The retention and storage of pathological records and specimens (5th edition)

Guidance from The Royal College of Pathologists and the Institute of Biomedical Science

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Comments	This issue replaces all previous versions of *The retention and storage of pathological records and archives/specimens*. In accordance with the College's pre-publications policy, it was on the College website for consultation from 21 October to 19 November 2014, following pre-consultation with SAC Chairs and others. Over 260 items of feedback were received and the guidance was amended accordingly. Please email publications@rcpath.org to see the responses. **Dr David Bailey, Vice-President for Communications** **Dr Peter Cowling, Director of Clinical Effectiveness**

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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	30 years
Information (paper or electronic) or permanent specimens held in the laboratory that may also be regarded as primary components of the patient's medical record	30 years
Records relating to cells and tissue used for transplantation, including transfusion	Lifetime of recipient
Records and serum samples used for microbiological investigations prior to transplantation	Lifetime (recipient) At least ten years (donor)
Tissue sections and other permanent microscopy preparations replaceable from a primary specimen such as a tissue block	Minimum of 15 years If from a child, until they reach the age of 25
Working records (paper or electronic) needed for laboratory accreditation	Minimum of eight years (two accreditation cycles)
Instrument and equipment performance logs	Lifetime of instrument/equipment plus minimum of four years
Primary copy of record in patient's paper or electronic medical record after death	Eight years
Records (paper or electronic) or specimens held in the laboratory after death, that may be regarded as primary	Eight years
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
Records of specimens stored with consent for research/biobanking	Lifetime of specimen in storage
Records of archived 'surplus' diagnostic samples released for research	Five years from closure of study, or as determined by study sponsor(s)

Please refer to Appendices 1 and 2 for more detailed information.

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 Archives*.

Key updates and additions in this edition

- Revised advice for molecular genetics, reflecting the increasing use of genome-wide sequencing technologies.
- Expanded advice for point-of-care testing.
- Adjusted document retention times reflecting move to ISO standards 15189 and I7043 accreditation.
- Guidance for samples and records made available for research after diagnostic use.
- Summary of general principles applicable to retaining key categories of records and specimens.

Terms of reference, history and development 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.

For consideration in the 2015 edition, growth of molecular genetic testing continues apace, with evolving data storage requirements as whole-genome sequence technologies gain prominence in the diagnostic repertoire. Storage of electronic records also poses evolving challenges, particularly for data security and continued availability in accessible formats at reasonable cost as hospitals' information platforms are updated. Increased diversity of point-of-care testing has warranted further advice. Guidance for bodies providing external quality assessment programmes has been extended to reflect feedback since the introduction of this topic in the 2009 edition. Transition to laboratory accreditation by UKAS against ISO standards 15189, 18025 and 17043 has implications for the inspection cycle time over which some records should be held. A general principle in all versions of this document has been to advise retention of relevant records for three inspection cycles; this would lead to an extension from ten to 12 years, anticipating an overall cycle time of four years to complete all elements of the cumulated annual inspections against ISO standards. This is becoming an unreasonable and unnecessary burden and we therefore propose to recommend retaining relevant records for two accreditation cycles (eight years). With increasing experience of accreditation against these ISO standards, it may be possible, in the next iteration of this guidance, to recommend reducing storage times for relevant documents to the length of a single cycle plus a safety margin (say, five years). Lastly, with the increasing involvement of diagnostic pathology archives as sources of biosamples for clinical trials and for research biobanking, we have added guidance covering these activities.

To date, medical records legislation has not been amended to extend retention requirements in line with increased longevity in the general population. Should this change before publication of a future revised edition of this guidance, references to 30-year retention of records and specimens, where these constitute primary medical records, will need extending to match any new, legally defined minimum period. A new EU data protection regulation is also currently under consideration (January 2015), which may impose new consent requirements for patient data and sample sharing; general principles arising from Article 8 of the Human Rights Act (1998) also require consideration.

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 and 2009 can be found within the text of the relevant versions. This revision builds upon their work.

Contributors to the 2015 revision were:

Dr Jeff Adams	Forensic Science Regulation Unit, Home Office
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Key stakeholders were the Human Tissue Authority, Institute of Biomedical Science and all Chairs of the College's Specialty Advisory Committees.

Context

The 17 years since the 1998 edition of this document have seen major changes in attitudes towards the use of personal data and human tissue. In 1998, following the guidance of the 1995 report from the Nuffield Council on Bioethics, most pathologists believed that human tissue samples held in their laboratories could be used for any ethically acceptable purpose (as defined by the Nuffield Council) without further consent from the patient, as long as the tissue was surplus to diagnostic requirements.

A similar view pertained to research and other work using confidential patient information. Confidentiality should be maintained, but consent was not regarded as necessary. The Chief Medical Officer of the time reinforced this view, and the preamble to the 1998 version of this document quoted his opinion as:

"information which seems likely to provide material for medical research should be scrutinised with a view to permanent preservation, and acknowledging the value to genetic services of retaining informative medical records and biological samples where resources are available for this".

This comment makes no mention of consent. The potential benefit to society of such work was regarded as sufficient. Of course, the patient's interests must not be harmed by such work, or the patient would have had recourse to redress under common law. This situation has changed radically, the most obvious manifestations being reflected in the implementation of the Data Protection Act 1998 and the Human Tissue Act 2004.

In parallel, 17 years of technological development in laboratories and medical information systems have passed, accompanied by rapidly increasing use of electronic media to store and share information. These developments create new requirements relating to retention of new categories of specimens and records; capacity and long-term accessibility are now pressing issues. The revalidation of individual pathologists by the General Medical Council (GMC) also creates new requirements to retain specimens, records and correspondence that may have an evidential role in the revalidation process.

These changes justify ongoing modification of the advice of the College and the Institute of Biomedical Science (IBMS) on the retention and storage of pathological records and specimens.

Scope 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, 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. 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.

The updated guidance produced in 2005 and 2009 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 and the Human Tissue Act (Scotland) 2006. The principles of patient autonomy and consent are fundamental to these Acts and so 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 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.

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 Human Tissue Authority (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 work 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 are not yet in place covering retention and storage of patients' tissue and data for future use, 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; its diversion into research use now needs greater consideration. It is now no longer justifiable to make over-arching assumptions that archived tissue or 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 ease of specimen retrieval and to the alternative or additional storage of unfixed specimens to avoid artefacts associated with formalin fixation and tissue processing.

