if initial consent is not requested and recorded, valuable research or educational activity could be prevented.

Informed patient consent has become a requirement for some types of activity (especially the storage and use of tissue and data for many research studies), even if the work produces no risk to the patient and is intended for the benefit of all in society. Where consent procedures covering retention and storage of patients' tissue and data for future use are not yet in place, laboratory professionals have a vital role in promoting these with hospital managers. Laboratory staff are also best placed to implement tracking mechanisms to ensure retention or disposal in accordance with patients' wishes.

Finally, a potential tension between retention of archived 'surplus' diagnostic material for the patient's benefit and for other uses, such as research, is highlighted by the increased personalisation of treatment. Currently, this involves re-analysis of stored samples in a high proportion of cases, sometimes after many years of 'fallow' storage. This thoroughly justifies laboratories' traditional practices in storing such material, where possible, for long periods; its diversion into research use now needs greater consideration.

It is no longer justifiable to make over-arching assumptions that archived tissue or derived materials such as nucleic acid samples, after initial diagnosis, have completed their direct benefit for the patient. This assumption has typically been the basis of allowing their use for research or transfer to a research collection or biobank for future research use. Requirements for retrospective genetic testing will undoubtedly evolve further (i.e. decline) as more proactive testing of samples for germline mutations and predictive biomarkers is undertaken at diagnosis. However, the need to re-investigate samples upon development

of treatment resistance or emergence of new targetable treatments will remain at least until whole-genome sequences are captured for such samples, permitting reinvestigation of stored data rather than stored samples. Attention will need to be paid to the practicality of specimen retrieval and to the alternative or additional storage of unfixed specimens to avoid artefacts associated with, for example, formalin fixation and tissue processing of histological blocks.

# 2 The nature of pathology records

## 2.1 Clinical and diagnostic records and reports

These are hard-copy (paper) 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 electronic records, the same criteria that cover hard-copy records apply unless they have been converted to hard-copy records and preserved as such. If held only as electronic files, extra care is needed to prevent corruption or deterioration of data; any compression or other modification made to reduce data storage requirements must not impair the functionality of the record.

Arrangements should be in place for frequent and secure back-up of electronic data. These are usually administered centrally within hospitals for all laboratory sections encompassed by their pathology LIMS. LIMS must be configured and operated with due care for resilience and recovery of access to data in case of accidental or malicious interruption of function. Equivalent arrangements need to cover POCT and tests undertaken in satellite venues, such as GP surgeries. As information technology (IT) equipment becomes obsolete, rerecording may need to be considered.

The minimum periods of retention specified for records for certain categories of patients are embodied in the NHS Transformation Directorate's *Records Management Code of Practice 2023* applying to the NHS throughout England.[4] In relation to patients in the private sector in England, minimum retention times for medical records should be equivalent to those in the NHS. Additional records guidance for Wales can be found in the Welsh Government's *Records Management Code of Practice for Health and Social Care 2022*.[5] In Scotland, the position is set out in *Scottish Government Records Management Code of Practice for Health and Social Care 2024*.[6] The Northern Ireland Department of

Health offers general guidance of record-keeping in their *Good Management, Good Record*[7] advice covering all Health and Social Care services.

The UK Departments of Health, in their published codes of practice covering records management in the NHS referred to above, set the policy, standards and retention periods for health and corporate NHS records, both paper-based and electronic. The British Standards Institute code *BS 10008* encompasses legal standards for electronic records storage more broadly.[8]

In general, however, hard-copy reports of pathological investigations for patients should continue to be produced and incorporated into patients' individual clinical notes for as long as hard copy remains the primary and comprehensive form of record; see below with regard to electronic GP records. Although there is no obligation to destroy them at all, patient records may not be destroyed until the minimum period for retention has elapsed. Longer retention should be by authorisation from/transfer to an approved place of deposit (see *Records Management Code of Practice 2023*).[4]

Under this code, paediatric medical records must be kept, as previously, until the patient is 25 years old. Those of adult patients should be retained for 20 years from last entry or 30 years if the patient has a cancer diagnosis. The latter variation, introduced in the 2021 code and its 2023 update, creates complexity for the retention by laboratories of records and some patient samples capable of long-term storage, such as tissue blocks and slides, that are generally regarded as forming part of a patient's primary medical record. Unless systems are in place that permit the flagging of materials and reports before archiving, and their accurate identification for disposal at an appropriate earlier time-point, we continue to recommend storage for 30 years when discussing long-term retention for items regarded as components of primary medical records.

To complicate the picture further, the 2024 Scottish Government's *Code of Practice for Records Management in Health and Social Care* [6] sets a new single period for retention of adult healthcare records until 3 years after death and extends retention of GP records until 10 years after death. More helpfully, perhaps, the Scottish code automatically converts the status of paediatric records into adult healthcare records at 25 years of age if the patient is receiving healthcare services at that time.

For pragmatic reasons, we recommend retention of post-mortem reports for 10 years after death, to align with the recommendation in England and Scotland for retention of GP records for this period. In any of the UK jurisdictions, the important principle is to make a

considered and consistent judgement about the benefits and risks of retention and disposal, for the patient's relatives and wider society, informing transparent and rationally defensible policy.

It is primarily the responsibility of hospitals, surgeries, etc. to ensure that filing of reports into patients' records is performed in a comprehensive, accurate and timely manner. Electronic patient records have now been widely adopted by many GP practices and hospitals, with secure networking arrangements in place to receive pathology reports by email or another directly transmitted electronic format. With explicit and formal agreement between the hospital Trusts, commissioners and GP practices involved, it is reasonable to dispense with sending out paper copies of such reports, providing procedures are in place to ensure that correct transmission and receipt of the electronic report occur and are confirmed by both the laboratory and GP surgery. Transmission of electronic records that will stand as final reports should be in an unalterable, 'read-only' format such as PDF.

POCT services are offered to generate a rapid result for guidance of immediate patient care or public health intervention; their purpose should be defined (to diagnose/treat, to support a care pathway, to monitor long-term conditions, for public health and population screening etc). They must be provided and operated in accordance with government recommendations[9] (see the Medicines and Healthcare products Regulatory Agency's (MHRA) *Management and use of IVD point of care test devices guidance*) and, as soon as feasible after introduction, accredited in accordance with the ISO 152198:2022 standard, in line with services provided by medical laboratories.

The guidelines on storage of specimens and records that apply to a pathology laboratory apply also to any POCT service. Results from POCT tests must be entered into a patient's medical record, either by electronic transfer or manually. Where no hard copy or electronic file is generated as an output from POCT analyses, the results must be transcribed as a contemporaneous record into the patient's clinical notes. The transcript should contain sufficient detail to create a complete audit trail of performance as detailed below for hard copy/electronic outputs. Data security of information stored on hard drives of POCT instruments, including those placed in community settings, must be assured. The integration of POCT devices into LIMS, or directly into electronic patient record systems, enables accurate and high-quality data recording; this should be a priority for any POCT implementation. POCT results generated as hard copy or electronic outputs should be recorded in the patient's notes with sufficient detail to provide a complete audit trail for the result, including the operator's identity, instrument/technology used, reagent lot number(s)

and reference range(s) if these are not recorded in another way. It is good practice and may be clinically important to record a result specifically designated as being POCT generated to distinguish it from a laboratory-generated result. Also, while all such testing should be undertaken by trained and competent staff, POCT designation may also be needed to indicate any risk arising from interpretation of test data by non-laboratory personnel. RCPath, IBMS and the ACB have produced national guidance to support the implementation and operation of POCT services, recognising the increasingly diverse contexts in which such services are provided (home, community healthcare and diverse commercial settings; self-administered testing and tests conducted by a diversity of trained professionals).[10]

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 for transmission, such as encryption and password protection. They also carry different risks of corruption or loss from those of hard-copy records. Arrangements for regular and 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; robust data ‘take-on’ must be ensured when IT systems are upgraded or replaced. Laboratory professionals should ensure that electronic record-keeping and transfer are encompassed by, and compliant with, their organisations’ overall data security policies, including the safe-keeping and regular updating of passwords and encryption keys, and restricted transfer to portable media. LIMS should be configured and operated with attention to resilience in case of unexpected accidental or malicious data loss.

## 2.2 Laboratory and mortuary working records

These are records and documentation created and retained for internal use by laboratory and mortuary service providers. It is recognised, within the scope of ISO15189:2022, that these have different purposes and significance from clinical records held by laboratories. The guidance for their retention can, therefore, be more nuanced than that for clinical records, reflecting the different purposes for which particular laboratory records are created. Overall, after appropriate risk assessment and mitigation, most such records can

be disposed of after considerably shorter retention than records of clinical results. Such working records include (this list is not exhaustive):

- request forms
- day books
- worksheets
- batch records (of reagent batches linked to series of specimens; also specimens analysed as cohorts on automated instruments)
- graphic outputs from instruments
- refrigerator and freezer temperature records
- photographic records
- catalogues of pathological archives or museum holdings
- bound duplicate copies of reports and records
- correspondence not directly related to clinical advice/management
- records of transmission of reports by telephone, email and fax
- equipment maintenance logs
- quality control and quality assurance records, including validation and verification data for laboratory methods
- standard operating procedures
- accreditation documents
- records of inspections.

Where these items are held in electronic form, the same criteria that cover hard-copy records apply. However, extra care is needed to ensure data security and prevent corruption or deterioration of data (see 2.1 Clinical and diagnostic records and reports). Suitable back-up systems should be employed and, as equipment becomes obsolete, data transfer or the production of durable hard copy may become necessary to maintain access during the minimum retention period.

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

## 2.3 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 including electrophoretic strips, immunofixation preparations, nucleic acid and protein blots
- photographic images (predominantly but not exclusively digital) used for diagnosis
- museum specimens
- test cards (e.g. neonatal screening test cards)
- microbiological swabs and cultures, freeze-dried or otherwise preserved
- extracted nucleic acids of patient or cultured microbial origin.

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[1] (see Appendix 3). However, this document is not limited to such material, as it includes reference to human biological material that is regarded by the HTA as acellular (such as serum and plasma) and derived materials such as nucleic acids, including naturally occurring cell-free DNA. In general, such material is not covered by the Human Tissue Act 2004, although there are caveats in the HTA’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.[11] Further advice concerning the definition of ‘relevant material’ within the Act can be found at: https://www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004.

# 3 The management of records and specimen archives: general comments

Diagnostic records are properly retained in individual patient notes or in electronic form. The safekeeping of these records is primarily the responsibility of hospital records departments or recipient GPs or private practitioners, once the pathologist has issued the

reports. Where pathologists have reason to doubt the reliability of systems of patient record keeping, they should bring this to the attention of those responsible, rather than attempt to rectify it by duplication with local and prolonged laboratory storage of diagnostic records. The primary purpose of diagnostic records retention by laboratories is for internal use, including correlation with results from previous and subsequent specimens, responding to queries from other healthcare professionals, audit and quality assurance. When information relevant to clinical care has been recorded in the laboratory, either formally or informally, the occurrence and its content should be copied to the patient's primary medical record or signposted in that record for cross-reference if transcription is not feasible.

Where storage of material is no longer required for clinical purposes, but is desirable for teaching, quality assurance, audit, research or other purposes of public benefit, the ethical and legal acceptability of continued storage must be reviewed. The legitimacy of future storage for such purposes is influenced by the presence or absence of appropriate consent. This will depend on the intended future use; storage of relevant material for a scheduled purpose under the terms of the Human Tissue Act 2004 requires an appropriate licence, even for de-identified specimens.[1]

Research use will also require approval by a recognised REC or equivalent body. A HTA licence will be required for storage of relevant material removed after death, or for storage of relevant material from the living for future research not covered by a current REC approval. Where a diagnostic archive of specimens is used regularly as a source of material for research, advertises its availability or invites applications as such a resource, the relevant material within it must be stored on HTA-licensed premises. In many cases an existing HTA licence on the same premises, which will most commonly relate to post-mortem or research storage activities, can be extended, or the diagnostic archive can be licensed as a satellite site associated with such licensed premises; see the section on diagnostic archives.[12]

The HTA should be consulted if extension to an existing licence is required to cover intended storage for research use of relevant material within a primarily diagnostic specimen archive.

For compliance with requirements of current human tissue legislation, a recognised REC is either:

- a REC established under, and operating to, standards set out in governance arrangements issued by the UK Health Departments

or:

- an ethics committee recognised by the UK Ethics Committee Authority (UKECA) to review clinical trials of investigational medicinal products under the Medicines for Human Use (Clinical Trials) Regulations 2004.

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 activities undertaken for 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. More information about the roles and responsibilities of designated individuals can be found via the HTA website.

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 (this term should be interpreted selectively to encompass defined, planned and documented audit activities rather than being used as a generic reason to retain samples ‘just in case’)
- quality assurance, including internal quality control and external quality assessment
- 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 REC. Specimens used for such research may continue to be held for audit of the completed

research but such storage must be under an HTA licence unless (a) there is continuing REC approval for the particular study or (b) REC approval for further use is pending. Consent is needed for the continued storage of specimens for any of the scheduled purposes set out in Schedule 1, Part 1 of the Human Tissue Act 2004.[1]

- archives of specimens in hospital laboratories, for which the predictable diagnostic purposes are complete, may in some circumstances be approved as tissue banks for anonymous research use, by application to the National Research Ethics Service (for further guidance see www.hra.nhs.uk). This does, however, constitute a change in the status of the archive and requires HTA licensing; advice should be sought from local designated individuals and the HTA to ensure compliance with their requirements. With exceptions for anonymised use of archived samples in studies approved by a recognised REC, appropriate consent for research storage and use must be in place for relevant material accrued after 1 September 2006.

It is nevertheless good practice, when practical, to check that the patient has not lodged a specific objection to such use during the normal consent processes for the procedure(s) they have undergone. Organisations within the NHS – and private clinical care providers operating to equivalent standards – should have policies and procedures in place that allow patients to register such an objection at any time after initial consent. To maintain public confidence, if diagnostic archives are to be used even for anonymised research only, communication of such decisions and appropriate specimen tracking within laboratories should operate to ensure that patients' wishes are respected in this regard.

Under the Human Tissue Act 2004, retention without appropriate consent of specimens obtained at post-mortem examination is not permissible unless under 1 of the exclusions specified in the Act, notably with the authority of the Coroner or for the requirements of the criminal justice system. Under the Human Tissue Act 2004, authority to store human tissue for a scheduled purpose without consent does not persist after the Coroner's work is complete, unless under police authority.[1] The situation in Scotland for Procurator Fiscal post-mortem examinations is different; this is discussed below, as is the position regarding retention of organs, tissue blocks and slides from a post-mortem examination instructed by a Procurator Fiscal.

Separate regulatory arrangements apply to retention and use of donor material (from living or deceased individuals) for the potential benefit of transplant recipients. These are governed under the Human Tissue (Quality and Safety for Human Application) Regulations 2007.[13]

The following reasons for retention were listed in early versions of this guidance, but they are no longer acceptable as primary reasons to retain samples and data unless appropriate consent has been given (unless the material is for some reason exempt from the requirements of the Data Protection Act, e.g. by adequate anonymisation, and the Human Tissue Act, e.g. as a result of procurement before the Act came into force).