The nature of pathology records

Clinical and diagnostic records and reports

1. These are hard copy or electronic records of the results of pathological investigation(s) sent or made available to the requesting clinicians, with the expectation that they will be stored within the patient's individual clinical record. With respect to computer-generated, electronic records, the same criteria that cover conventional records apply, unless they have been converted to hard copy records and preserved as such. If held only on microfilm, microfiche or original magnetic data files, extra care is needed to prevent corruption or deterioration of data. 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 IT systems. However, equivalent arrangements need to cover point-of-care testing and tests undertaken in satellite venues such as GP surgeries. As equipment becomes obsolete, re-recording may need to be considered. The minimum periods of retention specified for records for certain categories of patients are embodied in *Records Management: NHS Code of Practice Part 1 (2006) and Part 2 (Second Edition, 2009)*, applying to the NHS throughout England (see Bibliography); additional records guidance for Wales can be found at www.nhswalesgovernance.com. In relation to patients in the private sector in England, minimum retention times for medical records are specified in Statutory Instrument 2001 No. 3968, Schedule 3(1). In Scotland, the position is set out in MEL(1993)152, which was the subject of consultation in 2005 followed by publication in 2008 and revision in 2012, of a code of practice essentially equivalent to that applicable in England: *Scottish Government Records Management: NHS Code of Practice (Scotland) Version 2.1, 2012* (see Bibliography).

2. The UK Departments of Health, in their published codes of practice covering records management in the NHS referred to in paragraph 1 above, set the policy, standards and retention periods for health and corporate NHS records, both paper-based and electronic. However, concerns have been raised as to whether NHS electronic records are capable of maintaining systems of retention as outlined in that guidance. The Department, together with NHS Connecting for Health (disbanded in March 2013) and stakeholders have continued to develop proposals for an appropriate electronic records retention policy for the NHS, to be cost-effective, meet legal requirements and not compromise patient care. Current strategic views, not yet enshrined in legislation or codes of practice, may be found via the Health and Social Care Information Centre website (www.hscic.gov.uk). The British Standards Institute code BSI BIP 0008 encompasses legal standards for electronic records storage more broadly (see Bibliography). 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 (*Records Management – NHS Code of Practice Part 2 [2nd edition], 2009*). Clearly, with increased longevity, 30 years is becoming too short a period but medical records legislation has not yet been amended to change this. Hence, we still refer to 30 years throughout this document. 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. Increasingly, GP surgeries are adopting electronic patient records and have 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 Trust, commissioners and GP practices involved, it is reasonable to dispense with sending out secondary paper copies of such reports, providing procedures are in place that ensure 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.

3. Point-of-care testing (POCT) services must be provided and operated in accordance with recommendations from the Medicines and Healthcare products Regulatory Agency (MHRA) (DB 2002(03) *Management and Use of IVD Point of Care Test Devices*; with update in 2013 – see Bibliography) The guidelines on storage of specimens and records that apply to a pathology (including genetics/genomics) laboratory should also, in general, apply to any POCT service. Where no hard copy or electronic file is generated as output from POCT analyses, the results must be transcribed as a contemporaneous record into the patient's clinical notes. Data security of information stored on hard drives of POCT instruments, including those placed in community settings, must be assured. Increasing direct networking of POCT services to laboratory information management systems is welcomed.

4. POCT services are offered to generate a rapid result for guidance of immediate patient care. These should be subject to accreditation and quality control procedures and should meet standards equivalent to those which would be expected in a routine laboratory. Results from POCT tests must be entered into a patient's medical record and should include the name of the POCT operator. The record should make it obvious to any user of the information that those results are from a POCT system that is not necessarily fully compliant with routine laboratory standards.

5. 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, and 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. Laboratory professionals should ensure that electronic record-keeping and transfer are encompassed by, and compliant with, their organisations' overall IT security policies, including the safe-keeping and regular updating of passwords and encryption keys, and transfer to portable media.

Laboratory and mortuary working records: reports and documentation for internal use

6. These include:
    - request forms
    - day books
    - worksheets
    - batch records (of reagent batches linked to series of specimens; also specimens analysed as cohorts on automated instruments)
    - graphic output from instruments
    - refrigerator and freezer temperature records
    - photographic records
    - catalogues of the pathological archive or museum
    - bound copies of reports and records
    - point-of-care test data
    - correspondence
    - records of telephoned, faxed and emailed reports
    - equipment maintenance logs
    - quality control and quality assurance records
    - standard operating procedures

- accreditation documents
- records of inspections.

(This list is not exhaustive.)

7. Where these items are held in electronic form, often as digital image files, the same criteria that cover conventional records apply. However, extra care is needed to ensure data security and prevent corruption or deterioration of data (see paragraph 5 above). Suitable back-up systems should be employed and, as equipment becomes obsolete, re-recording or the production of durable hard copy may become necessary to maintain access.

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

Specimens

9. 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
- museum specimens
- test cards (e.g. neonatal screening [Guthrie test card] and faecal occult blood test cards)
- some POCT strips
- microbiological swabs and cultures, freeze-dried or otherwise preserved
- extracted nucleic acids of patient or cultured microbial origin.

10. When the term “tissue” is used in this document, it is used broadly in parallel with the definition of “relevant material” in the Human Tissue Act 2004, i.e. material that consists of or includes human cells. However, this document is not limited to such material, as it includes reference to human biological material that is regarded by the Human Tissue Authority as acellular (such as serum and plasma) and derived materials such as nucleic acids, 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 Human Tissue Authority’s guidance regarding plasma and serum. The professional requirement to adhere to relevant ethical standards should be regarded as binding for all human tissue and derived materials. Further advice concerning the definition of “relevant material” within the Act can be found at: www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm

The management of records and specimen archives: general comments

11. 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 general practitioners 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: 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.

12. 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.

13. Research use will also require approval by a recognised Research Ethics Committee (REC) or equivalent body. A Human Tissue Authority (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.
(www.hta.gov.uk/legislationpoliciesandcodesofpractice/statementonextendingexistinglicencestocovertheremovaloftissuefromthedeceasedforresear.cfm)
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.

14. For compliance with requirements of current human tissue legislation, a recognised Research Ethics Committee is either:

    - a Research Ethics Committee established under, and operating to, standards set out in the 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.

15. 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; see Bibliography.

16. 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 Research Ethics Committee (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 there is continuing REC approval for the particular study or 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 (see Appendix 2 and Bibliography)
- 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 (see paragraph 13 above) and requires HTA licensing; advice should be sought from local Designated Individuals (see paragraph 15 above) and the HTA to ensure compliance with their requirements. With exceptions for anonymised use of archived samples in studies approved by an REC, appropriate consent for research storage and use must be in place for material accrued after 1 September 2006).

17. 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.