- research (other than that covered above).
- historical purposes.
- holding of pathological material and records in dedicated tissue banks.

What form of consent is 'appropriate' is defined by the Information Commissioner in respect of data and by the Human Tissue Act 2004 and the HTA in respect of tissue. It is not necessarily the case that consent must be written and individually signed, although it must be documented. The nature of consent in different circumstances may range from generic to highly specific.

The need to store specimens and data will vary according to the discipline of pathology that is practised. Where specimens or permanent or semi-permanent preparations are kept, they should be appropriately labelled, indexed and catalogued, so that the record remains accessible, usable and under professional control and guidance. If the material is not needed for clinical purposes but continued retention is desirable, in some circumstances anonymisation will be necessary. If information is rendered 'not identifiable', this removes it from the remit of the Data Protection Act 2018 (as does the death of the patient). Under some circumstances, secure coding of data may have the same effect, but expert advice should be sought, usually from an institution's data protection officer.

In the case of human biological samples, information on the nature of any consent pertaining to each sample should be retained even after irreversible anonymisation, as this will influence the uses to which a sample can be put after anonymisation. For example, consent for research use of individual tissues sampled at post-mortem examination may be specified in detail by relatives of the deceased; it is important to retain a clear record of which tissues may or may not be stored for research use. Patients, and relatives on behalf of the deceased, may also specify objections to use of tissue in research involving animals, while permitting other research uses. Where the retention of human tissue would be unlawful, anonymisation does not override this and cannot make continued retention lawful.

The recommendations that follow refer to the minimum times of retention that are consonant with acceptable practice. If any of our recommendations indicate a shorter time for retention than those required by recognised systems of good laboratory practice, the UK Blood Services (NHS Blood and Transplant, Scottish National Blood Transfusion Service, Welsh Blood Service and Northern Ireland Blood Transfusion Service), the NHS Patient Safety Authority, the Home Office or any other relevant regulatory body, we recommend that the latter be followed by subscribing laboratories. Many laboratory professionals will have good and cogent reasons for retaining records and materials for longer periods than our minimum recommendations.

Where laboratories or hospitals are to be closed, where a contract to provide a pathology service is transferred to another provider or where a public/private partnership is established for pathology service provision, pathologists and laboratory/hospital managers must consider the need to retain and relocate certain records and materials, so that continuity of essential data storage is maintained and the records remain accessible at all times for clinical purposes. There should be an explicit agreement as to which organisation assumes responsibility for the retained records and materials; access procedures should be defined clearly and made known to users. Also, depending on the nature of the material being transferred, the receiving organisation may require an HTA licence. This will all necessitate careful organisation but provides opportunity for the disposal of records that are no longer needed. Any records for disposal that contain patient-identifiable data should be disposed of by incineration or shredding as confidential waste. An auditable record of the disposed items should be kept.

Private companies providing outsourced pathology services on behalf of patients should operate policies for retaining and disposing of internally generated records and residual specimens in accordance with the guidance in this document. They may receive tissue and other biosamples from many different sources, with different customer preferences for the fate of residual material. We recommend that they operate clearly advertised and standardised protocols for retention and disposal of such residual material, returning any surplus to its source if longer retention is requested by the supplying organisation.

It has been established legally that the mere possibility of pathological material or related documentation constituting material evidence in future litigation is not a sufficient ground for the imposition of a duty to store indefinitely (Dobson versus North Tyneside HA [1996]).[14] As litigation can arise very many years after the relevant treatment is complete, maintaining records for extended periods sufficient to satisfy all potential medicolegal

interests is unrealistic. It should be noted, however, that once particular legal proceedings have commenced, or there is a reasonable expectation that they are about to commence, any archive destruction policy should be suspended in respect of all documents or specimens relevant to that matter (Criminal Procedure and Investigations Act 1996).[15]

This document does not discuss maximum retention times. If a patient dies, it may be that data and samples taken during life are held in the archives but now have no foreseeable future use and the wishes of the patient in relation to retention are not known. Such data and samples may be disposed of, although their identification within a large archive may be laborious. If samples are taken before death and the patient subsequently dies, that death does not alter the status of the samples under the Human Tissue Act 2004. In contrast with samples obtained after death, there is no legal requirement to dispose of data and samples from patients who have subsequently died.

In early versions of this guidance, the word ‘permanently’ was used widely, with an explanation that this was not intended to enforce retention for longer than 30 years. For greater clarity, this version uses the phrases ‘for 30 years’ or ‘for at least 30 years’, as introduced in the 3rd edition in 2005. However, this is intended to have the same meaning, i.e. ‘without limit of time’, if retention longer than 30 years is justified. Furthermore, to preserve material of potential historical importance, records predating the establishment of the NHS in 1948 should not be destroyed and should be kept in an authorised place of Deposit in accordance with the UK Department of Health guidance. Wherever possible, pathological preparations and any documentation pertaining to them should be kept for the same period of time; but see above. The NHS *Records Management Code of Practice 2023* anticipates that permanent retention of medical records held for more than 30 years, or pre-1948, will be achieved by transfer to an approved place of deposit or to the National Archive; individual institutions may apply to be recognised as approved places of deposit.[4]

It is not the purpose of this guidance to consider in detail the conditions under which cells, tissues, derived materials, reagents and records are kept. With regard to reagents, there is clear guidance from Control of Substances Hazardous to Health (COSHH).[16] With regard to records, hospitals and other institutions generally have local policies and procedures to ensure appropriate back-up and secure data storage, with which pathology laboratories should comply. Where specific requirements are needed for particular specimens, e.g. refrigerated or frozen storage, appropriate arrangements should be in place to ensure maintenance of the correct storage temperature, including emergency arrangements in case of power supply failure. Appropriate light, temperature and humidity conditions should

be provided for temporary storage of ‘transient’ preparations such as fluorescently labelled cells and tissue sections, and for other ‘wet’ preparations. These requirements are all encompassed by the UKAS ISO 15189:2022 standard in accordance with which diagnostic laboratories are expected to be accredited. Institutions that may not require such accreditation are recommended to meet equivalent standards if they are not governed by other arrangements such as those of GCP applicable to research laboratories (see the MHRA’s *Good clinical practice for clinical trials*).

Currently, there are no specific requirements that materials designated for storage under ambient conditions should be stored with controlled levels of ventilation, light or temperature. However, laboratory managers should be aware that, as potential uses of stored materials change, guidance in these areas may evolve; for example, where research biobanking of paraffin wax-embedded tissue blocks (and derivatives such as tissue microarrays) is undertaken, it may emerge that temperature and/or humidity control are important new considerations for long-term preservation of sample integrity. Similarly, the expansion of molecular genetic testing applicable to archived wax-embedded tissue blocks may require modification of storage conditions to optimise nucleic acid preservation.

Sustainability considerations are increasingly relevant for laboratories’ policies regarding storage and disposal of records and specimens. Creating records, processing specimens and the subsequent storage of both inevitably consume resources. Consideration should be given to the carbon footprint of creating and retaining both hard-copy and electronic records (paper and ink sources and volumes; usage and sources of electricity, etc.). Laboratory processes should be designed as far as possible to minimise duplication of hard-copy records for short-term uses such as MDT discussions, or printing to scan for sharing, where reference to the original electronic copy would suffice. Similarly, consideration should be given to the use of resources for processing and storing specimens (e.g. energy consumption and use of non-recyclable disposable items), with a view to increasing the sustainability of all laboratory activities over time.

With regard to disposal, institutions will have overarching policies largely dictated by health and safety and data security considerations, which should be followed. Within the scope of this document, however, it is relevant to note that storing records and specimens for long periods without a specific need to do so wastefully consumes space and resources. Technology (currently, digital imaging technology in particular) may enable the creation of a permanent specimen where previously only a semi-permanent or transient specimen

existed; there is then a potential obligation to retain the derived permanent specimen, with attendant resource implications as outlined above. In such circumstances, consideration should be given to ensuring that this is done only where it offers a genuine quality improvement for patient management or a safety improvement in an area of identified risk.

# 4 Documents, electronic and paper records

See also sections 6–8.

Note that storage of data relating to identifiable individuals is tightly regulated under the Data Protection Act 2018, overseen by the Information Commissioner's Office (see https://ico.org.uk/). For guidance about organisational policy and specific queries, consult your institution's data protection officer.

Unless stated otherwise, minimum retention periods are not influenced by whether information is in electronic or paper form, although measures to ensure the security and integrity of the information will differ.

## 4.1 Request forms

It is prudent to keep request forms until the authorised report, or reports on investigations arising from it, have been received by the requester. As this period of time may vary with local circumstances, we do not recommend a minimum retention time but believe that, ordinarily, request forms need not be kept for longer than 1 month after the final checked report has been despatched. For many uncomplicated requests, retention for 1 week should suffice. Where paper copy directly duplicates an electronic request (e.g. many order comms systems), there is no absolute requirement to retain the paper copy.

If the request form is known to contain clinical information not readily accessible in the patient's notes but used in the interpretation of test data, the request should be kept for 30 years, in line with the retention of primary medical records.

Where the request form is used to record working notes or as a worksheet, it should be retained as part of the laboratory record (see 4.5 and 4.6), unless the information is transcribed to another source such as a computer record. Where request forms are used as minor financial documents for accounting purposes, advice on retention should be sought from the local finance department with regard to their accounting period requirements.

It is not the purpose of this document to specify acceptance criteria for documentation and labelling of specimens received in laboratories. However, without certain minimum data, receipt is unsafe and reporting is rendered inefficient or impossible. Laboratories are recommended to operate policies according to locally agreed criteria, with a clear understanding between themselves and their users that items found to be non-compliant with the agreed acceptance policy will be disposed of. What constitutes a reasonable enquiry for missing information, if a replacement specimen cannot easily be provided, should be part of this local agreement. It is the responsibility of individual laboratories to decide whether or not inadequately identified specimens should undergo the requested analyses or be discarded without analysis.

Records of specimens disposed of without analysis should be kept for a minimum of 5 years, to facilitate audit over at least 1 full UKAS accreditation cycle, together with the primary request documentation and explanation of the reason for discard. Standard practice for adequate identification is to require 2 or 3 unique patient identifiers plus identifiers of the date and nature of sample.[17] Where records or samples are transferred between organisations, it is important that these identifiers are retained and cross-referenced by information tracking systems. Further guidance on specimen identification and acceptance criteria is available from the Institute of Biomedical Science.[17]

## 4.2 Daily work logs (day books and electronic equivalents) and other records of specimens received by a laboratory

5 years from specimen receipt to ensure availability for review through at least 1 full cycle of laboratory accreditation by UKAS.

## 4.3 Mortuary registers

Retain for at least 30 years and, ideally, in perpetuity since they may provide the sole source of valuable historical information about deaths in an institution or geographical area.

## 4.4 Protocols of standard operating procedures

Both current and outdated protocols should be dated and kept in a catalogued, accessible format for a minimum of 5 years. In histopathology and other laboratories storing permanent specimens such as tissue blocks for 30 years, records of the relevant protocols used over the lifetime of these specimens should be retained for an equivalent period. 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.

## 4.5 Worksheets

Keep at least until the final report has been authorised for all specimens in the worksheet, recognising that what is regarded as ‘final’ may need to include additional time for MDT discussion and/or for external referral and the reporting back of additional results. We recommend that results of tests undertaken by external laboratories, where records are held by those laboratories and the results are transcribed locally into a cross-referenced report, are kept as worksheets.

## 4.6 Laboratory file cards or other working records of test results for named patients

Keep as for worksheets if all results are transcribed into a separately issued and stored formal report. Otherwise, while recognising that the diversity of these types of working record is very wide, within individual specialties and departments consideration should be given to the potential audit or medicolegal value of storing such working records for 20 or 30 years, as for other primary medical records.

## 4.7 Records of reports communicated by telephone, email or fax

Note of the fact and date/time that a report has been issued by telephone, email or fax should be added to the laboratory electronic record of the relevant report, or to hard copies, and kept for the lifetime of that record as a component of its content. Where management advice is discussed in telephone calls, a summarised transcript should be retained long term, as for the retention of other correspondence (see 4.11). Clinical information or management advice provided by email or fax, in addition to pure transmission of a report, should also be kept as correspondence filed in the patient’s notes and/or stored with a laboratory copy of the specimen request/report for 20 or 30 years as a primary medical record.[18] Further guidance on the reporting of results by telephone is available from the IBMS[18] and there is also RCPath guidance on the related issue of ensuring appropriate transmission of critical results.[19]

## 4.8 Report copies (physical or electronic)

As needed for operational purposes. The primary record, which must be retained in line with legal requirements for all components of a patient’s medical record, is the copy placed

in their notes. Reports communicated between laboratories (e.g. resulting from analysis of a sample forwarded from a local laboratory to a reference laboratory) must be placed directly or transcribed into the patient's medical record. Identifying information sufficient to re-access the original reference laboratory results (including, specifically, any accession number(s)/code(s) used for the sample's identification at the reference laboratory) must be retained long term, ideally cross-referenced in the locally prepared final report placed in the patient's notes.

Where copies represent a means of communication or aide memoire, for example at a MDT meeting or case conference, they may be disposed of when that function is complete. Consideration should be given to minimising the resources used by repeatedly generating such copies for short-term use when an electronic record can be consulted as an alternative.

Copies of reports sent by fax or scanned to provide email attachments may also be disposed of after sending; a record should be kept for audit purposes detailing the date and time of transmission, patient and specimen identifiers and the intended recipient. As above, sharing of the electronic record (e.g. as a PDF created directly from the patient's report in the LIMS) without creation of a hard-copy intermediary should be considered wherever possible.

Report copies generated to substitute for an original report (e.g. if an original is misplaced) should be retained as for the original.

Report copies assembled as components of training portfolios by individual pathology trainee clinicians and scientists should be anonymised and retained by the individual, in the context of the intact portfolio only, for a minimum of 5 years after completion of training. Report copies assembled into revalidation portfolios should be anonymised and kept by the individual, in the context of the intact portfolio only, for at least the full length of 1 revalidation cycle (currently 5 years for clinical consultants).

## 4.9 Surgical (histological) reports

The report should be lodged in the patient's medical record, with the intention that this primary record will be retained for 20 years from its last entry (30 years for patients with a cancer diagnosis). As a back-up and for internal use, an electronic or hard copy should be kept for at least 30 years by the laboratory, with maintained accessibility of e-copies when laboratory computer systems are upgraded or replaced.

## 4.10 Post-mortem reports

The report should be lodged in the patient's record; in the case of Coroner's or Procurator Fiscal's reports, this is dependent on the Coroner's or Procurator Fiscal's approval. Electronic or hard copy should be kept for at least 10 years. The NHS *Records Management Code of Practice 2023* recommends that primary medical records, depending on clinical context, are retained for either 8 or 10 years after death.[4] We therefore recommend the longer period of 10 years to ensure that premature disposal is not made unwittingly in circumstances where the appropriate clinical category may not be known.

In cases of violent or suspicious death, we recommend that post-mortem reports are retained for 30 years (see also Section 7). In addition to accessible storage of paper copies, there must be continuation of access to electronic copies when laboratory computer systems are upgraded or replaced. This guidance applies equally to rapid, short reports that may be prepared for the Coroner or Procurator Fiscal, summarising cause of death, and to the final reports of post-mortem examinations.