18. Under the Human Tissue Act 2004, retention without appropriate consent of specimens obtained at post-mortem examination is not permissible unless under one 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. The situation in Scotland for 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 Fiscal.

19. 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 explained in paragraphs 52–58 of the HTA guidance document *The Quality and Safety of Organs Intended for Transplantation – A documentary framework* (July 2012; see Bibliography).

20. 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 in paragraph 16 above).
- historical purposes.
- holding of pathological material and records in dedicated tissue banks.

21. 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.

22. 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.

23. However, 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 1998 (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.

24. 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.

25. 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 Service, Scottish National Blood Transfusion Service, etc.), Public Health England laboratories, 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 much longer periods. Increasing longevity, although not yet reflected in a change of medical records legislation, provides justification for considering the retention of primary records and permanent specimens beyond the current statutory 30 years.

26. Where laboratories or hospitals are to be closed, or where a contract to provide a pathology service is transferred to another provider, pathologists, laboratory and 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 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.

27. 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]). 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).

28. 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.

29. 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 continues to use the phrase “for at least 30 years”, which was introduced in the 3rd edition in 2005. However, this is intended to have the same meaning, i.e. “without limit of time”. Furthermore, to preserve material of potential historical importance, records earlier than 1948 should not be destroyed and hard copy reports made to patients’ notes should be kept by records departments in accordance with UK Departments of Health guidance (see Bibliography). Wherever possible, pathological preparations and any documentation pertaining to them should be kept for the same period of time, but see above. The NHS Code of Practice cited above anticipates that 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.

30. Previous versions of this guidance have not considered 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) (www.hse.gov.uk/coshh). 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 accreditation standards now incorporated under the umbrella of UKAS (www.ukas.com) used by diagnostic laboratories, including ISO 15189 to which NHS diagnostic laboratories are currently in transition. 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. (www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice)

31. 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.

A Documents, electronic and paper records

(See also Sections C [blood transfusion laboratories], D [forensic material] and E [certain genetic services])

32. Note that storage of data relating to identifiable individuals is likely to be an offence under the Data Protection Act 1998 unless there is appropriate registration with the Office of the Information Commissioner. If in doubt, consult your institution's Data Protection Officer.

33. 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.

Request forms

34. 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 one month after the final checked report has been despatched. For many uncomplicated requests, retention for one 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.

35. Where the request form contains clinical information not readily accessible in the patient's notes but used in the interpretation of test data (as in screening for alpha fetoprotein, cytogenetic and molecular genetic testing), the request should be kept for at least 30 years. Similarly, 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 paragraphs 40 and 41 below for guidance regarding such working documents), unless the information is transcribed to another source (such as a computer record). Where regarded as minor financial documents for accounting purposes, the advice of the local finance department should be sought.

36. 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 four years, to facilitate audit over at least one full accreditation cycle, together with the primary request documentation and explanation of the reason for discard. Standard practice for adequate identification is to require two or three unique patient identifiers plus identifiers of the date and nature of sample. 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 (www.ibms.org/go/media/publications/professional-guidance and see Bibliography).

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

37. Eight years from specimen receipt, to ensure availability for review through at least two full cycles of laboratory accreditation.

Mortuary registers

38. Retain for 30 years.

Protocols of standard operating procedures

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

Worksheets

40. Keep for same length of time as related permanent or semi-permanent specimens or preparations. For temporary specimens (such as serum, body fluid and faecal samples) that are not suitable for retesting, keep at least until the final report has been authorised.

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

41. One year from specimen receipt if all results transcribed into a separately issued and stored formal report. Otherwise, they should be kept as for worksheets above. 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 30 years, as for other primary records. 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 regarded as such working documents.

Records of telephoned or faxed reports

42. Note of the fact and date/time that a telephoned or faxed report has been issued should be added to the laboratory electronic record of the relevant report, or to hard copies, and kept for a minimum of five years. Where management advice is discussed in telephone calls, a summarised transcript should be retained long term, as for the retention of other correspondence (see paragraph 49). Clinical information or management advice provided by 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 30 years. Further guidance on the reporting of results by telephone is available from the IBMS and there is also RCPath guidance on the related issue of ensuring appropriate transmission of urgent results (see Bibliography).

Report copies (physical or electronic)

43. Six months, or 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. Copies should be retained in the local laboratory for at least six months; identifying information sufficient to re-access the original reference laboratory results must be retained long term (minimum of eight years, as for day books, batch records, etc).

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

45. Copies of reports sent by fax 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.

45A. Report copies generated to substitute for an original report (e.g. if an original is misplaced) should be retained as for the original.

46. 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, for a minimum of five 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, for at least the full length of one revalidation cycle (currently five years for clinical consultants).

Surgical (histological) reports

47. Copy lodged in patient's notes. Electronic or hard copy to be kept for at least 30 years by the laboratory, with maintained accessibility of e-copies when laboratory computer systems are upgraded or replaced.

Post-mortem reports

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

Correspondence on patients

49. 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; this may be most conveniently done 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 correspondence but the times may vary according to local policy. Some laboratory information management systems 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. Until explicit guidance is available from the UK Departments of Health, laboratories should ensure that they comply with their institution's medical records and IT policies with regard to the status of email correspondence.

Point-of-care test data

50. Results should be entered into the patient's record; the log of specimens analysed should be retained for at least the lifetime of the instrument. With increasing POCT at venues outside healthcare establishments, the overseeing laboratories should implement governance arrangements to ensure equivalent protection of patient confidentiality to that pertaining to hospital-based tests. Particular consideration should be given to the security and integrity of patient-identifiable data stored on the hard drives of POCT equipment housed in non-clinical environments. Patients should be advised regarding the primary importance of any self-held records as a component of their overall medical record.

Bound copies of reports and records, if made

51. At least 30 years.

Pathological archive or museum catalogues

52. 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).

Photographic records

53. Where images represent a primary source of information for the diagnostic process, 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 records and images from post-mortem examinations.

54. 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. They must be linked to the patient's electronic clinical records and appropriately backed up. This is a rapidly developing field and the need for new, specific guidance on digital images in pathology practice in the near future should be anticipated.

55. 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). See Section E. As above, where such images represent the primary source of information for the diagnostic process, 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, with security of storage and maintained accessibility guaranteed.

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

Batch records

57. At least eight years.

Internal quality control records

58. At least eight years.

External quality assessment records

59. Subscribing laboratories or individuals: minimum of eight years, to ensure continuity of data available for laboratory accreditation purposes over two inspection cycles (see paragraph 60, following) and equivalence with performance records for the equipment used.

Accreditation documents and records of inspections

60. Minimum of eight years, or at least two inspection cycles (anticipating a four-yearly cycle for accreditation against ISO 15189), whichever is the longer.