## 4.11 Correspondence about patients

This should be lodged in the patient's record, if feasible. However, this is often beyond the control of the laboratory, particularly for cases referred distantly. Ensuring entry into the patient's notes is not primarily the responsibility of laboratory staff (although those with direct ward-based responsibilities, such as haematologists and microbiologists, will have direct responsibilities for this). Otherwise, keep for at least 30 years, if possible in association with stored paper or scanned copy of the relevant specimen request and/or report kept by the relevant laboratory. Paper documents, once scanned, may be disposed of as long as security and accessibility of the derived electronic records are assured.

The practicalities of storing email correspondence have yet to be fully addressed within the NHS. Logically, such communications should be retained as for correspondence on paper. Individual Trusts retain back-up copies of email correspondences, but the times may vary according to local policy. Laboratories should ensure that they comply with their institution's medical records and IT policies with regard to the status of email correspondence. Some LIMS can store email correspondence linked to specimen records and this – or alternative systems for comprehensive storage (and retrieval, when required) of emails – should be explored. Perhaps most importantly, laboratory departments should ensure all staff are aware of the requirement to regard emails containing patient-

identifiable clinical information, discussion or advice as part of the patient's record. As such, they should not be deleted unless the content has been transcribed into a report or otherwise incorporated into the patient's notes. The National Archives offer guidance for organisations on managing email records (see the National Archive's email management policy).[20] The recording of emails, instant messaging and social media use in the context of medical records is referenced in the NHS England *Records Management Code of Practice 2023*.[4]

## 4.12 Point-of-care test data

POCT results are clinical data that should be entered into the patient's record with sufficient detail to link to an audit trail of the production of that result, allowing traceability to the device and operator. The results themselves become a component of the patient's medical record and should be kept accordingly (30 years) in that format. A variety of other POCT records relate to certification and validation of technology, verification of reagent batches, internal and external quality control. Tests that are manual or eye-read, without electronic output, for example, should be subject to a central record of tests run on both patient and quality assurance samples. This is to support governance and oversight of services; it should be kept confidentially and securely, as for other clinical records.

For these operational data, subject to appropriate risk assessment and mitigation, both electronic records from POCT devices that are integrated and manual records should be kept, in line with laboratory practices and accreditation requirements, for a minimum of 5 years, allowing review for audit and accreditation purposes. POCT devices that contain patient-identifiable data should be locked to only allow authorised operator access; if portable, their security should be a matter for local consideration and risk assessment.

Such guidance is challenged by the increasing use of POCT in self-administered contexts and in non-traditional settings away from hospital, GP or community clinic environments. Records systems (for example, design and use of electronic or paper templates for incorporation into GP, hospital or patient-held records) should be used that enable, as far as possible, equivalence of POCT records and those generated within hospital laboratory settings.

## 4.13 Bound copies of reports and records, if made

These should be retained for at least 30 years.

## 4.14 Pathological archive or museum catalogues

These should be retained for as long as the specimens are held or until the catalogue is updated, subject to consent where required (with maintained and accessible documentation of consent).

## 4.15 Photographic records

Where images represent a primary source of information for the diagnostic process, without interpretation/transcription into a written report, whether conventional photographs (+/- negatives, e.g. for electron microscopy) or digital images, they should be kept for at least 30 years. In practice, most such circumstances are rare; they may include, for example, some macroscopic specimen photographs and images from post-mortem examinations.

In increasingly frequent circumstances, images of pathological specimens are being produced as an alternative to storing the specimen itself. At present, 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 medicolegal 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. Their identity must be maintained, linked to the patient's electronic clinical records and appropriately backed up.

Photographic images, typically digital, may also provide a permanent record of a non-permanent or semi-permanent sample or preparation. Relevant examples are digital images of direct and indirect immunofluorescence assays. For such preparations, digital images of diagnostic quality should be stored with a unique identifier, including linkage to patient demographics and the reported findings, and should allow traceability to the assay reagents and methods used at the time of testing. These data should be stored for at least 1 full UKAS accreditation cycle (4 years) plus a safety margin (1 additional year recommended). Any immunofluorescence images currently held without supporting linked data should be considered uninterpretable and deleted; a record of the deletion should be retained for 1 full accreditation cycle, as for other records of disposed specimens.

In genetics laboratories, large numbers of digitised images are routinely generated as part of the testing protocol (e.g. digital representations of molecular cytogenetic and nucleic acid test results). Where such images represent the primary source of diagnostic

information, the details should be transcribed and interpreted into a report that is entered into the patient's record. They can then be regarded as semi-permanent preparations or working documents, depending on context. If they are not transcribed, they should be kept for at least 30 years as a component of the patient's primary medical record, with security of storage, identity and maintained accessibility guaranteed.

Digital pathology, particularly histopathology, is a rapidly developing field and advice is available within the College's guidelines for the implementation of digital pathology reporting.[21] In contrast to the scenarios envisaged in the paragraphs above, in most circumstances of digital histopathology reporting, a primary sample (tissue block) and the derived stained sections are also stored in the laboratory according to usual principles (8 years for stained sections and 30 years for blocks). However, the diagnosis has been made from the image(s) prepared from the sections and issues may arise that specifically require review of the digital images. Ideally, all digital images used for diagnosis should be retained for as long as their physical counterparts, with their linked metadata and without compression. The cost and logistics of doing so currently may be significant inhibitors to the expansion of digital histopathology but retention for 8 years aligns with the best practice recommendations for digital pathology referenced above and also with the recommended retention period for PACS images used for radiological diagnosis and for static diagnostic ultrasound images. In future, particularly as assistive intelligence (AI) algorithms contribute to the pathologist's interpretation of digital images, we might anticipate that retention of the digital image, with its linked image analysis metadata, will gain primacy over retention of the original glass slide.

Where images represent solely 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.

## 4.16 Batch records

Batch records should be retained for at least 5 years.

## 4.17 Internal quality control records

These should be retained for at least 5 years.

## 4.18 External quality assessment records

Subscribing laboratories or individuals: minimum of 5 years, to ensure continuity of data available for laboratory accreditation purposes over at least 1 full inspection cycle (see 4.19) and equivalence with performance records for the equipment used.

## 4.19 Accreditation documents and records of inspections

Minimum of 8 years, or at least 2 inspection cycles (anticipating a 4-yearly cycle for accreditation against ISO 15189:2022), whichever is longer. If accreditation is withheld or provisional after inspection by UKAS, the retention of these records must be extended until full accreditation for the relevant services has been achieved and maintained for 2 cycles.

## 4.20 Temperature records for refrigerators and freezers (including those used for post-mortem body storage)

Plots of continuous records, where made, should be summarised regularly to provide summated statistics (including occurrence and duration of any variation outside an agreed acceptable range). The primary traces or other raw data should be retained for a reasonable period: a minimum of 2 months is recommended for these, if transcribed regularly into summary format. If continuous or intermittent daily records are retained as the primary record, without transcription or derivation of summary statistics, retention should be as described below:

If storage is of blood for transfusion, the *Blood Safety and Quality Regulations 2005* provide the appropriate standard, which is a minimum of 15 years[22] (see 6.1.5).

For refrigerators and freezers used for long-term storage of specimens for purposes other than human applications (e.g. for research, quality control, assay validation or potential future retesting), automated or summarised manual temperature data should be regarded as a type of internal quality control record and retained for at least 5 years.

If storage is of analytical reagents and/or ‘temporary’ specimens that are used and replaced rapidly, retention should allow continuity of data availability between UKAS (or equivalent) inspection cycles; 5 years is recommended. This is the scenario that probably best matches the pattern of use of a mortuary refrigerator.

When a freezer is being used for potentially very long-term storage, e.g. in biobanking, data summarised from daily temperature records should be kept for at least the lifetime of the equipment. The records of all affected individual specimens should be annotated with,

or linked accessibly to details of, any temperature deviation beyond ‘normal’ variance. These details should remain accessible as a component of the specimen record, following transfer to a new freezer, for the lifetime of the specimen.

Temperature records for freezers used to store forensic samples for potential medicolegal use should be retained for at least as long as the oldest sample held. There is general guidance from the Metropolitan Police regarding the retention and storage of frozen exhibits.[23]

## 4.21 Equipment maintenance logs

Lifetime of instrument plus a minimum of 4 years (to encompass at least 1 full accreditation cycle after lifetime complete).

## 4.22 Records of service inspections and instrument maintenance

Lifetime of instrument plus a minimum of 4 years, as above.

## 4.23 Records relevant to diagnostic products or equipment

Comprehensive records relevant to procurement, use, modification and supply: at least 5 years.

## 4.24 Records of assay validation and verification

Performance claims are required by UKAS to be verified prior to introduction. Records should be kept of the methods used and results obtained for at least 5 years.

## 4.25 Research data

See 5.12 and 5.13.

## 4.26 Records relating to cell/tissue transplantation

Records not otherwise kept or issued to patient records that relate to investigations or storage of specimens relevant to cell/tissue transplantation, including donated organs from deceased individuals, should be kept for at least 30 years or the lifetime of the recipient, whichever is longer. Identification should link these records and specimens unequivocally to the recipient but also maintain traceability to the donor.

Records and specimens arising from testing of donor tissues not subsequently used for transplantation should be kept as for equivalent samples/records for a patient and should

be identified by the donor's details. There are also requirements to retain data specifically relating to activities in the human application sector licensed by the HTA.[24]

### 4.27 Records relating to retention of semen, spermatozoa, oocytes and tissues for fertility assessment and use in assisted reproduction

Records not otherwise retained or issued to patient records that relate to investigation or storage of specimens of semen, spermatozoa, testicular tissue, oocytes, ovarian tissue, embryos created by IVF/ICSI, biopsied polar bodies, blastomeres and trophectoderm should be kept for at least 30 years.

## 5 Specimens and preparations

See also sections 6, 7 and 8.

### 5.1 Legal issues

With a few exceptions, the Human Tissue Act 2004 prohibits the removal and/or storage of any material obtained after death and containing human cells, including fluid samples, for a scheduled purpose (see Appendix 3) unless undertaken on premises that have an appropriate licence from the HTA and with appropriate consent in place. There are also licensing requirements for storage of tissue removed from the living; detailed advice on licensing may be obtained from the HTA.[25] The Human Tissue Act 2004 applies in England, Wales and Northern Ireland, replacing previous legislation. For a brief summary, see: https://www.hta.gov.uk/guidance-professionals/hta-legislation. The position in Scotland is somewhat different and is set out at the end of this section.

Under the Human Tissue Act 2004, neither consent nor a licence is required for the storage of material for diagnostic purposes for the benefit of the person from whom the tissue was removed during life. This exemption includes genetic testing carried out for the same purposes.

Appropriate consent (as defined in the Act and elaborated in the relevant HTA Codes of Practice[26]) is required for storage for purposes listed in part 1 of Schedule 1 of the Act if the samples came from the body of a living person, and for any of the purposes listed in Schedule 1 if the samples were obtained from a deceased person.[26]

Post-mortem samples of human tissue (including fluids) may be retained by the Coroner without consent for as long as they are required to fulfil the Coroner's duties. The Coroner,

not the pathologist, should decide when these duties are complete and, hence, for how long the retention of relevant tissue samples should be authorised. The instructions of the Coroner should, therefore, be obtained and followed in regard to retention of tissue samples from all post-mortem examinations conducted under the Coroner's authority.

Note that the Coroner has no power to authorise retention of tissue after the coronial investigation is complete (e.g. following the conclusion of an inquest). The HTA has issued guidance for pathologists to follow in circumstances when the Coroner's authority has expired but instructions have not been received regarding what to do with the tissue.[27] Where the period of retention authorised by the Coroner is insufficient to allow the pathologist to address the issues raised by the death, the pathologist should make this known to the Coroner but must not keep the tissue beyond the authorised period. The police may authorise further retention for evidential purposes, if required, under the remit of the Police and Criminal Evidence Act 1984.

Samples and accompanying records, from living or deceased individuals, may be retained for as long as they are required for the purposes of investigation of crime or for the criminal justice system. In effect, this may in some cases require storage in perpetuity and, depending on individual circumstances, may involve retention on the premises of the original hospital laboratory, those of a forensic specialist service provider or elsewhere. Storage as potential criminal evidence includes maintenance of a chain of custody consistent with requirements of the Police and Criminal Evidence Act 1984.

Guidance on the retention of exhibits for use in criminal investigation and prosecution has been published by the National Police Chiefs' Council; see *Retention, Storage and Destruction of Materials and Records relating to Forensic Examination* (2021).[28] Further advice may be obtained from the Forensic Science Regulator, the Forensic Capability Network, the Crown Prosecution Service or the Home Office. Pathologists are also advised to seek from the police the precise legal authority underlying any request for retention that they initiate to ensure that provisions of the Human Tissue Act are not breached.

As soon as post-mortem samples are no longer required by the Coroner or the criminal justice system, appropriate consent will be needed for storage for any of the purposes listed in Schedule 1 of the Human Tissue Act. If the function of the Coroner has been completed but for some reason the pathologist has not been informed of the wishes of the relatives in relation to retention or disposal, continued retention of the material is not

permissible. The HTA has provided advice, in the form of a Code of Practice (Code B – see https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/codes-practice), on the length of time for which such material should be retained pending clarification of the wishes of the relatives.[27]

Similarly, as soon as samples from living patients are no longer required by the criminal justice system, appropriate consent (as defined by the Human Tissue Act) will be needed for storage for any of the purposes listed in part 1 of Schedule 1 of the Human Tissue Act.

Section 45 and Schedule 4 of the Human Tissue Act 2004 applies in Scotland, relating to the non-consensual analysis of DNA. The position in Scotland is otherwise defined by the Human Tissue (Scotland) Act 2006, in which 'authorisation' has the same fundamental status and importance as 'consent' in the Human Tissue Act 2004. Section 39 of the 2006 Act provides that once the necessary notice has been received from the Fiscal, all tissue blocks and slides from the examination automatically become part of the medical records of the deceased person. They can be used, without the need to obtain authorisation, for the purposes of:

- providing information about or confirming the cause of death
- investigating the effect and efficacy of any medical or surgical intervention carried out on the person
- obtaining information which may be relevant to the health of any other person (including a future person)
- audit.[3]

It should be noted, however, that storage and use of cells or tissue for human application, whether from a living or deceased donor, are regulated under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, which apply throughout the UK including Scotland.[29]

Only once the necessary authorisation has been given will it be possible for the blocks and slides to be used for purposes such as medical education, training and research.

Larger specimens (such as whole organs) retained at a Procurator Fiscal post-mortem examination do not automatically become part of the medical record once the Procurator Fiscal's purposes have been satisfied. For these to be retained for any purpose, the necessary authorisation would have to be given by the family.

The provisions of the COSHH Regulations 2002 and of current Health and Safety at Work legislation must be observed.

Diagnostic laboratories storing hazardous micro-organisms, chemicals or radio-isotopes for 'reasonable periods' in the course of their normal work are generally exempted from security requirements of the Anti-terrorism, Crime and Security Act 2001.[30] However, the Home Office must be notified in the rare event of an exceptional need for any such material to be retained beyond the reasonable time needed for diagnosis. An example might be post-diagnostic retention of known biohazardous samples for research purposes; security arrangements for storage should include consideration of protection against theft/misuse for terrorism and will need to meet the Home Office's requirements for such. A list of hazardous toxins and pathogens is provided in Schedule 5 of the Anti-terrorism, Crime and Security Act 2001 (see https://www.legislation.gov.uk/ukpga/2001/24/schedule/5).

## 5.2 Plasma and serum

Keep for 48 hours after the final report has been issued by the laboratory, unless there is a reasonable expectation that additional testing will be required, e.g. if the final report has requested that a follow-up test is done in parallel with retesting of the original sample. If there is a requirement to store for longer, specimens that have been centrifuged but not separated should be separated to prolong stability. Cell-free nucleic acids from plasma are increasingly useful as analytes (e.g. in non-invasive antenatal diagnosis and in cancer monitoring); storage should be in a suitable form for such analyses, where relevant.

In transplant centres, serum samples obtained from recipient(s) for the purposes of matching in cell/tissue transplantation and their accompanying records must be kept for the lifetime of the recipient. For transplant-related virology/microbiology samples, a minimum of 10 years for donor material, and 30 years for recipient material is recommended, which is consistent with Safety of Blood, Tissues and Organs (SaBTO) guidance on the microbiological safety of human organs, tissues and cells used in transplantation; the associated virology/microbiology records should be stored retrievably for 30 years.[31]

Serum from the first booking visit for pregnancy should be kept for 2 years by microbiology/virology and other laboratories offering antenatal screening to provide a baseline for further serological or other tests for infections or other disease during pregnancy and the first 12 months after delivery. Further guidance and more detailed

standards have been developed by the National Screening Committee for the Infectious Diseases in Pregnancy Screening Programme, last updated in February 2023.[32]

Sera for virological assessment of individuals dialysed overseas should be retained for a minimum of 1 year.

Because of its rarity and value to future research, wherever possible, fetal serum (from cordocentesis) should be kept for at least 20 years. Although plasma and serum are not covered by the Human Tissue Act 2004 in the absence of cellular content, it is recommended that systems are set in place prospectively to request consent for such long-term storage for potential future research.

Serum taken after needlestick injury or other hazardous exposure should be kept for a minimum of 2 years.

Other leftover sera or plasma should be stored for as long as practicable, to provide an array of material for future research and disease surveillance purposes. While long-term storage may be impractical in many settings, virology centres and laboratories involved routinely in public health activities should retain sera for a minimum of 1 year to facilitate 'look-back' exercises, identification of emerging infections and vaccine programme monitoring. Samples that do not contain human cells are not regulated as human tissue by the Human Tissue Act, although ethical constraints on appropriate storage and use nevertheless apply; consent should be sought where appropriate. Storage of samples of cellular material with the intention of human DNA analysis without appropriate consent may be an offence under the Human Tissue Act.

## 5.3 Newborn blood spot screening cards

A minimum of 5 years' storage is mandated as part of quality management, in accordance with the Public Health England NHS Newborn Blood Spot Screening Programme's *Code of Practice for the Retention and Storage of Residual Newborn Blood Spots (2018).*[33] Controversy persists regarding the legal status of blood-spot screening cards held long term and their use for additional testing without specific and individual consent. Screening laboratories are currently requested not to destroy any residual newborn blood spot cards.

## 5.4 Faecal immunohistochemical test (FIT) samples for bowel cancer screening

The primary specimens should be kept for a minimum of 48 hours after report authorisation to allow answering of queries regarding receipt, etc.

## 5.6 Body fluids, aspirates and swabs (including liquid-based cytology specimens)

Keep for 48 hours after the final report has been issued by the laboratory, unless sample deterioration precludes storage. Examples of the latter include joint fluids examined for crystals and semen specimens examined for spermatozoa, which may be discarded immediately after analysis, and coagulation samples, which may be discarded after 24 hours. Samples that are easily and non-invasively repeated, such as most urine samples, may be destroyed once the examination is concluded and the final report has been authorised. Reference laboratories receiving all or part of a specimen of this sort from another laboratory should follow the same guidance.

## 5.7 Whole blood samples, for full blood count

Retain specimens for 24 hours.

## 5.8 Donor lymphocyte preparations in cell or tissue transplantation

Donor lymphocytes and relevant identifying documentation should be retained for the lifetime of all recipients of cell or tissue grafts from that donor (see Blood Safety and Quality Regulations 2005 and HTA Code of Practice G: Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation).[22,34]

## 5.9 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.

## 5.10 Cells for molecular genetic analysis

Retention for at least 3 months is recommended for cytogenetic cell suspensions in fixative.

## 5.11 Paraffin wax or resin embedded blocks for histology

Storage for at least 30 years is recommended, if facilities permit. This is to align with current medical records retention guidance that anticipates primary medical records being kept for 20 years from last accession and for 30 years from diagnosis if the patient has cancer. Where facilities are limited, it is acceptable to review the need for archiving at 10

years (and at intervals thereafter) and select representative blocks, containing the relevant pathology, for longer retention while disposing of the others. Blocks representing rare diseases and those (including representative normal tissue) from patients with diseases known, or thought likely, to have an inherited genetic predisposition should be particularly considered for permanent retention. The labour, cost and potential risk involved in selection of representative material to retain should not be underestimated by employers and, wherever possible, storage of all histology blocks should be for at least the current minimum of 30 years. As an alternative to destruction, transfer to an HTA-licensed research biobank should be considered, at least for selected samples and data. It is anticipated that future IT solutions to the 'up front' assignment of blocks to different categories for retention, combined with automated (possibly robotic) processes for regularly culling archived block stores, will enable a more nuanced and sustainable approach to long-term tissue block retention.

Where destruction of blocks at less than 30 years is being considered, blocks that have provided the basis for a diagnosis of malignancy should be identified and retained for the full 30 years or until 10 years after the patient's death.

Early destruction of blocks from paediatric cases is inappropriate; these should not be destroyed until the child has reached adulthood and is at least 25 years old. Retention for at least 30 years should be considered in all cases and is particularly recommended for all cancers (including material representing normal background tissue) arising in children. Specimens representing other conditions known or thought likely to be associated with inherited genetic abnormalities should be retained permanently. Special considerations apply in forensic practice (see section 7).

Post-mortem tissue blocks must only be taken, stored and used in accordance with the consent given for post-mortem examination. The Human Tissue Act 2004 does not specify minimum or maximum retention times for such material stored with consent of a relative or other authorised individual; no specific legislation applies to post-mortem blocks stored before September 2006. We recommend applying the principles described in section 5.11. In the case of tissue taken during an autopsy performed for the Coroner or Procurator Fiscal, the guidance under 'Legal issues' at the head of this section must be followed. It should be noted that the situation in Scotland differs from that in the rest of the UK. The details of consent for retention of all post-mortem tissue should be documented, and that documentation should be retained for as long as any specimens are retained.

Care must be taken that the chain of custody for tissue blocks is not broken when material is referred between hospitals for additional testing and/or specialist review. Dispatch, receipt, temporary storage, long-term retention or return must be tracked and documented by audited systems, operating in both the sending and receiving hospitals, to minimise risk of loss at any stage. The Royal College of Pathologists' archived guidance on inter-hospital referral of cases includes advice on this subject that remains relevant.[35]

## 5.12 Retention of specimens and records in the context of biosample banking for research

The types of sample and records are fundamentally the same as those discussed elsewhere in this guidance and the same general principles apply. Differences in approach arise where the longevity of data and biosample availability for research exceeds legal requirements applicable to medical records kept for purposes of supporting clinical practice. There is no maximum retention time for biosamples (including their linked clinical information and biological data) stored with consent for research use, unless otherwise specified as a condition of the donor's consent. Variations may also arise where biosample processing and storage occur in facilities that are not within or closely linked to a clinical laboratory environment

Operational records, to ensure that equipment, facilities and processes work appropriately and that faults and remedial actions are recorded, should be kept in the same way as those kept for clinical governance in relation to diagnostic specimens.

It is particularly important, as far as possible, to link specimens with details of their pre-analytical handling, such as warm/cold ischaemic times, methods of freezing and frozen storage, duration of fixation, processing schedule and any non-standard details of preservation (alternative fixatives, cold storage of paraffin blocks, etc.).

If biosamples issued for research are not exhausted by an end-user and are returned to the biobank, records should be cumulated to document their movements and the conditions of storage while under the custodianship of the researchers.

A material transfer agreement (MTA) will be in place between the biobank and the researcher or researcher's institution and this should include definition of the storage conditions for any biosample that will be returned. This MTA, with linked details of the studies and biosamples to which it relates, should be kept by the biobank for at least as long as any of the included biosamples remains available for further study. The researcher

should keep an equivalent record in relation to their study in accordance with their institution's requirements for research records. If the end-user is required by the MTA to dispose of, rather than return to the biobank, any surplus material from the biosample at the end of their study, they must keep auditable records of the date and method of disposal, for a minimum period of time compliant with their institution's requirements.

The biobank should keep records of internal and external quality assurance performance and audits for at least 12 years (see 4.17 and 4.18). This is particularly important for those banks not housed physically in clinical laboratory premises subject to regular inspection by UKAS. Alternative or additional regulatory review may be required by the HTA, other accreditation bodies and research funding organisations.

A biobank will keep the biosamples and records of any adopted sub-collection for the same length of time and, as far as possible, to the same standard, as their ongoing collections. Such legacy collections may arise, for example, following closure of another biobank or adoption (with appropriate consent and ethical approvals) of biosamples after the completion of a specific research project or clinical trial.

## 5.13 Release and return of archived diagnostic samples for clinical trials purposes

Translational research using diagnostic samples traditionally regarded as 'surplus' is an increasingly frequent component of clinical trials; it can be anticipated that this trend will continue for the foreseeable future. Molecular or immunohistological testing of a pre-existing specimen as a component of selection for trial entry or allocation to a specified trial arm is another increasing requirement. These types of study now predominate greatly over traditional observational studies within clinical trials involving review and return of the original diagnostic material (such as stained histological sections). They are often accompanied by a request to retain material for future, unspecified studies by the academic institution or commercial company coordinating the trial.

Hospital pathology laboratories with diagnostic specimen archives should endeavour to support the decisions of patients who have given consent for their samples to be used for such research purposes. However, they have a duty to maintain the patient's diagnostic record and consider the potential future value for the patient of retaining samples to be available for future diagnostic tests. With the advance of 'personalised medicine', the retention of diagnostic samples after completion of their initial purpose is becoming

increasingly justified in anticipation of future needs and the definition of ‘surplus’ now requires assessing on a case-by-case basis.

Clinical trial protocols and the patient information accompanying them should acknowledge that availability of ‘surplus’ material cannot be guaranteed for all patients (e.g. when tumour is represented in a single tissue block or the original specimen was a small needle core or endoscopic sample). Pathologists have a responsibility to engage with the design of protocols and patient information materials to ensure that expectations among patients and researchers are accurate. The patient’s potential current and future diagnostic need is paramount while they remain alive and the sole source of testable material must not be consumed for research without full understanding, on the patient’s part, of the implications of this being done.

Where minimal diagnostic sampling (such as endoscopy and needle biopsy) is the norm, clinicians undertaking these investigations may be encouraged to consider obtaining multiple cores/fragments at diagnosis to anticipate generating sufficient ‘surplus’ for future clinical trials. Cellular pathology department protocols should incorporate the possibility of maximising this potential by embedding needle cores and endoscopic fragments individually in separate blocks where feasible. For larger excision and resection specimens that are not usually processed in their entirety, pathologists should consider preparing additional tissue blocks at the time of macroscopic sampling; these can then be flagged in the LIMS and the specimen report as being available for research.

Wherever possible, derived materials from a stored tissue block (e.g. tissue sections, extracted nucleic acids) should be provided, rather than the block itself, unless multiple representative blocks exist. Arguably, even in the latter circumstance, provision of sections rather than release of a block ensures that material is available for the greatest possible number and range of research studies. This approach upholds the general ethical principle of maximising the research benefit to be gained from any sample ‘gifted’ by a patient for research.

Small biopsy samples may generate no surplus. There is cost but no scientific value in sending away, or preparing sections from, a depleted block for clinical trial use; in these circumstances, the researchers should be informed that no material is available. Clinical research staff need to bear this in mind, particularly when considering recruitment of patients into trials requiring additional research tests for initial trial entry and stratification.

Pathology staff should note that the supply of ‘surplus’ material for clinical trials or other defined research studies with qualifying ethical approval, undertaken with the patient’s specific consent, is not subject to regulation under the Human Tissue Act 2004. Where trial protocols include long-term biobanking for future unspecified studies, the biobanking arrangements in England and Wales must be HTA compliant and subject to appropriate REC approval; an accreditation scheme in Scotland provides an equivalent governance structure; evidence of similar standards should be sought when considering release of diagnostic biosamples for research biobanking overseas. Retention of surplus diagnostic samples by researchers as a biobank resource requires specific patient consent for that storage, in addition to their consent to the specific biological studies covered by the current clinical trial protocol.

If research will involve non-return or destruction of a primary resource such as a tissue block, destruction must not occur before expiry of the legal minimum retention term for medical records (30 years). The material should be returned to its hospital source rather than being destroyed if earlier destruction would otherwise occur. The patient information must make these aspects of specimen governance clear for potential research participants.

## 5.14 Blocks for electron microscopy

Keep for at least 30 years.

## 5.15 Grids and derived photographic images for electron microscopy

Requirements in different specialties differ. Grids prepared for human tissue diagnosis (e.g. renal, muscle, nerve or tumour) should be kept for at least 8 years and preferably longer, if practicable, since their replication from the original resin blocks may not be possible after a long interval. Grids prepared for virus identification may be discarded 48 hours after the final report has been issued. All derived images used for diagnosis should be retained and remain accessible for at least 8 years if interpreted into a text-based final report transcribed into the patient’s record. If the images themselves are used as that record, without interpretation and transcription, they should be retained for 30 years.

## 5.16 Wet tissue (representative portion or whole tissue or organ)

For surgical specimens from living patients, keep for 4 weeks after issue of final report. For cases in which a supplementary report is anticipated after additional investigations (such as molecular genetic tests 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.

The HTA has issued guidance on the disposal of pregnancy remains after pregnancy loss or termination that may be appropriate to consider in relation to retention and disposal of products of conception received for histopathological assessment.[36]

For post-mortem specimens, appropriate consent for a scheduled purpose under the Human Tissue Act 2004 must have been obtained if any retention (other than that legitimately authorised by the Coroner or Procurator Fiscal) is to be legal. The terms of that consent must be complied with in relation to storage and use.

Whole organs, wet tissue samples or fetal specimens retained before the implementation of the Human Tissue Act 2004 should be kept only if there is genuine interest and intention to use them for a scheduled purpose or for education/training in relation to human health. If this is not the case, they should be disposed of.