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

61. 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 two 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:

62. 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 (see paragraph 152 below).

63. For refrigerators and freezers used for long-term storage of specimens for purposes other than human application (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 (paragraph 58) and retained for at least eight years.

64. 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; five years is recommended. This is the scenario that probably best matches the pattern of use of a mortuary refrigerator.

65. 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.

66. 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: www.met.police.uk/foi/pdfs/policies/handling_of_frozen_exhibits_policy.pdf

Equipment maintenance logs

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

Records of service inspections and instrument maintenance

68. Lifetime of instrument plus a minimum of four years, as above.

Records relevant to diagnostic products or equipment

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

Records of assay validation and verification

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

Research data

71. See below.

Records relating to cell/tissue transplantation

72. 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 the 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 (see www.hta.gov.uk/_db/_documents/Annex_-_Guide_to_Quality_and_Safety_Assurance_for_Tissues_and_Cells_for_Patient_Treatment.pdf).

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

73. 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.

B Specimens and preparations

(See also Sections C [blood transfusion laboratories], D [forensic material] and E [certain genetic services])

Legal issues

74. 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 2) unless undertaken on premises that have an appropriate licence from the Human Tissue Authority 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 Human Tissue Authority. The Human Tissue Act 2004 applies in England, Wales and Northern Ireland, replacing previous legislation.

For a brief summary see:
www.hta.gov.uk/legislationpoliciesandcodesofpractice/legislation/humantissueact.cfm.
The position in Scotland is somewhat different and is set out at the end of this section.

75. 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.

76. Appropriate consent (as defined in the Act and elaborated in the relevant Human Tissue Authority Codes of Practice, www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm) 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 (see Appendix 2).

77. 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.

78. 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 Human Tissue Authority 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 (see HTA Code of Practice 5). 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.

79. 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 Policing Improvement Agency (2012; see www.acpo.police.uk/documents/FoI%20publication/Disclosure%20Logs/Crime%20%20FOI/2012/199%2012%20Att%2001%20of%201%20Forensic%20Exhibit%20Retention%20Guidance.pdf).
Further advice may be obtained from the Forensic Science Regulator (see Bibliography), from 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 which they initiate, to ensure that provisions of the Human Tissue Act are not breached.

80. 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 (see Appendix 2). 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 Human Tissue Authority has provided advice, in the form of a Code of Practice (Code 5; see paragraph 77 above and

www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm), on the length of time for which such material should be retained pending clarification of the wishes of the relatives.

81. 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 (see Appendix 2).

82. 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.

83. 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 (see www.legislation.gov.uk/uksi/2007/1523/resources).

84. 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.

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

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

Plasma and serum

87. 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.

88. 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 ten years for donor material, and 30 years for recipient material is recommended, which is consistent with SaBTO (Safety of Blood, Tissues and Organs) 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. (www.gov.uk/government/publications/guidance-on-the-microbiological-safety-of-human-organs-tissues-and-cells-used-in-transplantation).

89. Serum from the first booking visit for pregnancy should be kept for two 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. See their *Handbook for Laboratories (2nd edition),* 2012 (listed in Bibliography) and infectiousdiseases.screening.nhs.uk/standards.

89A. Sera for virological assessment of individuals dialysed overseas should be retained for one year (see www.gov.uk/government/publications/smi-v-10-bloodborne-virus-testing-in-dialysis-patients).

90. Because of its rarity and value to future research, wherever possible, fetal serum (from cordocentesis) should be kept for at least 30 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.

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

92. Other left-over 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 one 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:
www.hta.gov.uk/licensingandinspections/sectorspecificinformation/dna.cfm

Newborn blood spot screening cards

93. A minimum of five years' storage is mandated as part of quality management, with longer-term storage recommended in accordance with the Public Health England NHS Newborn Blood Spot Screening Programme's *Code of Practice for the Retention and Storage of Residual Spots (2005)* – see 'Residual Spots' page at newbornbloodspot.screening.nhs.uk. 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. An EU recommendation is anticipated favouring requirement for such consent. Revised storage guidance is anticipated once the EU opinion and its implication for UK law are clear.

Faecal occult blood screening cards and derived faecal suspensions

94. The primary specimens (test cards) should be kept for a minimum of 48 hours after report authorisation, to allow answering of queries regarding receipt etc. The derived faecal suspensions in buffer may be required for retesting of equivocal results and should be stored for at least two weeks, frozen at –20°C.

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

95. 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.

Whole blood samples, for full blood count

96. Retain specimens for 24 hours.

Donor lymphocyte preparations in cell or tissue transplantation

97. 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 6: Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation).

Frozen tissue for immediate histological assessment (frozen section)

98. 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.

Frozen tissue or cells for histochemical or molecular genetic analysis

99. Keep for at least ten years and preferably longer if storage facilities permit. This advice includes EBV-transformed and fibroblast cell lines. Retention for at least three months (longer if space permits) is recommended for cytogenetic cell suspensions in fixative.

Paraffin wax or resin embedded blocks for histology

100. Storage for at least 30 years is recommended, if facilities permit. If not, review the need for archiving at ten years (and at similar intervals thereafter) and select representative blocks, showing the relevant pathology, for permanent retention. 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 in this way 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.

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

102. 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. Permanent retention 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 also be retained permanently. Special considerations apply in forensic practice (see Section D).

103. 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, and no specific legislation applies to post-mortem blocks stored before September 2006. We recommend applying the principles described in paragraph 100 above. In the case of tissue taken during an autopsy performed for the Coroner or 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.

104. 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' guidance on inter-hospital referral of cases includes relevant advice on this subject (www.rcpath.org/Resources/RCPath/Migrated%20Resources/Documents/G/G137_Interdept dispatch_Mar14.pdf).

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

105. 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

106. Operational records kept 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.

107 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.).

108. 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.

109. 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 retention (see 'Research data and records', paragraphs 184 and 185 below). 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.

110. The biobank should keep records of internal and external quality assurance performance and audits for at least 12 years (see paragraphs 58 and 59). This is particularly important for those banks not housed physically in clinical laboratory premises subject to regular inspection by bodies such as CPA or UKAS. Alternative or additional regulatory review may be required by the Human Tissue Authority, other accreditation bodies and research funding organisations.

111. 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.

Release and return of archived diagnostic samples for clinical trials purposes

112. Translational research using diagnostic samples traditionally regarded as 'surplus' is an increasingly frequent component of clinical trials and 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.

113. 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.

114. 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.

115. 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 laboratory information management system (LIMS) and the specimen report as being available for research.

116. 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.

117. 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.

118. Pathology staff should note that the supply of 'surplus' material for clinical trials or other defined research studies 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 research ethics committee 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.

119. 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.

Blocks for electron microscopy

120. Keep for at least 30 years.

Grids for electron microscopy

121. Requirements in different specialties differ. Grids prepared for human tissue diagnosis (e.g. renal, muscle, nerve or tumour) should be kept for ten years; preferably longer, if practicable. Grids prepared for virus identification may be discarded 48 hours after the final report has been issued, provided that all derived images are retained and remain accessible for at least 30 years.

Wet tissue (representative portion or whole tissue or organ)

122. For surgical specimens from living patients, keep for four weeks after issue of final report. For cases in which a supplementary report is anticipated after additional tests (such as various molecular investigations or referral for expert opinion), which may occasionally exceed this period, arrangements should exist to ensure that individual specimens are retained until the additional report has been finalised.

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

124. 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 line with HTA Code of Practice 5 *Disposal of Human Tissue:*
www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code5disposal.cfm

125. In England and Scotland, for a five-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 five 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 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 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 a Research Ethics Committee.

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

126. 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.

127. 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 (see Bibliography).

128. 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.

Stained slides

129. 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; see www.hta.gov.uk/legislationpoliciesandpractice/definitionofrelevantmaterial.cfm

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

131. Blood films, routine: seven days after final report. Note that increasing storage of digital images is anticipated (see Sections 53 and 54 above).

132. Cytogenetic preparations: two years after final report, if photographic or digitised record kept; five years otherwise. If photographed or digitised, the image should be stored with maintained accessibility for 30 years, if feasible. The RCPath and IBMS recognise that, particularly in genetics, increasing data complexity and frequency of IT system replacement may confound this ideal. 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.

133. 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 for 30 years, with the proviso expressed in paragraph 55 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.

134. Bone marrow films: Stained films used for diagnosis, 30 years minimum. 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. Increasing storage of digital images as an alternative to the original slides is anticipated (see paragraphs 53 and 54 above).

135. Cytology, including population screening: ten years minimum, and longer if possible, for audit purposes. Note that cytoblock preparations should be retained as for other paraffin-embedded tissue blocks described above, and the cytoblock sections should be retained for the same period as their accompanying cytological slides.

136. Histology: at least ten years, in general (but see comments below regarding scanned digital images) and 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 ten 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 re-cutting the fixed tissue block cannot be regarded as a robust means of replacement. The reservations stated in paragraphs 100–102 regarding selection of material for earlier disposal apply equally to diagnostic slides. However, the use of digital slide scanning and the potential for retention of images as an alternative to retaining the physical slides has advanced considerably since the 2009 edition of this guidance. In centres with robust scanning and digital archiving arrangements, this may be considered as an acceptable alternative to long-term storage of glass slides; the physical slides should remain available for two cycles of laboratory accreditation (eight years). All of the principles applying to other electronic record formats must apply to the digitised images in this circumstance (safety and security of storage, legacy arrangements etc.).

137. 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 paragraph 104).

138. 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.

Human DNA and RNA

139. Keep for a minimum of eight 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; see www.hta.gov.uk/licensingandinspections/sectoRspecificinformation/dna.cfm

140. The need for retention of diagnostic specimens should be assessed at the time of sampling, and appropriate consent obtained; see The Joint Committee on Medical Genetics report *Consent and Confidentiality in Clinical Genetic Practice: Guidance on genetic testing and sharing genetic information* (2011; see Bibliography). Once DNA/RNA has been legitimately extracted from the tissue, this material does not fall under the remit of the Human Tissue Act, 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.

141. 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 ultra-low temperature (–80°C) freezers with systems in place to ensure continuity of power supply at all times. However, this is costly and incurs 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.

Microbiological cultures

142. 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.

143. 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 meticillin resistant *Staphylococcus aureus*, ‘outbreak’ strains, *M. tuberculosis*, Group A streptococci and unusual pathogens of clinical significance) should be retained for at least seven 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.

144. 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.

145. 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 four weeks after final report unless with consent in a research context; see paragraphs 139 and 140).

Freeze-dried or other permanently preserved cultures

146. 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.

Electrophoretic strips and immunofixation plates

147. Keep for five years, unless digital images are taken. If digital images of adequate quality for diagnosis are taken, then the original preparations may be discarded after two years. The images should than be stored as discussed above under 'Photographic records', bearing in mind the need to maintain the ability to read archived digital images when equipment is updated.

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

(Minimum requirements for retention times may differ from those detailed in Sections A and B. In all instances, the longer period is recommended.)

Documents and records

Request forms for grouping, antibody screening and cross-matching

148. Retain for one month.

Worksheets

149. Documentation to allow full traceability of all blood components, whether used or discarded, must be kept for at least 30 years (The Blood Safety and Quality Regulations 2005, incorporating previous EU Blood Directives into UK law; see Bibliography). 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.

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

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

Blood Bank Register, blood component audit trail and fates

151. 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).

Refrigerator and freezer charts

152. These should be kept for 15 years.

Records of serious events

153. 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.

Annual reports (where required by The Blood Safety and Quality Regulations, 2005)

154. These should be kept for 15 years.

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.

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

155. Keep for a minimum of seven days from group and screen, stored at 4°C. Samples must be available for a minimum of three days post-transfusion for investigation of acute transfusion reactions. Practically, requirements for paragraph 156 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 (see Bibliography and www.bcshguidelines.com

Separated serum or plasma, stored for transfusion purposes

156. 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 paragraph 155, above. Storage of donated serum/plasma should optimally be at –30°C or colder. These materials may be stored for up to three 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 three years, and preferably longer if it is practicable, in order to facilitate ‘look-back’ exercises.

D Forensic material

Criminal cases

157. 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 re-investigations. They are not normally entered in the patient records.

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

158. HM 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/Human Tissue Act (Scotland) 2006 in respect of such materials, are covered in earlier parts of this document.

159. 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.

E Genetics

160. The College endorses the *Code of Practice and Guidance* of the Advisory Committee on Genetic Testing (1997) and its recommendations on storage, archiving and disposal of specimens and records related to Human Testing Services (Genetics) offered and supplied direct to the public. Those who intend to offer such services should follow its guidance. Additional recent guidance in this area can also be found in the report of the Joint Committee on Medical Genetics' *Consent and Confidentiality in Clinical Genetic Practice: Guidance on genetic testing and sharing genetic information' (2nd edition)*, 2011 (see Bibliography).