In England and Scotland, for a 5-year period from 18 April 2002 until 2007, families were entitled to reclaim organs, tissue blocks and slides retained under past post-mortem practice, by which was understood cases from before 2000 where there was doubt about the extent to which families were involved in agreeing to retention. Following formal review of this process, the Scottish Executive accepted the recommendation of the Review Group on Retention of Organs at Post-Mortem that organs and tissue unclaimed at the end of the 5 years should be legally deemed to come under the authority of the relevant hospital, which should be able to make use of it for legitimate research or educational projects. Where organs or tissues are not considered necessary or suitable for those purposes, the hospital should ensure their respectful disposal. The Scottish Executive also accepted the Review Group’s recommendation that there should be no moratorium on existing research involving organs or tissue retained under past post-mortem practice, including material from Coronarial or Procurator Fiscal post-mortem examinations. It has been possible to start new research projects since 18 October 2002 using material retained under past practice. All such projects must be non-destructive (i.e. sufficient tissue for potential future diagnostic review must remain in the block after study) and be likely to contribute significantly to diagnosis or therapy. They must also have the approval of an REC.

## 5.17 Museum specimens, where these are generally accessible for undergraduate or postgraduate study (teaching collections not accessible by members of the public)

These may be retained permanently (provided there is no deterioration, or until replaced by a better specimen). Since 1 September 2006, appropriate consent has been a legal requirement under the Human Tissue Act for the retention of tissue for teaching purposes, only if the tissue was obtained after death. Nevertheless, it is good practice to obtain consent from living patients before entering preserved surgical specimens into a museum.

There is no consent requirement for museum specimens obtained before the implementation of the Act on 1 September 2006, although a licence is required for storage of tissue obtained from a deceased person to use for teaching purposes, unless the material is more than 100 years old. With regard to historic and ancient specimens, the Department of Culture, Media and Sport has produced guidance on the care of human remains held in museums and equivalent institutions.[37]

If specimens are stored under conditions that can be regarded as representing public display, the Human Tissue Act requires that consent must be given. If the specimens are from a deceased person, the consent must have been given in writing by the person in life and witnessed. The consent of a relative is not adequate to sanction public display. Public display of paediatric specimens is, therefore, invariably illegal unless the child has attained Gillick competence and has given consent during life. A licence from the HTA is also required if displayed specimens are from a deceased person who consented for their display to occur after death.

## 5.18 Stained slides

Appropriate retention times depend on their nature and purpose. Note that where sections are likely to contain intact human cells, or are intended to be representative of whole cells, they constitute ‘relevant material’ under the Human Tissue Act 2004.[11] However, storage for diagnostic purposes does not constitute a ‘scheduled purpose’ under the Act if the cells or tissue have been obtained from a living individual. Storage of stained slides for research, for public display or from a deceased person do constitute ‘scheduled purposes’ regulated by the Act.

### 5.18.1 Microbiological (e.g. cerebrospinal fluid preparations, malarial blood films, blood culture films, acid-fast bacilli cultures) and slides from easily repeatable investigations such as semen analysis for fertility testing

7 days after final report. Standard Gram-stained preparations from culture plates may be discarded immediately after use.

### 5.18.2 Blood films, routine

7 days after final report.

### 5.18.3 Cytogenetic preparations

2 years after final report, if photographic or digitised record kept; 5 years otherwise. If photographed or digitised, the image should be stored with maintained accessibility for 8 years, if the content is interpreted into an authorised report placed in the patient's medical record. Uninterpreted images that themselves form the diagnostic output placed in or copied into the patient's record should be kept for 30 years, if feasible. The College and IBMS recognise that, particularly in genetics, increasing data complexity and frequency of IT system replacement may confound this ideal.[38] The key principle to observe, before destruction of any such images or other primary test data, is transfer of descriptive information and appropriately authorised interpretation into a report placed in the patient's medical record, with secure back-up of that report.

### 5.18.4 Molecular genetic and molecular cytogenetic preparations (e.g. microarray slides, fluorescence in-situ hybridisation [FISH] slides)

A representative photographed or digitised image should be captured for all patients and stored with maintained accessibility as in above. Long-term storage of fluorescently stained slides is problematical; these should be retained at least until the final written report has been authorised and issued.

### 5.18.5 Bone marrow aspirate films

Stained films used for diagnosis should be stored for a minimum of 8 years (equivalent to a stained diagnostic histology side) and longer if possible – up to 30 years – as a primary and non-replaceable sample. Surplus unstained films may be discarded upon completion of the clinical report, including the reports for any accompanying flow cytometry, cytogenetic, molecular genetic and trephine histology specimens; this would typically be safely covered by retaining for 4 weeks after the verification of the patient's integrated haematopathology report, agreed at MDT discussion where appropriate.

### 5.18.6 Cytology films used for diagnosis, excluding those prepared for population screening (most non-gynaecological cytology preparations)

8 years minimum and longer if possible – up to 30 years – as a primary and non-replaceable sample. Note that cytoblock preparations should be retained as for other paraffin-embedded tissue blocks described above in section 5.11. The cytoblock sections should be retained for the same period as their accompanying cytological slides.

### 5.18.7 Cytology films prepared for population screening

These should be retained for the full 30 years as primary and non-replaceable samples required additionally for screening programme audit and population health survey purposes.

### 5.18.8 Histology sections used for diagnosis

At least 8 years, longer if practicable. It should be realised that retention of the paraffin block alone does not always guarantee the retention of relevant diagnostic material, especially with small biopsy specimens or specimens with only focal representation of disease. If the disposal of slides at 8 years is contemplated, it may be appropriate, although extremely laborious, to select slides from small specimens and those difficult or impractical to replace (e.g. slides representing focal involvement by disease or essential additional stains, including immunostains) for longer retention. Retention for a minimum of 30 years is recommended for stained slides where recutting the fixed tissue block cannot be regarded as a robust means of replacement. The reservations stated in section 5.11 regarding selection of material for earlier disposal apply equally to diagnostic slides. As for tissue blocks, it is anticipated that future IT solutions for the ‘up-front’ assignment of stained sections to different categories for retention, combined with automated (possibly robotic) processes for regularly culling archived slide stores, will enable a more nuanced and sustainable approach to long-term retention of histology slides.

Chain of custody for cytology and histology slides referred between hospitals, for purposes such as specialist review, should be assured as for tissue blocks (see section 5.11). RCPath/IBMS guidance on chain of custody for evidential samples in medicolegal contexts includes many principles that are more generally applicable to maintaining traceability and integrity of pathology specimens[38] and archived RCPath guidance on interhospital transfer of samples also includes relevant principles and practices.[35]

Semi-permanent preparations such as direct immunofluorescence slides, used in a variety of pathology disciplines, should be kept at least until the final specimen report has been

issued. Since the latter may be an integrated report, requiring inputs from other disciplines and MDT approval, we recommend retaining for 4 weeks after verification of the final report. If digital images are prepared from such semi-permanent materials, the images should be retained according to the principles outlined in section 4.15.

In previous editions, this College/IBMS guideline on records and specimen retention has envisaged increasing use of digital slide scanning to enable retention of images as an alternative to retaining the physical slides used for diagnosis. In centres with robust scanning and high-capacity digital archiving arrangements, this may be considered as an acceptable alternative to long-term storage of glass slides but there remain unresolved questions of feasibility, affordability and long-term durability of digital image archives that limit such a major shift in practice at present. Meanwhile, the use of digital images as an alternative to direct microscopy of stained histological is advancing steadily within diagnostic histopathology and new guidance is needed in this different context:

### 5.18.9 Digital image files created by scanning histology sections and used for diagnosis

Retain for the same length of time as the glass slides from which they originate (8 years). The RCPath *Best practice guidance for implementation of digital pathology*, published in 2018, recommends that 8 years is satisfactory (2 cycles of UKAS inspection), in line with other international recommendations in this field.[21]

Ultimately, retention of the digital images may replace retention of glass slides, or vice versa, but we cannot recommend this at present; the RCPath Digital Pathology Committee will continue to review and update its guidance as experience in this diagnostic arena widens. The RCPath and IBMS wish to promote the speedy implementation of digital histopathology. Priority should be placed on setting up robust, reliable and clinically safe workstreams. We anticipate that the cost of long-term digital image archiving will fall rapidly and cost considerations in that regard and should not be seen as major barriers to embarking on or consolidating digital pathology.

All the principles applying to other electronic record formats must apply to archived digitised histology images (safety and security of storage, accessibility, legacy arrangements etc.).

## 5.19 Human DNA and RNA

Keep for a minimum of 4 weeks after final report for diagnostic specimens. As the range of acquired mutations relevant as targets for stratified medicine approaches is expanding rapidly, requirement for considerably longer storage should be anticipated in some circumstances, to avoid the need to re-extract nucleic acid from (sometimes limited) paraffin-embedded samples. Retain samples for at least 30 years if needed for family studies in those with genetic disorders or if stored as donor/recipient material in the context of cell or tissue transplantation. With some exceptions it is an offence under the Human Tissue Act merely to possess human tissue with the intention of analysing its DNA without consent. Exceptions include analysis for diagnosis/treatment of the person whose body manufactured the DNA/RNA.[39]

The need for retention of diagnostic specimens should be assessed at the time of sampling, and appropriate consent obtained.[40] Once DNA/RNA has been legitimately extracted from the tissue, this material does not fall under the remit of the Human Tissue Act 2004, because it no longer contains human cells; but ethical requirements impose a duty to apply similar restrictions to use and storage. Storage conditions must be suitable for preservation of the integrity of the material. Specimens used in research should be kept indefinitely if the consent status permits this.

Surplus may be generated at several stages of sample preparation for molecular genetic testing. Where blood or another body fluid is the source of nucleic acids, this is clearly non-permanent and should be disposed of accordingly as soon as the analysis is complete or sooner if the material is incapable of storage without degradation. Where potentially semi-permanent or permanent samples are created for the purpose of DNA/RNA extraction (e.g. curls from wax-embedded fixed tissue or unstained sections provided for scraping/microdissection of tissue), any unused surplus material (curls, slides etc.) should be discarded once the final report has been completed. Most such samples represent a component of reflex testing to provide supplementary data to accompany the primary specimen report. These data typically require integrating into a more holistic report in the patient's record, with or without additional MDT discussion. We, therefore, recommend retaining such materials for 4 weeks after issue of the completed molecular genetic report, to ensure sufficient time for integration of the results into the patient's clinical record.

Long-term storage of extracted DNA and RNA in increasing volumes as molecular pathology expands raises logistical and environmental concerns. Laboratories of all sub-specialties within pathology have differing needs to address providing appropriate storage

facilities. To guarantee maintenance of specimen quality, nucleic acids may be stored in ULT (–80°C) freezers with systems in place to ensure continuity of power supply at all times. However, this is costly and cannot entirely exclude all risk of freezer failure. Long-term storage may be achieved more practically by freeze-drying samples or by simple drying of DNA onto filter paper. Records of the identity and tissue source of the specimen must be retained.

## 5.20 Microbiological cultures

Microbial cultures are derived from patient specimens, but they do not come under the scope of the Human Tissue Act unless they contain residual human cells and the intention of their storage is for use for a 'scheduled purpose' as defined in the Act.

Most positive cultures, including viral cultures, can be discarded within 24–48 hours of issuing a final authorised report. Specified cultures of clinical importance (e.g. blood culture isolates, cerebrospinal fluid isolates, enteric pathogens, multiple antibiotic resistant or methicillin-resistant *Staphylococcus aureus*, 'outbreak' strains, *M. tuberculosis*, Group A streptococci and unusual pathogens of clinical significance) should be retained for at least 7 days.

Where isolates have been referred to reference laboratories, they should be retained until receipt of the reference laboratory's final report; longer retention locally, with potential for hazard, is not needed under these circumstances and the reference sample in most cases remains available as a reserve.

Microbial isolates may be required to support investigation of local outbreaks of infection or for wider epidemiological investigations. Consideration should be given to longer retention of specific isolates, e.g. group A streptococci, in response to local or national information about such requirements. 6 months is recommended in such circumstances.

Whenever cultures are stored, pathology staff have a duty to ensure that specimens are held safely and securely to guard against accidental or non-accidental mishap. Some cultures of viable organisms and other preparations deemed hazardous may need to be stored in locked containers and in secure laboratory premises with restricted and controlled access.

Although non-human in derivation, nucleic acids derived from microbiological cultures, and the molecular diagnostic outputs from microbiology/virology laboratories relating to these, represent integral components of the patient's diagnostic record and should be retained in

line with the general guidance provided for human DNA and RNA (minimum of 4 weeks after final report unless with consent in a research context; see section 5.19.

### 5.21 Freeze-dried or other permanently preserved cultures

These should be retained permanently where archived in collections accessible for reference and research, such as those nationally or locally recognised. Security must be assured for hazardous samples, as outlined above.

### 5.22 Electrophoretic strips and immunofixation plates

Keep for 5 years (1 full 4-year UKAS accreditation cycle, assuming successful completion, plus 1 year margin). If digital or other photographic images of adequate quality for diagnosis are taken, then the original preparations may be discarded after a shorter interval but not until the final report has been verified and issued. The images should be stored as discussed above under section 4.15, bearing in mind the need to maintain the ability to read archived digital images when equipment is updated.

### 5.23 Specimens and derived materials prepared for technical verification and validation

A wide variety of preparations are made from the surplus of samples that have completed their diagnostic purpose to assist in the verification of new techniques, in the validation of assay consistency and in validation of data interpretation by operatives. Specific control materials are also prepared for calibration and quality assurance in many assays. The range of materials includes body fluids, tissue blocks and sections, microbiological isolates, nucleic acids and many other sample derivatives. If potentially permanent preparations are created, such as cytological or histological slides, freeze-dried materials or digital images, these can usually be regarded in the same light as internal quality control records and retained for 5 years (1 UKAS accreditation cycle plus a 1-year margin).

## 6 Documents, records, specimens and preparations: specific advice for transfusion laboratories

Minimum requirements for retention times may differ from those detailed in sections 4 and 5. In all instances, the longer period is recommended.

## 6.1 Documents and records

### 6.1.1 Request forms for grouping, antibody screening and cross-matching

Retain for 1 month.

### 6.1.2 Worksheets

Documentation to allow full traceability of all blood components, whether used or discarded, must be kept for at least 30 years[22] (as per the Blood Safety and Quality Regulations 2005, incorporating previous EU Blood Directives into UK law; see https://www.legislation.gov.uk/uksi/2005/50/contents/made). The requirement for traceability extends from initial collection to ultimate fate (transfusion or discard); for most hospital laboratories, this will start from receipt of products from the NHS Blood Transfusion Service. The data may be held in electronic form if robust archiving arrangements are in place. According to the 2005 Regulations, some worksheets in paper format may be discarded after 15 years although the expectation for electronic equivalents would be 30 years; therefore, we recommend retaining documents of this type, whatever their format, for 30 years.[22]

### 6.1.3 Results of grouping, antibody screening and other blood transfusion-related tests

Retain records for 30 years, in compliance with the Blood Safety and Quality Regulations 2005.[22]

### 6.1.4 Blood Bank Register, blood component audit trail and fates

Documentation to allow full traceability of donor and recipient must be kept for at least 30 years. The data may be held in electronic form if robust archiving arrangements are in place. For hospital laboratories, this record should include:

- blood component supplier identification
- issued blood component identification
- transfused recipient identification
- for blood units not transfused; confirmation of subsequent disposition (discard/other use)
- lot number(s) of derived component(s) if relevant
- date of transfusion or disposition (day, month and year).

### 6.1.5 Refrigerator and freezer charts

These should be kept for 15 years.

### 6.1.6 Records of serious events

Records of any serious events which may affect the quality or safety of blood or blood components must be retained for at least 15 years, as required by The Blood Safety and Quality Regulations, 2005.

### 6.1.7 Annual reports

These should be kept for 15 years (where required by The Blood Safety and Quality Regulations, 2005).

## 6.2 Specimens and preparations

Note that the following requirements may need modification in the case of high-risk samples, where the risk of storage is deemed to outweigh the potential benefits.

### 6.2.1 Blood for grouping, antibody screening and saving and/or cross-matching

Keep for a minimum of 7 days from group and screen, stored at 4°C. Samples must be available for a minimum of 3 days post-transfusion for investigation of acute transfusion reactions. Practically, requirements for separated serum or plasma below will dictate keeping for 14 days in most circumstances. Recently revised guidance from the British Committee for Standards in Haematology (BCSH) covers this topic in their *BCSH Guidelines for Pre-Transfusion Compatibility Procedures in Blood Transfusion Laboratories,* 2012.[41]

### 6.2.2 Separated serum or plasma, stored for transfusion purposes

Recipient plasma/serum samples should be stored for up to 14 days post-transfusion for investigation of a delayed transfusion reaction; see *BCSH Guidelines for Pre-Transfusion Compatibility Procedures in Blood Transfusion Laboratories*, 2012, as referenced in above. Storage of donated serum/plasma should optimally be at –30°C or colder. These materials may be stored for up to 3 months and guidelines for the timing of sample collection prior to blood transfusion must be followed. Archived blood donor samples should be stored by blood services for at least 3 years – preferably longer if it is practicable – to facilitate ‘look-back’ exercises.

# 7 Forensic material

## 7.1 Criminal cases

In cases where criminal proceedings can be anticipated, all recordings made at the autopsy – be they handwritten notes (by everyone, i.e. pathologist, technician, trainee, etc.), tape recordings, drawings or photographs – are all documentary records and, as such, their existence must be declared (disclosed) and they must be kept permanently. They must be available to all involved throughout the lifetime of the case, including appeals and other reinvestigations. They are not normally entered in the patient records.

## 7.2 Autopsy reports, specimens, archived material and other, where the deceased has been the subject of a Coroner's autopsy

Coroners or Procurators Fiscal have absolute dominion over autopsy reports. They are confidential to them and may not be released without their consent to any third party. We believe that it is good practice to lodge copies of autopsy reports in the deceased's notes, but the consent of the Coroner or Procurator Fiscal should be obtained. Guidance relating to retention of tissue specimens and the operation of the Human Tissue Act 2004 and Human Tissue Act (Scotland) 2006 in respect of such materials are covered in earlier parts of this document.

Independent pathology practitioners undertaking post-mortem examinations on behalf of Coroners or Procurators Fiscal must ensure that they use facilities to store records and specimens that have governance arrangements equal to those pertaining in NHS and academic institutions used for these purposes. Indeed, all practices regarding retention and disposal of post-mortem records and specimens by such practitioners in the UK must be directly comparable to those applicable to practitioners directly employed by HTA-licensed NHS or academic institutions.

# 8 Genetics

Medical genetics laboratories providing diagnostic services into the NHS are expected to be accredited by UKAS against the ISO 15189:2022 standard, as for other diagnostic laboratories. Additional guidance on record-keeping in genetic and genomic medicine can be found in the report of the Royal College of Physicians' Joint Committee on Genomics in Medicine *Consent and confidentiality in genomic medicine: Guidance on the use of genetic and genomic information in the clinic (3rd edition)*, 2019.[40]

The House of Lords' Select Committee on Science and Technology (2009) recommended that the provisions of the Data Protection Act should be the primary means of regulating human genetic databases. The response of the Human Genome Strategy Group (HGSG) is contained in their report *Building on our inheritance: Genomic technology in healthcare* (2012).[42] Their recommendation is that the UK Departments of Health, in partnership with the HGSG's Bioinformatics Subgroup and other relevant partners, should develop proposals to establish a central repository for storing genomic and genetic data, plus relevant phenotypic data from patients, with the capacity to provide biomedical informatics services and an open-data platform that small and medium-sized enterprises can build upon.[42]

## 8.1 Storage of material following analyses of nucleic acids

Developing technologies means that there is ever-increasing variety of hard copy and/or electronic outputs associated with the analysis and interpretation of diagnostic tests using nucleic acids. It is recommended that such outputs should be stored for at least 30 years unless the technical details and interpretation are transcribed into permanently accessible report formats authorised by senior clinical laboratory staff or pathologists. The latter reports should then be kept for at least 30 years, as for other pathology reports, and the machine outputs may be regarded as working documents. For such working documents, storage for at least 5 years (1 UKAS accreditation cycle plus a safety margin) is recommended. Further challenges to this approach are posed by the development of next-generation sequencing (NGS) technologies, which generate files of many terabytes. Immediate needs can be met by transcription of specific results into conventional diagnostic reports. However, much of the efficiency of these technologies will be compromised if the raw data files are discarded, requiring repeat sampling and re-sequencing when analysis of new biomarkers is required. Personalised data storage strategies will be needed as NGS methods become routine unless massive data storage capacity can be assured for collective holdings.

The following is a list of current outputs, which is not meant to be comprehensive as new technologies and outputs are evolving continually.

- Molecular genetics:
  - storage of denaturing high performance liquid chromatography/wave profiles
  - storage of quantitative polymerase chain reaction data

  - storage of sequence, mutation and polymorphism information
  - storage of dosage profiles (multiplex amplification and probe hybridisation/multiplex ligation-dependent probe amplification)
  - storage of autoradiographs, SSCP, PTT DGGE (heteroduplex) gels
  - other agarose gels.
- Molecular cytogenetics:
  - storage of all FISH imaging data both qualitative (e.g. microdeletion test) and quantitative (e.g. CGH)
  - storage of array data (Array-CGH, cDNA micro-array, etc.)
  - all other diagnostic outputs associated with detection of genomic dosage imbalances.

# 9 Retention of records and materials by providers of external quality assessment

Most external quality assessment (EQA)/proficiency testing providers maintain the capacity to regenerate reports of participants' performance rather than the individual records themselves. This capacity should be maintained for at least 5 years to allow retrospective review in the event of an official enquiry into performance and as a back-up for retrieval of data needed by participants for their next cycle of UKAS accreditation. This should apply equally to laboratory technical EQA schemes and schemes addressing clinical competence. Updating of electronic records with any change of IT systems should be assured as described above (see section 2.1).

## 9.1 Additional records to be kept by EQA providers

Participants' returns (electronic or hard copy) received for data entry. These should be kept for at least 3 months (or 1 month after the report has been sent to the participant, if longer), as working documents, to facilitate identification, checking and correction of discrepancies.

## 9.2 Other records

- Performance surveillance records including communications with, and complaints from, participants.

- Ethical approval and consent records for donated material.
- Quality assurance and safety documentation relating to circulated materials, including virus testing, where relevant, and homogeneity results from third-party suppliers
- Records of contractual agreements with commercial and NHS suppliers.

Storage of such records is recommended for at least 5 years.

## 9.3 Retention times for materials stored by EQA providers

The usual reasons for retention of materials after distribution are to provide further samples for participants to use in troubleshooting or verification of new or amended procedures, equipment or reagents and to assist in investigating or resolving anomalous performance data. As most materials have limited stability, no universally applicable recommendation is appropriate. Retention of degraded material has limited value.

Appropriate retention periods should, therefore, be determined through risk assessment, based primarily on consideration of:

- the stability of the material in storage
- the expected uses of such material
- the risk of not retaining such material
- any special features of some samples (e.g. clinical specimens, reference method values)

Relevant materials comprise:

- reference samples of the materials distributed to participants, if any remain (e.g. liquid or freeze-dried plasma/serum, whole blood, urine, slides, tissue blocks, bacteriological cultures, DNA, digital images)
- reference samples tested ‘in house’ in preparation or in parallel with EQA distributions

Storage is recommended for at least 5 years if the material represents or can be converted to a valid ‘permanent’ preparation. Retention should not take precedence over legitimate use. Degradable materials should be kept, if possible, for 1 month after the relevant circulation has been assessed.

### 9.4 Cells, tissues and other materials stored prior to preparation and circulation

Such materials will be stored until used or disposed of if surplus to requirements.

# 10 Disposal of human tissue

## 10.1 General

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 HTA has included advice on disposal in each of its Codes of Practice where disposal is relevant (Code B – post-mortem examination;[27] Code C – anatomical examination;[43] Code D – public display;[44] Code E – research[45]). The current versions of the codes are available from the Authority's website: https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/codes-practice.

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, as a specific and documented clinical waste stream, 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 not undertaken on hospital premises within the governance framework of a hospital Trust, disposal may be outsourced to an appropriate organisation certified to meet all regulatory (including environmental) requirements for sensitive clinical waste disposal.

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, it is the responsibility of the laboratory to indicate any hazards that may be present in the returned material. A record of the transfer must be placed in the patient's notes and correspondence relating to the transfer should be kept by the laboratory for at least 10 years.

## 10.2 Fetal tissues

Currently, fetal remains of less than 24 weeks' gestation are not defined as human remains but are regarded as components of the mother's tissue. Hospital systems for the sensitive disposal of such tissue should comply with HTA guidance.[36]

Clinical staff should ask the mother to provide consent for histological examination of products of conception, including ectopic gestations. The surgical consent process is not directly controlled by pathologists, but it should include information about (and consent for) histological examination and options for disposal, in line with HTA guidance. The option of taking away the material for a private funeral should be offered. Where the wishes of parents are known, they should be followed.

Laboratories should have a policy for the disposal of samples containing fetal parts. It should comply with guidance issued the Royal College of Nursing[46] and guidance from the HTA.[47]

It is acknowledged that crematoria are licensed for the cremation of human remains only, but it is considered quite reasonable for such remains to be buried or cremated if this is the wish of the parents. Communal burial or cremation is acceptable where parents do not wish to make their own arrangements, provided that the guidance of the Institute of Cemetery and Crematorium Management is adhered to. This guidance includes a requirement that hospitals maintain a register of the disposal of fetal remains and that this register, with all other documentation relating to the disposal of fetuses, is kept for a minimum of 50 years.[48]

Procedures for handling material from terminations of pregnancy may differ, as histological examination should rarely be required; the Abortion Act 1967 imposes a requirement to maintain confidentiality. Nevertheless, efforts should be made to comply with any known wishes of the parents, as set out in the HTA's guidance of March 2015.[47]

Where doubt exists, guidance should be sought. The advice of the hospital chaplaincy service or a clinical ethics committee (if available) may be of value. The HTA can also advise on such matters.

# 11 Medicolegal value of archived material

For forensic purposes (whether civil, criminal or coronial), documents consisting of original and contemporaneous notes are the most desirable. Handwritten working records are regarded as the best documentary evidence. Hard copy reports lodged in the patient's medical records are preferable to records held electronically in the laboratory or in integrated electronically held patient information systems. This is especially applicable to autopsy and surgical pathology reports but applies to laboratory reports of all kinds. The primary value of direct witness testimony on oath should not be forgotten.

However, courts are prepared to accept computerised records in civil cases and, provided additional safeguards are complied with, also in criminal cases. In criminal and civil cases, statements contained in documents that are received in evidence may be proven by copies of the original documents, provided that such copies are adequately authenticated. Thus, although original records are desirable, this must be balanced against the convenience and practicality of making copies or preserving them in computerised or microfilm form. However, as a matter of practice, it is necessary to maintain records of the fact of computerisation or of the copying process in relation to any documents to facilitate subsequent authentication and admissibility.

Archived material is important for 'look-back' exercises, where a historical risk (say of a blood-borne infectious agent in the case of transfusion practice) is being sought, or reviews of alleged reporting errors or misjudgements are being commissioned. In such circumstances, the material used must usually be patient-identifiable, but precautions should be taken to secure appropriate confidentiality. Under the General Medical Council's (GMC) powers to regulate fitness-to-practise of individual pathologists, both documentary and specimen archives may be scrutinised.

# 12 Specimens and records for teaching

Selected photographs, preserved cultures, mounted specimens and stained slides, with the relevant tissue blocks in the case of surgical pathology, are an invaluable resource and should be lodged, adequately indexed, described and catalogued, in collections either in the laboratory of first instance or in local, central or national archives. If diagnostic requirements have been fulfilled and the integrity of patients' clinical records will not be compromised, patient identity should be protected by irreversible anonymisation or, as a minimum, a secure coding process for linked anonymisation. Digital images, which are being used increasingly, should be treated in an equivalent manner.

Under the Human Tissue Act 2004, the public display of human biological samples from a deceased person, even if anonymised, is unlawful unless the person (not a relative) has given consent; if the person has died, they must have given consent in writing and this must have been witnessed.[1] These requirements do not apply to material already held before 1 September 2006. A HTA licence is required for public display of human biological samples that have been taken from the body of a deceased person.

# 13 Research data and records

Confidential named patient data (documentation) collected in the course of investigation and held separately from patients' records should be destroyed or anonymised 6 months after the research has been completed, the data have been analysed and final publication of findings has been made. If further recourse to identifiable information is anticipated, it should be kept for as long as such a need may exist, if this is permissible under the Data Protection Act (2018); advice should be sought.

Working records and other research data should be retained for at least 10 years to rebut allegations of scientific fraud but, wherever possible, these records should not include patient-identifiable data unless consent for such retention has been obtained. Records and clinical trial data on medicines must be kept for at least 15 years. The provisions of the Data Protection Act (2018) must be observed for these, as for other pathological records. The Medical Research Council's *Good research practice* (2014)[49] and *Human tissue and biological samples for use in research: Operational and ethical guidelines* (2019)[50] contain further advice.

Universities and other academic institutions will also have their own rules, which may involve longer storage of such information; local guidance should be sought, as appropriate. In general, such local policies will align with the broad principles of UK Research and Innovation's *'Policy on the Governance of Good Research Practice*.[51]

# 14 Confidentiality of records

The GMC considers that doctors carry a prime responsibility for the protection of information given to them by patients or obtained in confidence about patients. They must, therefore, take steps to ensure, as far as lies in their control, that the records, manual or computerised, that they keep, to which they have access, or which they transmit are protected by effective security systems with adequate procedures to prevent improper disclosure. The operation of LIMS and local implementation of aspects of information technology in accordance with NHS strategies in England and the devolved UK nations should be conducted in accordance with this general principle, paying particular attention to data security.

Confidential information on patients may be transmitted by fax or from 1 computer to another. With increasing access to secure electronic transmission via the internet, use of fax communication should be substituted with a more secure method wherever feasible. It

is important to ensure that the information is sent to the correct location and that only the intended recipient will be able to access it. Both sender and recipient must establish arrangements to allow this, compliant with their organisations' data security policies. The primary responsibility lies with the sender.

Confidential data transmitted electronically, especially over the internet, for example by email, must be assumed to be liable to interception and, therefore, must be encrypted unless the addresses of both sender and recipient are within the secure NHS network (e.g. email addresses with an 'nhs.net' suffix and NHS network links established between GP surgeries and hospitals). Where data are shared via web-based access to information held on a remote server or in the cloud, security of access must be assured. The most suitable methods of ensuring data security will vary with the circumstances and over time. Institutional policy should be followed and, with increasing requirements for such transmission, pathologists should remain vigilant in ensuring that confidential information (including information regarding deceased persons) is not accessed by unauthorised individuals.