161. The House of Lords' Select Committee on Science and Technology (2009) has recommended that the provisions of the Data Protection Act 1998 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):
www.gov.uk/government/publications/genomic-technology-in-healthcare-building-on-our-inheritance

    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.

Storage of material following analyses of nucleic acids

162. 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 five years (one 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.

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

a) Molecular genetics:

- storage of dHPLC/Wave profiles
- storage of quantitative PCR data
- storage of sequence, mutation and polymorphism information
- storage of dosage profiles (MAPH/MLPA)
- storage of autoradiographs, SSCP, PTT DGGE (heteroduplex) gels
- other agarose gels.

b) 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.

Retention of records and materials by providers of external quality assessment

164. 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 five 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 (paragraphs 1–2).

Additional records to be kept by EQA providers

165. Participants' returns (electronic or hard copy) received for data entry. These should be kept for at least three months (or one month after the report has been sent to the participant, if

longer), as working documents, to facilitate identification, checking and correction of discrepancies.

166. **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 five years.

Retention times for materials stored by EQA providers

167. 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.

168. 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 (eg 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 five 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 one month after the relevant circulation has been assessed.

169. 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.

Disposal of human tissue

General

170. Disposal of human biological samples must be carried out in a respectful manner. Exactly what constitutes a respectful manner will vary with the specimen type. The Human Tissue

Authority has issued Codes of Practice relevant to this subject, particularly Code 5; the current versions of the codes are available from the Authority's website (www.hta.gov.uk/legislationpoliciesandcodesofpractice.cfm).

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

172. 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 ten years.

Fetal tissues

173. 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 Human Tissue Authority guidance ('*Guidance on the disposal of pregnancy remains following pregnancy loss or termination*', March 2015). See also paragraph 175 below.

174. 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.

175. Laboratories should have a policy for the disposal of samples containing fetal parts. It should comply with guidance issued by The Royal College of Obstetricians and Gynaecologists (*Good Practice No. 5: Disposal following pregnancy loss before 24 weeks gestation*) published in 2005, guidance from The Royal College of Nursing (2007) and guidance from the Human Tissue Authority (2015).

176. 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 (www.iccm-uk.com). 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 (*ICCM: The Sensitive Disposal of Fetal Remains 2011* – see Bibliography).

177. Procedures for handling material from terminations of pregnancy may differ, as histological examination should rarely be required and 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.

178. 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 Human Tissue Authority can also advise on such matters.

Medicolegal value of archived material

179. 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.

180. 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.

181. 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 GMC's powers to regulate fitness-to-practise of individual pathologists, both documentary and specimen archives may be scrutinised.

Specimens and records for teaching

182. 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.

183. 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. These requirements do not apply to material already held before 1 September 2006. A Human Tissue Authority licence is required for public display of human biological samples that have been taken from the body of a deceased person.

Research data and records

184. Confidential named patient data (documentation) collected in the course of investigation and held separately from patients' records should be destroyed or anonymised six 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 (1998); advice should be sought.

185. Working records and other research data should be retained for at least ten 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 (1998) must be observed for these as for other pathological records. The Medical Research Council's *Good Research Practice* (2000) and *Human tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines* (2001) contain further advice; see Bibliography. Universities and other academic institutions will also have their own rules, which may involve longer storage of such information, and local guidance should be sought as appropriate.

Confidentiality of records

186. The General Medical Council instructs 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, which 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 laboratory information management systems, and local implementation of aspects of the NHS National Programme for Information Technology, should be conducted in accordance with this general principle, paying particular attention to data security.

187. Confidential information on patients may be transmitted by fax or from one computer to another. With increasing access to secure electronic transmission via the internet, routine use of fax communication should be questioned and substituted with a more secure method where 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. The primary responsibility lies with the sender. With regard to fax transmission, a key step is to establish that the receiving fax machine is physically located where it is accessible only to individuals who have a right to see the information transmitted.

188. 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, 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.

189. 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.

Long-term or permanent retention of records

190. 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. In practice, the Officer appointed by health authorities (HC[89]20) deals with these matters. The statutory position of health records in Scotland is different (MEL[1993]152 and the subsequently updates code of practice on records management for Scotland [v2.1, 2012]). There is equivalent guidance for Wales and Northern Ireland; see Bibliography.

191. 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 paragraph 190 above, or unless the records under their immediate care are already secured in an approved place of deposit. Records logging authorised destruction may be helpful and are recommended as good practice but are not mandatory.

192. 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 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 2005 *Records Management: NHS Code of Practice* (other than in Scotland, where MEL(1993)152 and the *Records Management NHS Code of Practice (Scotland) 2008* applies).

193. Use of pathological archives for research, teaching, training, scholarship, disease surveillance or quality control raises important socio-political, 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.

A note on veterinary pathology specimens and records

194. Storage of records and specimens is not an issue that has been addressed systematically in veterinary pathology clinical practice to date. Diagnostic services are mainly provided by commercial laboratories and each laboratory has its own policy on retention of tissues. Most will dispose of formalin-fixed biopsy tissue within 30 days. There is wide variation in retention practices with regard to histology blocks and slides. It is not uncommon for requests for immunohistochemistry or reassessment of histology specimens up to two years old to be required and this need should be anticipated, so that retention of blocks for at least two years would be advisable as good practice. Not many laboratories offer a post-mortem examination service and there is no consistency on whether any tissue is retained from such examinations in the form of blocks or slides. Bodies are cremated or disposed of as clinical waste unless the post-mortem examination is undertaken for legal purposes. If the latter, the body and all tissues are retained, usually frozen, by the litigating body (almost always the RSPCA) until the legal process is complete.

Bibliography and further guidance

Note regarding PDFs: External PDF links provided below may well become outdated before this document is revised, so if any references can no longer be located, readers can access an archive folder (crated by the College in March 2015) by emailing publications@rcpath.org, stating which references they wish to view. Readers should also contact the documents' publishers directly to ensure they follow the latest guidance.