In the case of specimens and preparations, the pathologist has a duty to ensure that they are kept not only confidentially, but also safely and securely, so as to guard against accidental or non-accidental mishap. Some specimens and derived materials may need to be stored in locked containers and in secure laboratory premises with restricted and controlled access. Back-up procedures for electronic records must be robust and secure; copies of particularly valuable records, whether paper or electronic, may need to be kept in fireproof containers and possibly also in duplicate, on different premises.

# 15 Long-term or permanent retention of records

Retention of records and specimens for historical purposes beyond 30 years, other than in the case of recognised historical or teaching or research archives already kept in approved places of deposit (which may include the premises of medical institutions), requires an application to the Lord Chancellor through the Keeper of Public Records, if there is a need for them to be retained by a Health Authority rather than transferred to a place of deposit or destroyed. The statutory position of health records in Scotland is different and there is equivalent guidance for Wales and Northern Ireland; see Further Guidance.

Pathologists and other laboratory professionals should be prepared for records, including stored pathological material, to be destroyed after 30 years unless they wish to state a

case for their further retention (e.g. for teaching or research) as outlined in section 12, or unless the records are already secured in an approved place of deposit. A log or logs containing details of clinical records and patient samples disposed of (dates, nature of materials, methods used) should be kept.

Property in pathological records, as in other health service (NHS) records and items, is ultimately vested in the Secretary of State for Health or in NHS Foundation Trusts and, in Scotland, in Health Boards. Human tissue samples can accrue property rights if skill has been used to modify them. The level of skill needed is not defined in law, but this argument is likely to apply to fixed and processed tissue samples, so these too could be argued to be the property of the NHS Trust where the work was done. However, in practice, this property right will in almost always be ceded to the patient if requested. In private practice, ownership is vested in the maker of the records. In both instances, it is subject to the restraints of professional regulation and to statutory and common law. Property in records, reports and materials relating to procedures within the jurisdiction of an appointed and legally competent authority (Coroner, Procurator Fiscal) is not vested in the same way. The long-term retention of documentary material is subject to the guidance of the Keeper of Public Records and, in the NHS, also to that of the officer appointed in accordance with the records management codes applicable in England, Wales, Scotland and Northern Ireland.

Use of pathological archives for research, teaching, training, scholarship, disease surveillance or quality control raises important sociopolitical, ethical and legal issues. Long-term retention of material of potential value in genetic or other medical research is desirable, but its use and access to it must be subject to the law, professional guidance and ethical standards.

# 16 A note on veterinary pathology specimens and records

The Royal College of Pathologists has issued guidance, based on similar principles to those in this document, for the storage and retention of animal tissues and records.[52]

# Further guidance

## Medical records management

Department of Health and Social Care (England). *Records Management Code of Practice 2023*. Available at: https://transform.england.nhs.uk/media/documents/NHSE_Records_Management_CoP_2023_V5.pdf

Scottish Government. *Records Management Code of Practice for Health and Social Care 2024*. Available at: https://www.gov.scot/publications/records-management-code-practice-health-social-care/

Welsh Government. *Records Management Code of Practice for Health and Social Care 2022*. Available at: https://www.gov.wales/sites/default/files/publications/2022-03/records-management-code-of-practice-for-health-and-social-care-2022.pdf

Northern Ireland Department of Health. *Records Management: Good Management, Good Records 2017.* Available at: https://www.health-ni.gov.uk/articles/gmgr-records-management

British Medical Association. *Retention of Health Records*. Available at: https://www.bma.org.uk/advice-and-support/ethics/confidentiality-and-health-records/retention-of-health-records

## Data protection, information governance and electronic records

UK Government. *The Data Protection Act 2018*. Available at: https://www.gov.uk/government/collections/data-protection-act-2018

Information Commissioner's Office. *UK GDPR Guidance and resources*. Available at: https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/

Institute of Biomedical Science. *Communication of pathology results*. Available at: www.ibms.org/go/media/publications/professional-guidance

Institute of Biomedical Science. *Patient sample and request form identification criteria*, 2019. Available at: www.ibms.org/go/media/publications/professional-guidance

The National Archives. *Preserving digital records*. Available at: https://www.nationalarchives.gov.uk/information-management/manage-information/preserving-digital-records/

The Royal College of Pathologists. *Communication of critical and unexpected pathology findings*. Available at: https://www.rcpath.org/profession/guidelines/cross-specialty-publications.html

## Digital histopathology

The Royal College of Pathologists. *Best practice recommendations for implementing digital pathology*. Available at: https://www.rcpath.org/profession/guidelines/specialty-specific-publications.html

## Laboratory accreditation

United Kingdom Accreditation Service: www.ukas.com

International Standards Organisation (ISO). For more information about ISO 15189:2022 (medical laboratories), ISO 17043 (proficiency testing), see www.iso.org. Copies of the standards may also be purchased from ISO.

## Clinical genetics

NHS Newborn Blood Spot Screening Programme: https://www.gov.uk/government/collections/nhs-newborn-blood-spot-nbs-screening-programme

## Point-of-care testing

MHRA: www.mhra.gov.uk

MHRA. *Management and use of IVD point of care test devices*. Available at: https://www.gov.uk/government/publications/in-vitro-diagnostic-point-of-care-test-devices/management-and-use-of-ivd-point-of-care-test-devices

## Transfusion and transplantation

UK Government. *Blood Safety and Quality Regulations, 2005 (Setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components*). Available at: www.legislation.gov.uk/uksi/2005/50/pdfs/uksi_20050050_en.pdf

Serious Hazards of Transfusion guidance: www.shotuk.org/resources

SaBTO. *Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used in Transplantation*, 2011. Available at:

www.gov.uk/government/publications/guidance-on-the-microbiological-safety-of-human-organs-tissues-and-cells-used-in-transplantation

## Post-mortem retention of organs and tissue

Department of Health. *Disposal of Existing Holdings of Post-Mortem Material*, 2007. Available at: webarchive.nationalarchives.gov.uk/20080910134953/dh.gov.uk/en/Policyandguidance/Healthandsocialcaretopics/Tissue/Tissuegeneralinformation/DH_4137493

Institute of Cemetery and Crematorium Management. *The Sensitive Disposal of Fetal Remains: Policy and Guidance for Burial and Cremation Authorities and Companies*, 2015. Available at: https://www.iccm-uk.com/iccm/wp-content/library/iccm_Fetal%20Remains%20Policy%20Updated%20Sept2015%20.pdf

Human Tissue Authority. *Guidance on the Disposal of Pregnancy Remains Following Pregnancy Loss or Termination,* 2015. Available at: https://content.hta.gov.uk/sites/default/files/2021-06/Guidance%20on%20the%20disposal%20of%20pregnacy%20remains.pdf

The Department for Culture, Media and Sport. *Guidance for the Care of Human Remains in Museums,* 2005. Available at: https://collectionstrust.org.uk/resource/guidance-for-the-care-of-human-remains-in-museums/

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Forensic Science Regulator. *Codes of Practice and Conduct for forensic science providers and practitioners in the Criminal Justice System*. Available at: https://www.gov.uk/government/collections/forensic-science-providers-codes-of-practice-and-conduct

Metropolitan Police. *Policy on the Handling and Storage of Frozen Exhibits and Samples within Operational Command Units*. Available at: https://www.met.police.uk/cy-GB/SysSiteAssets/foi-media/metropolitan-police/policies/handling-and-storage-of-frozen-exhibits-and-samples-within-operational-command-units---policy

## The Human Tissue Act and HTA

UK Government. *The Human Tissue Act 2004*. Available at: www.legislation.gov.uk/ukpga/2004/30/contents

Scottish Government. *The Human Tissue Act (Scotland) 2006*. Available at: https://www.legislation.gov.uk/asp/2006/4/contents

The HTA: www.hta.gov.uk

HTA. *Guidance for professionals*. Available at: https://www.hta.gov.uk/guidance-professionals

HTA. *Codes of Practice*: *Code A: Guiding Principles and the Fundamental Principle of Consent*. Available at: https://content.hta.gov.uk/sites/default/files/2023-06/Code%20A%20-%20Guiding%20principles%20and%20the%20fundamental%20principle%20of%20consent.pdf

HTA. *Codes of Practice: Code B: Post-mortem Examination*. Available at: https://content.hta.gov.uk/sites/default/files/2023-06/Code%20B%20-%20Post-mortem%20examination.pdf

HTA. *Codes of Practice: Code C: Anatomical Examination*. Available at: https://content.hta.gov.uk/sites/default/files/2023-06/Code%20C%20-%20Anatomical%20examination.pdf

HTA. *Codes of Practice: Code D: Public Display*. Available at: https://content.hta.gov.uk/sites/default/files/2023-06/Code%20D%20-%20Public%20Display.pdf

HTA. *Codes of Practice: Code E: Research*. Available at: https://content.hta.gov.uk/sites/default/files/2023-06/Code%20E%20-%20Research.pdf

HTA. *Codes of Practice: Code F (Part 1): Living Organ Donation*. Available at: https://content.hta.gov.uk/sites/default/files/2023-06/Code%20F%20Part%20one%20-%20Living%20organ%20donation.pdf

HTA. *Codes of Practice: Code F (Part 2): Deceased Organ and Tissue Donation*. Available at: https://content.hta.gov.uk/sites/default/files/2023-07/Code%20F%20part%20two%20-%20Deceased%20organ%20and%20tissue%20donation.pdf

HTA. *Codes of Practice: Code G: Donation of Allogeneic Bone Marrow and Peripheral Blood Stem Cells for Transplantation*. Available at: https://content.hta.gov.uk/sites/default/files/2023-06/Code%20G%20-

%20Donation%20of%20allogeneic%20bone%20marrow%20and%20peripheral%20blood%20stem%20cells%20for%20transplantation.pdf

HTA. *Code of Practice on the Human Transplantation (Wales) Act 2013 (updated June 2023)*. Available at: https://content.hta.gov.uk/sites/default/files/2023-06/Code%20of%20Practice%20on%20the%20Human%20Transplantation%20%28Wales%29%20Act%202013.pdf

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HTA. *Guidance on the disposal of pregnancy remains following pregnancy loss or termination, reviewed in April 2021*. Available at: https://www.hta.gov.uk/guidance-professionals/guidance-sector/post-mortem/guidance-sensitive-handling-pregnancy-remains

## Additional relevant reports and guidance

Institute of Biomedical Science's professional guidance: www.ibms.org/go/media/publications/professional-guidance

UK Government. *The Human Tissue (Quality and Safety for Human Application) Regulations, 2007*. Available at: www.legislation.gov.uk/uksi/2007/1523/resources

NHS. *Infectious Diseases in Pregnancy Screening Programme Standards*. Available at: https://www.gov.uk/government/publications/infectious-diseases-in-pregnancy-screening-programme-standards

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3. UK Government. *Human Tissue Act (Scotland) 2006.* Accessed August 2024. Available at: https://www.legislation.gov.uk/asp/2006/4/contents

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# Appendix 1 Summary of records retention guidance

| Record type | Document section | Minimum retention unless stated otherwise | Related guidance |
|---|---|---|---|
| 'Simple' request form (see below for variations) | 4.1 | Until report authorised, longer than 1 month not required. If uncomplicated, 1 week is sufficient | |
| Request form containing clinical information not transcribed into report or otherwise readily accessible in patient's notes | 4.1 | 30 years | |
| Request form used as laboratory worksheet | 4.1 | Retain as part of the laboratory working record | |
| Minor financial document used for accounting purposes | 4.1 | Seek local advice from accounts department | |
| Records of specimens disposed of without analysis, together with primary request documentation and reason for discard | 4.1 | 5 years (4-year UKAS accreditation cycle plus 1 year margin; extended if needed until accreditation complete) | IBMS Patient sample and request form identification criteria: www.ibms.org/go/media/publications/professional-guidance |
| Records of specimens received by a lab | 4.2 | 5 years (4-year UKAS accreditation cycle plus 1 year margin; extended if needed until accreditation complete) | |
| Mortuary registers | 4.3 | 30 years minimum | |
| SOP protocols | 4.4 | Depends on context/discipline; 5 years to 30 years | |

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| Worksheets for permanent/semi-permanent specimens | 4.5 | At least until final report has been authorised | |
| Worksheets for temporary specimens (serum, body fluid and faecal samples) | 4.5 | At least until final report has been authorised | |
| Working records of test results for named patients, if all results included in separate stored report | 4.6 | As for worksheets – at least until final report has been authorised | |
| Working records of test results for named patients, if results are NOT in separate stored report | 4.6 | Varies with specialty and purpose; up to 30 years if the record represents a unique component of the patient's primary medical record | |
| Records of telephoned/e-mailed reports | 4.7 | 5 years (4-year UKAS accreditation cycle plus 1 year margin; extended if needed until accreditation complete) | |
| Records of telephone calls giving clinical management advice | 4.7 | 30 years, as for other correspondence, ideally within the patient's medical notes | |
| Records of e-mails giving clinical management advice | 4.7 | 30 years, as for other correspondence, ideally within the patient's notes | IBMS Communication of pathology results: https://www.ibms.org/resources/professional-guidance/<br>College guidance: Communication of critical and unexpected pathology results: https://www.rcpath.org/profession/guidelines/cross-specialty-publications.html |

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| Report copies (electronic/physical), including those used for communication between laboratories | 4.8 | 6 months, or as needed for operational purposes | |
| Report copies (electronic/physical) communicated between laboratories | 4.8 | 6 months, or as needed for operational purposes | |
| Report copies for communication/aide memoire | 4.8 | Disposed when function complete | |
| Report copies sent by fax | 4.8 | Disposed after sending. Transmission details recorded | |
| Report copies to replace original | 4.8 | As original | |
| Report copies as part of training portfolios | 4.8 | 5 years after training completion | |
| Report copies in revalidation portfolios | 4.8 | Length of 1 revalidation cycle (currently 5 years) | |
| Surgical (histological) reports (electronic/physical) | 4.9 | 30 years | |
| Post-mortem report copies (electronic/physical) | 4.10 | 8 years | |
| Post-mortem report copies of violent/suspicious deaths | 4.10 | 30 years | |
| Patient correspondence not lodged in patient's record | 4.11 | 30 years | |
| Patient correspondence by email | 4.11 | See local medical records and IT policies | |

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| POCT specimens log | 4.12 | Instrument lifetime | |
| Bound copies of reports and records | 4.13 | 30 years | |
| Pathological archive or museum catalogues | 4.14 | Time specimens held or until catalogue updated | |
| Photographs as primary source for diagnosis | 4.15 | 30 years if not interpreted into a text-based report; 8 years for digital histopathology images | College guidance on Best practice recommendations for implementing digital pathology: https://www.rcpath.org/profession/guidelines/specialty-specific-publications.html |
| Images of pathological specimens | 4.15 | As long as recommended for original specimens | |
| Digitised images in genetics testing protocols transcribed into report | 4.15 | Treated as semi-permanent preparations or working documents | |
| Digitised images in genetics testing protocols NOT transcribed into report | 4.15 | 30 years | |
| Photographic images for communication/aide memoire | 4.15 | Disposed when function complete | |
| Batch records | 4.16 | 5 years (4-year UKAS accreditation cycle plus 1 year margin; extended if needed until accreditation complete) | |
| Internal quality control records | 4.17 | 5 years (4-year UKAS accreditation cycle plus 1 year margin; extended if needed until accreditation complete) | |