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Appendix 1 Summary of records guidance

Record type	Paragraph	Minimum retention unless stated otherwise	Related paragraphs	Related guidance
'Simple' request form (see below for variations)	34	Until report authorised, longer than one 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	35	30 years		
Request form used as laboratory worksheet	35	Retain as part of the laboratory record	40, 41	
Minor financial document used for accounting purposes	35	Seek local advice from accounts department		
Records of specimens disposed of without analysis, together with primary request documentation and reason for discard	36	4 years		www.ibms.org/go/media/publications/professional-guidance
Records of specimens received by a lab	37	8 years from specimen receipt		
Mortuary registers	38	30 years minimum		
SOP protocols	39	30 years minimum		
Worksheets for permanent/semi-permanent specimens	40	Retain as for related specimens		
Worksheets for temporary specimens (serum, body fluid and faecal samples)	40	At least until final report has been authorised		
Working records of test results for named patients, if all results included in separate stored report	41	1 year from specimen receipt		
Working records of test results for named patients, if results are NOT in separate stored report or undertaken by external laboratories	41	At least until final report has been authorised – possibly up to 30 years for audit or medicolegal reasons		
Records of telephone/faxed reports	42	5 years minimum		

Record type	Paragraph	Minimum retention unless stated otherwise	Related paragraphs	Related guidance
Records of telephone calls re. management advice	42	Long term, as for other correspondence		
Records of faxes re. clinical advice	42	30 years, as for other correspondence	49	IBMS/RCPath guidance: Communication of unexpected findings, urgent reports, delayed reports and the use of Alert systems in diagnostic cellular pathology
Report copies (electronic/physical)	43	6 months, or as needed for operational purposes		
Report copies (electronic/physical) communicated between laboratories	43	6 months		
Identifying information of report copies (physical or electronic) communicated between laboratories	43	8 years to re-access original results		
Report copies for communication/*aide memoire*	44	Disposed when function complete		
Report copies sent by fax	45	Disposed after sending. Transmission details recorded		
Report copies to replace original	45A	As original		
Report copies as part of training portfolios	46	5 years after training completion		
Report copies in revalidation portfolios	46	Length of 1 revalidation cycle (currently 5 years)		
Surgical (histological) reports (electronic/physical)	47	30 years		
Post-mortem report copies (electronic/physical)	48	8 years	Section D	

Record type	Paragraph	Minimum retention unless stated otherwise	Related paragraphs	Related guidance
Post-mortem report copies of violent/suspicious deaths	48	30 years		
Patient correspondence not lodged in patient's record	49	30 years		
Patient correspondence by email	49	See local medical records and IT policies		
POCT specimens log	50	Instrument lifetime		
Bound copies of reports and records	51	30 years		
Pathological archive or museum catalogues	52	Time specimens held or until catalogue updated		
Photographs as primary source for diagnosis	53	30 years		
Images of pathological specimens	54	As long as recommended for original specimens. New guidance anticipated		
Digitised images in genetics testing protocols transcribed into report	55	Treated as semi-permanent preparations or working documents	Section E	
Digitised images in genetics testing protocols NOT transcribed into report	55	30 years	Section E	
Photographic images for communication/*aide memoire*	56	Disposed when function complete		
Batch records	57	8 years		
Internal quality control records	58	8 years		
External quality assessment records	59	8 years or 2 accreditation cycles against ISO 15189 (currently 4-year cycle), whichever is longer		
Accreditation documents and records of inspection	60	As paragraph 59		
Primary traces of temperature records for fridges and freezers	61	2 months (unless used for paragraphs 62–66)		BSQR 2005
As 61. Summarised data, if blood for transfusion	62	15 years	152	

Record type	Paragraph	Minimum retention unless stated otherwise	Related paragraphs	Related guidance
As 61. Summarised data, if long-term storage of specimens not for human application	63	8 years	58	
As 61. Summarised data, if storage of analytical reagents/temporary specimens	64	5 years		
As 61. Summarised data if for very long-term storage	65	Lifetime of equipment		
As 61. Summarised data, if for biobanked specimens	65	Lifetime of specimen		
As 61. Summarised data, if for forensic samples for potential medicolegal use	66	As long as oldest sample held		www.met.police.uk/foi/pdfs/policies/handling_of_frozen_exhibits_policy.pdf
Equipment maintenance logs	67	Instrument lifetime plus one full accreditation cycle (4 years)		
Service inspection and instrument maintenance records	68	Instrument lifetime plus one full accreditation cycle (4 years)		
Records relevant to diagnostic products or equipment	69	8 years		
Assay validation and verification records	70	8 years		
Records of specimens relevant to cell/tissue transplantation not in patient records	72	30 years/lifetime recipient whichever longer		
Records from donor tissues not used for transplantation	72	Same as equivalent samples/records for a patient		www.hta.gov.uk/_db/_documents/Annex_-_Guide_to_Quality_and_Safety_Assurance_for_Tissues_and_Cells_for_Patient_Treatment.pdf
Records of fertility specimens not in patient records	73	30 years		

Record type	Paragraph	Minimum retention unless stated otherwise	Related paragraphs	Related guidance
Transplant-related virology/microbiology records	88	30 years		www.gov.uk/government/publications/guidance-on-the-microbiological-safety-of-human-organs-tissues-and-cells-used-in-transplantation
Operational records in biosample banking	106	As for clinical governance in diagnostic specimens		
Biobank records of internal and external quality assurance performance	110	12 years	58, 59	
Biobank records of adopted sub-collection	111	As for ongoing collections		
Request forms	148	1 month		
Worksheets (electronic/physical)	149	30 years		The Blood Safety and Quality Regulations 2005, incorporating previous EU Blood Directives into UK law
Results of transfusion-related tests	150	30 years		The Blood Safety and Quality Regulations 2005
Blood Bank Register blood component audit trail records (electronic/physical)	151	30 years		
Refrigerator and freezer charts	152	15 years		
Records of serious events	153	15 years		The Blood Safety and Quality Regulations 2005

Record type	Paragraph	Minimum retention unless stated otherwise	Related paragraphs	Related guidance
Annual reports	154	15 years		
Criminal case records in any medium	157	Permanently		
Machine outputs from diagnostic tests using nucleic acids	162	5 years (1 accreditation cycle plus safety margin)		
Ability to regenerate records of external quality assessment (EQA) proficiency testing	164	5 years		
Participants' returns (electronic/physical) from EQA providers	165	3 months or 1 month after report sent to participant if longer		
Performance surveillance records in EQA	166	5 years		
Confidential patient documentation held separately from patient records	184	Destroyed/anonymised 6 months after completion of research		
Working records and other research data	185	10 years		
Records and clinical trial data on medicines	185	15 years		The Medical Research Council's *Good Research Practice* (2000) and *Human tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines* (2001)