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| External quality assessment records | 4.18 | 5 years (4-year UKAS accreditation cycle plus 1 year margin; extended if needed until accreditation complete) | |
| Accreditation documents and records of inspection | 4.19 | 8 years minimum (2 accreditation cycles with full UKAS accreditation achieved) | |
| Primary traces of temperature records for fridges and freezers | 4.20 | 2 months (unless used for purposes covered in section 6) | Blood Safety and Quality Regulations: https://www.legislation.gov.uk/uksi/2005/50/contents/made |
| Temperature records for fridges and freezers; summarised data, if blood for transfusion | 4.20 | 15 years | |
| Temperature records for fridges and freezers; summarised data, if long-term storage of specimens not for human application | 4.20 | 8 years | |
| Temperature records for fridges and freezers; summarised data, if storage of analytical reagents/temporary specimens | 4.20 | 5 years (4-year UKAS accreditation cycle plus 1 year margin; extended if needed until accreditation complete) | |
| Temperature records for fridges and freezers; summarised data if for very long-term storage | 4.20 | Lifetime of equipment | |
| Temperature records for fridges and freezers; summarised data, if for biobanked specimens | 4.20 | Lifetime of specimen | |
| Temperature records for fridges and freezers; summarised data, if | 4.20 | As long as oldest sample held | Metropolitan Police Policy on the handling and storage of frozen exhibits |

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| for forensic samples for potential medicolegal use | | | and samples within operational command units: https://www.met.police.uk/cy-GB/SysSiteAssets/foi-media/metropolitan-police/policies/handling-and-storage-of-frozen-exhibits-and-samples-within-operational-command-units---policy |
| Equipment maintenance logs | 4.21 | Instrument lifetime plus 1 full accreditation cycle of 4 years | |
| Service inspection and instrument maintenance records | 4.22 | Instrument lifetime plus 1 full accreditation cycle of 4 years | |
| Records relevant to diagnostic products or equipment | 4.23 | 5 years (4-year UKAS accreditation cycle plus 1 year margin; extended if needed until accreditation complete) | |
| Assay validation and verification records | 4.24 | 5 years (4-year UKAS accreditation cycle plus 1 year margin; extended if needed until accreditation complete) | |
| Records of specimens relevant to cell/tissue transplantation not in patient records | 4.26 | 30 years or lifetime of recipient, whichever longer | |
| Records from donor tissues not used for transplantation | 4.26 | Same as equivalent samples/records for a patient | Human Tissue Authority guidance on human application: https://www.hta.gov.uk/guidance-professionals/guidance-sector/human-application |

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| Records of fertility specimens not in patient records | 4.27 | 30 years | |
| Transplant-related virology/microbiology records | 5.2 | 30 years | Government guidance on SaBTO microbiological safety guidelines: https://www.gov.uk/government/publications/guidance-on-the-microbiological-safety-of-human-organs-tissues-and-cells-used-in-transplantation |
| Operational records in biosample banking | 5.12 | As for clinical governance in diagnostic specimens | |
| Biobank records of internal and external quality assurance performance | 5.12 | 12 years | |
| Biobank records of adopted sub-collection | 5.12 | As for ongoing collections | |
| Transfusion request forms | 6.1.1 | 1 month | |
| Transfusion-related worksheets (electronic/physical) | 6.1.2 | 30 years | The Blood Safety and Quality Regulations 2005: https://www.legislation.gov.uk/uksi/2005/50/contents/made |
| Results of transfusion-related tests | 6.1.3 | 30 years | The Blood Safety and Quality Regulations 2005: https://www.legislation.gov.uk/uksi/2005/50/contents/made |
| Blood Bank Register blood component audit trail records (electronic/physical) | 6.1.4 | 30 years | |

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| Blood Bank refrigerator and freezer charts | 6.1.5 | 15 years | |
| Transfusion records of serious events | 6.1.6 | 15 years | |
| Transfusion service annual reports | 6.1.7 | 15 years | |
| Criminal case records in any medium | 7.1 | Permanently | |
| Machine outputs from diagnostic tests using nucleic acids | 8.1 | 5 years (4-year UKAS accreditation cycle plus 1 year margin; extended if needed until accreditation complete) | |
| EQA Providers – summary data to regenerate records of external quality assessment (EQA) proficiency testing, if required | 9 | 5 years (4-year UKAS accreditation cycle plus 1 year margin; extended if needed until accreditation complete) | |
| EQA Providers – participants' returns (electronic/physical) from EQA providers | 9.1 | 3 months or 1 month after report sent to participant if longer | |
| EQA Providers – performance surveillance records in EQA | 9.2 | 5 years (4-year UKAS accreditation cycle plus 1 year margin; extended if needed until accreditation complete) | |
| Research – confidential patient documentation held separately from patient records | 13 | Destroyed/anonymised 6 months after completion of research | |
| Research – working records and other research data | 13 | 10 years | |

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| Research – records and clinical trial data on medicines | 13 | 15 years | The Medical Research Council's *Good Research Practice* (2014): https://www.ukri.org/publications/principles-and-guidelines-for-good-research-practice/<br>and *Human tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines* (2019): https://www.ukri.org/publications/human-tissue-and-biological-samples-for-use-in-research/ |

## Appendix 2 Summary of specimen retention guidance

| Specimen type | Document section | Minimum retention unless stated otherwise | Related guidance |
|---|---|---|---|
| Material containing human cells obtained post mortem | 5.1 | Prohibited unless licence from HTA and consent | Human Tissue Authority legislation: https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/legislation |
| Post-mortem samples of human tissue retained by Coroner | 5.1 | As long as required to fulfil Coroner's duties | |
| Samples for criminal investigations | 5.1 | As long as required for investigation | Forensic Capability Network guidance on retention: https://www.fcn.police.uk/node/142 |
| Post-mortem samples no longer required by Coroner or criminal justice system | 5.1 | Consent needed in Schedule 1 of HTA | Human Tissue Authority Code of Practice: https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/codes-practice |
| Sample from living patient no longer required for diagnostic purposes | 5.1 | Consent needed in Schedule 1 of HTA | |
| Plasma and serum | 5.2 | 48 hours after final report | |
| Plasma and serum with expectation of follow up | 5.2 | Retained until follow-up tests | |

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| Serum for transplantation matching | 5.2 | Lifetime of recipient | |
| Transplant virology/microbiology serum samples | 5.2 | 10 years donor material, 30 years recipient material | Government guidance on SaBTO microbiological safety guidelines: https://www.gov.uk/government/publications/guidance-on-the-microbiological-safety-of-human-organs-tissues-and-cells-used-in-transplantation |
| Serum from first pregnancy booking visit | 5.2 | 2 years | Government guidance on infectious diseases in pregnancy screening: https://www.gov.uk/government/publications/infectious-diseases-in-pregnancy-screening-programme-standards |
| Sera for virological assessment of patients dialysed overseas | 5.2 | 1 year | |
| Fetal serum from cordocentesis | 5.2 | 30 years | |
| Serum after needlestick injury/hazardous exposure | 5.2 | 2 years | |
| Left-over sera or plasma | 5.2 | 1 year | |
| Newborn blood spot screening cards | 5.3 | 5 years | Government guidance on newborn blood spot screening: https://www.gov.uk/government/publications/newborn-blood-spot-screening-code-of-practice-for-the-retention-and-storage-of-residual-spots |

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| Faecal suspensions used as samples for FIT bowel cancer screening | 5.4 | 48 hours after report authorisation | |
| Body fluids, aspirates and swabs | 5.6 | 48 hours after final report | |
| Deteriorated body fluids, aspirates and swabs | 5.6 | Discarded immediately after analysis | |
| Coagulation samples | 5.6 | 24 hours | |
| Easily and non-invasively repeated samples | 5.6 | Destroyed once examination concluded and final report issued | |
| Whole blood samples for FBC | 5.7 | 24 hours | |
| Donor lymphocyte preparations | 5.8 | Lifetime of all recipients | The Blood Safety and Quality Regulations 2005: https://www.legislation.gov.uk/uksi/2005/50/contents/made<br>Human Tissue Authority Code of Practice: https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/codes-practice |
| Microscope slides of frozen sections | 5.9 | As for other diagnostic histological sections | |
| Residual tissue of frozen sections | 5.9 | Process and retain as fixed tissue block(s) once frozen section examination is complete | |
| Cytogenic cell suspensions in fixative | 5.10 | 3 months (longer if space permits) | |

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| Wax/resin embedded blocks for histology | 5.11 | 30 years, if storage facilities permit. Blocks representing cancer diagnoses must not be discarded sooner and paediatric samples must be kept until the patient is >25 years old. For other specimens, disposal after 10 years may be considered, with caveats as described in 5.11. | |
| Wax/resin embedded blocks for histology with rare pathology | 5.11 | At least 30 years or transfer to licensed biobank | |
| Post-mortem wax/resin embedded blocks for histology | 5.11 | According to consent given for examination | |
| Biosamples held for research in approved biobank facilities | 5.12 | Retain and use in accordance with consent given until sample exhausted | |
| Tissue blocks/slides released for research | 5.13 | Residual material returned to hospital source for ongoing storage once research use complete. Aim to release sections and retain primary material (tissue block) at source if possible | |
| Electron microscopy blocks | 5.14 | 30 years | |
| Electron microscopy grids for human tissue diagnosis | 5.15 | 8 years, preferably longer | |
| Electron microscopy grids for virus identification | 5.15 | 48 hours after final report | |

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| Photographic images prepared from electron microscopy grids | 5.15 | 8 years, or 30 years if not interpreted into a text-based report | |
| Wet tissue surgical specimens from living patients | 5.16 | 4 weeks after final report issued. Longer if anticipating report on further tests | |
| Post-mortem wet tissue specimens | 5.16 | As authorised by Coroner | |
| Whole organs, wet tissue or fetal specimens retained before HTA 2004 | 5.16 | Only keep if intending to use for a scheduled purpose under the HTA or for human health education/training | |
| Teaching collections in museums | 5.17 | Can be retained permanently | |
| Microbiological and easily repeatable stained slides | 5.18 | 7 days after final report | |
| Gram-stained preparations from culture plates | 5.18 | Discarded immediately after use | |
| Blood films | 5.18 | 7 days after final report | |
| Cytogenetic slide preparations | 5.18 | 2 years after final report, if photographed; otherwise 5 years | |
| Digital or other photographic images of molecular genetic/cytogenetic slide preparations | 5.18 | 8 years, if interpreted into a text-based final report; 30 years if the uninterpreted image constitutes the diagnostic report | |
| Fluorescently stained slides | 5.18 | Until final report issued | |
| Stained bone marrow aspirate films | 5.18 | 8 years minimum and longer if possible, up to 30 years | |

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| Surplus unstained bone marrow aspirate films | 5.18 | Discarded after report complete | |
| Cytology films, excluding those for population screening | 5.18 | 8 years minimum and longer if possible, up to 30 years | |
| Cytology films prepared for population screening | 5.18 | 30 years | |
| Cytoblock preparations | 5.18 | As for other tissue blocks. Sections as long as accompanying slides | |
| Histology sections used for diagnosis | 5.18 | At least 8 years. If longer storage is not possible, retain selected slides | |
| Histology sections which cannot be replaced by recutting block | 5.18 | 30 years | |
| Digital images of histology sections used for diagnosis | 5.18 | 8 years, as for the physical microscopy slides | College guidance on Best practice recommendations for implementing digital pathology: https://www.rcpath.org/profession/guidelines/specialty-specific-publications.html |
| Human DNA and RNA | 5.19 | 4 weeks after final report | |
| Human DNA and RNA for family studies with genetic disorders/ context of transplantation | 5.19 | 30 years | |
| Positive microbiological cultures | 5.20 | Retain for 24–48 hours from issue of final report | |
| Positive microbiological cultures of clinical importance | 5.20 | 7 days | |

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| Positive microbiological cultures referred to reference laboratories | 5.20 | Until receipt of reference laboratory's final report | |
| Positive microbiological cultures of potential value for local outbreak or epidemiological investigation | 5.20 | 6 months | |
| Nucleic acids from microbiological cultures | 5.20 | 4 weeks after final report | |
| Permanently preserved cultures | 5.21 | Permanently retained in recognised and appropriately secure collections | |
| Electrophoretic strips and immunofixation plates | 5.22 | 5 years (4-year UKAS accreditation cycle plus 1 year margin; extended if needed until accreditation complete), unless photographed; if photographed, retain until final report issued | |
| Digital/photographic images prepared from electrophoretic strips and immunofixation plates | 5.22 | 5 years (4-year UKAS accreditation cycle plus 1 year margin; extended if needed until accreditation complete) | |
| Materials prepared for technical verification and validation | 5.23 | As for internal quality assurance samples; 5 years (4-year UKAS accreditation cycle plus 1 year margin; extended if needed until accreditation complete) | |
| Blood transfusion: blood for grouping, antibody screening, saving and/or cross-matching | 6.2.1 | 7 days from group and screen. Available for 3 days post- | BCSH Guidelines for Pre-Transfusion Compatibility Procedures in Blood Transfusion Laboratories: https://b-s- |

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|---|---|---|---|
| | | transfusion. Practically will be 14 days | h.org.uk/guidelines/guidelines/pre-transfusion-compatibility-procedures-in-blood-transfusion-laboratories |
| Blood transfusion: stored separated serum or plasma from recipient | 6.2.2 | 14 days post-transfusion | BCSH Guidelines for Pre-Transfusion Compatibility Procedures in Blood Transfusion Laboratories: https://b-s-h.org.uk/guidelines/guidelines/pre-transfusion-compatibility-procedures-in-blood-transfusion-laboratories |
| Blood transfusion: stored separated serum or plasma from donor | 6.2.2 | Up to 3 months | |
| Blood transfusion: archived blood donor samples | 6.2.2 | 3 years | |
| EQA providers: materials stored by EQA providers if they can be converted to permanent preparation | 9.3 | 5 years (4-year UKAS accreditation cycle plus 1 year margin; extended if needed until accreditation complete) | |
| EQA Providers: degraded material stored by EQA providers | 9.3 | 1 month after relevant circulation assessed | |

# Appendix 3 Schedule 1 of the Human Tissue Act 2004

## Scheduled purposes*

### Part 1: Purposes requiring consent: general

1. Anatomical examination.
2. Determining the cause of death.
3. Establishing after a person's death the efficacy of any drug or other treatment administered to him/her.
4. Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person).
5. Public display.
6. Research in connection with disorders, or the functioning, of the human body.
7. Transplantation.

### Part 2: Additional purposes requiring consent: deceased person

8. Clinical audit.
9. Education or training relating to human health.
10. Performance assessment.
11. Public health monitoring.
12. Quality assurance.

* Scheduled purposes relate to 'relevant material' as defined within the Act; https://www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004