Appendix 2 Summary of specimens guidance

Specimen type	Paragraph	Minimum retention unless stated otherwise	Related paragraphs	Related guidance
Material containing human cells obtained post mortem	74	Prohibited unless licence from HTA and consent	Appendix 2	www.hta.gov.uk/legislationpoliciesandcodesofpractice/legislation/humantissueact.cfm
Post-mortem samples of human tissue retained by Coroner	77	As long as required to fulfil Coroner's duties		
Samples for criminal investigations	79	As long as required for investigation		www.acpo.police.uk/documents/FoI%20publication/Disclosure%20Logs/Crime%20%20FOI/2012/199%2012%20Att%2001%20of%201%20Forensic%20Exhibit%20Retention%20Guidance.pdf
Post-mortem samples no longer required by Coroner or criminal justice system	80	Consent needed in Schedule 1 of HTA	Appendix 2	www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm
Sample from living patient no longer required by criminal justice system	81	Consent needed in Schedule 1 of HTA	Appendix 2	
Plasma and serum	87	48 hours after final report		
Plasma and serum with expectation of follow up	87	Retained until follow-up tests		
Serum for transplantation matching	88	Lifetime of recipient		

Specimen type	Paragraph	Minimum retention unless stated otherwise	Related paragraphs	Related guidance
Transplant virology/microbiology serum samples	88	10 years donor material, 30 years recipient material		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	89	2 years		infectiousdiseases.screening.nhs.uk/standards
Sera for virological assessment of patients dialysed overseas	89A	1 year		www.gov.uk/government/publications/smi-v-10-bloodborne-virus-testing-in-dialysis-patients
Fetal serum from cordocentesis	90	30 years		
Serum after needlestick injury/hazardous exposure	91	2 years		
Left-over sera or plasma	92	1 year		www.hta.gov.uk/licensingandinspections/sectorspecificinformation/dna.cfm
Newborn blood spot screening cards	93	5 years		'Residual Spots' page at newbornbloodspot.screening.nhs.uk
Faecal occult blood screening test cards	94	48 hours after report authorisation		
Derived faecal suspensions in buffer	94	2 weeks		

Specimen type	Paragraph	Minimum retention unless stated otherwise	Related paragraphs	Related guidance
Body fluids, aspirates and swabs	95	48 hours after final report		
Deteriorated body fluids, aspirates and swabs	95	Discarded immediately after analysis		
Coagulation samples	95	24 hours		
Easily and non-invasively repeated samples	95	Destroyed once examination concluded and final report issued		
Whole blood samples for FBC	96	24 hours		
Donor lymphocyte preparations	97	Lifetime all recipients		Blood Safety and Quality Regulations 2005 and HTA Code of Practice 6
Microscope slides of frozen sections	98	As fixed specimens		
Residual tissue of frozen sections	98	As normal fixed specimens once section complete		
Frozen tissue/cells for histochemical or genetic analysis	99	10 years preferably longer		
Cytogenic cell suspensions in fixative	99	3 months (longer if space permits)		
Wax/resin embedded blocks for histology	100	30 years. If no facilities, 10 years, retaining most relevant blocks permanently		
Wax/resin embedded blocks for histology with rare pathology	100	Considered for permanent retention, otherwise at least 30 years or transfer to licensed biobank		
Wax/resin embedded blocks for histology considered for destruction <30 years	101	Blocks that provided basis malignancy diagnosis retained 3 years after patient death		
Paediatric wax/resin embedded blocks for histology	102	Until child >25 years old. Consider permanent particularly cancers, inherited abnormalities		
Paediatric wax/resin embedded blocks for histology in forensic practice	102	Special considerations apply	Section D	
Post-mortem wax/resin embedded blocks for histology	103	According to consent given for examination	100, 74-86	

Specimen type	Paragraph	Minimum retention unless stated otherwise	Related paragraphs	Related guidance
Adopted sub-collection of biosamples by biobank	111	As for ongoing collections		
Research involving non-return/destruction of primary resource	119	30 years or returned to hospital source if earlier		
Electron microscopy blocks	120	30 years		
Electron microscopy grids for human tissue diagnosis	121	10 years, preferably longer		
Electron microscopy grids for virus identification	121	48 hours after final report if images are accessible for 30 years		
Wet tissue surgical specimens from living patients	122	4 weeks after final report issued. Longer if anticipating report on further tests		
Post-mortem wet tissue specimens	123	As authorised by Coroner		
Whole organs, wet tissue, fetal specimens retained before HTA 2004	124	Only kept if intention to use for human health education		
Teaching collections	126	Can be retained permanently		
Microbiological and easily repeatable stained slides	130	7 days after final report		
Gram-stained preparations from culture plates	130	Discarded immediately after use		
Blood films	131	7 days after final report	53, 54	
Cytogenetic slide preparations	132	2 years after final report		
Digitised/photographed cytogenetic slide preparations	132	30 years, if feasible		
Digitised/photographed molecular genetic/cytogenetic slide preparations	133	30 years	55	
Fluorescently stained slides	133	At least until final report issued		
Stained bone marrow films	134	30 years minimum		

Specimen type	Paragraph	Minimum retention unless stated otherwise	Related paragraphs	Related guidance
Surplus unstained bone marrow films	134	Discarded after report complete		
Cytology slides including population screening	135	10 years, preferably longer		
Cytoblock preparations	135	As for other tissue blocks. Sections as long as accompanying slides		
Histology slides	136	At least 10 years. If longer not possible, retain selected slides		
Histology slides where cannot replace by re-cutting block	136	30 years		
Histology slides scanned and digitally archived	136	Physical slides for 2 accreditation cycles (8 years)		
Semi-permanent preparations	138	At least until final report issued		
Human DNA and RNA	139	8 weeks after final report		
Human DNA and RNA for family studies with genetic disorders/ context of transplantation	139	30 years		
Positive microbiological cultures	143	Discarded within 24–48 hours of final report		
Positive microbiological cultures of clinical importance	143	7 days		
Positive microbiological cultures referred to reference laboratories	143	Until receipt of reference laboratory's final report		
Nucleic acids from microbiological cultures	145	4 weeks after final report unless consent in research	139, 140	
Permanently preserved cultures	146	Permanently retained		
Electrophoretic strips and immunofixation plates	147	5 years		
Digitised electrophoretic strips and immunofixation plates	147	30 years, original preparations discard after 2 years		

Specimen type	Paragraph	Minimum retention unless stated otherwise	Related paragraphs	Related guidance
Blood for grouping, Ab screening, saving/ X-matching	155	7 days from group and screen. Available for 3 days post-transfusion. Practically will be 14 days	156	BCSH Guidelines for Pre-Transfusion Compatibility Procedures in Blood Transfusion Laboratories, 2012 (www.bcshguidelines.com)
Stored separated serum or plasma from recipient	156	14 days post-transfusion	155	
Stored separated serum or plasma from donor	156	Up to 3 months		
Archived blood donor samples	156	3 years		
Materials stored by EQA providers if can be converted to permanent preparation	168	5 years		
Degraded material stored by EQA providers	168	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. The Human Tissue Authority has now also produced a supplementary list of relevant material for guidance.