



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



The retention and storage of pathological records and specimens (4th edition, 2009)

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

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Introduction

This is an update of the advice of The Royal College of Pathologists on *The Retention and Storage of Pathological Records and Archives*.

The text has been updated to take account of modifications in practice arising from laboratories' experience of implementing procedures for compliance with the Human Tissue Act 2004 and the Human Tissue Act (Scotland) 2006. Also, increased molecular genetic testing has created the need to provide more specific guidance on specimen and record retention in this field. Requirements to retain records of requests and reports documented electronically have been also been considered further. Finally, previous guidance has not specifically considered the requirements of bodies providing external quality assessment programmes and we have now added recommendations for these.

History and terms of reference

The original Working Party 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.”

The Working Party was reconvened in 1998. In addition to the original terms of reference, it was required to consider the 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 2003, the College Executive decided that a further review was necessary to consider the implications of subsequent developments, notably the implementation of the Data Protection Act 1998, the Human Tissue Act 2004 and changes in public expectations in the intervening period. Experience of the operation of the Human Tissue Act 2004, increasing use of genetic testing in pathology and increasing use of electronic record-keeping makes it desirable to provide a further update of this guidance in 2009.

The 1994 report was prepared by Professor Dame Rosalinde Hurley and Dr Jonathan Kay.
The 1999 revision was prepared by Professor Dame Rosalinde Hurley and Mr Keith Lockyer.
The 2005 revision was prepared by Professor Peter Furness.
The 2009 revision was prepared by Dr Bridget Wilkins.

The names of the large number of individuals who have assisted with the production of the original document and each of its revisions can be found within the text of the relevant versions. This revision builds upon their work.

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Background to the 2009 revision

The decade since the 1998 revision of this document has 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 public manifestation of this change has been the publicity surrounding concerns about the retention of tissue removed at post-mortem examination in hospitals in the UK, leading to the introduction of the Human Tissue Act 2004. Even before this, however, a change of attitudes within society was evident in the wording and interpretation of the Data Protection Act 1998, which demands ‘fair processing’ of information. This Act puts particular emphasis on controlling the use of ‘sensitive’ information, a category that includes essentially all medical information about identifiable, living individuals.

In parallel, 10 years of technological development in laboratories and medical information systems have passed, accompanied by rapidly increasing use of electronic media to share information. These developments create new requirements relating to retention of new forms of specimens and records.

These changes have required modifications in the advice of the College and the Institute of Biomedical Science (IBMS) on the retention and storage of pathological records and specimens.

In most cases, records and archived specimens are held primarily to benefit the medical care of the patient concerned, as part of that patient’s medical record. Under the Human Tissue Act 2004, consent is not needed for retention and use of tissue from living individuals for this purpose. However, consent from a relative (or other appropriate third party) or the authorisation of a Coroner

(Procurator Fiscal in Scotland) is required for retention of all tissue obtained at post-mortem examination. In relation to data protection law, it is reasonable to infer that the information held in pathological records was generated legitimately in the first instance and that patients are aware of its continued existence within the confidential archives of the hospital. Indeed, patients would have legitimate grounds for complaint if their future healthcare was compromised because technical details of their previous investigations had been erased without their knowledge. We can therefore assume that pathologists have legitimate authority to retain records and archives for the benefit of individual patients, relying only on the consent that was a clinical requirement for their original generation.

The updated guidance produced in 2005 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 equivalent Act applicable in Scotland. 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 guidance is based on the assumption 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.

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 at the National Research Ethics service website (www.nres.npsa.nhs.uk) and the Integrated Research Application System website (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 to be welcomed as a further potential source of advice. In difficult cases, it may be necessary to seek advice from the Information Commissioner (www.ico.gov.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 blocked. 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.

The scope and 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* (published in 2006, applying to the NHS throughout England) and WHC (2000) 71 (Wales). 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 June 2008, of a code of practice essentially equivalent to that applicable in England: *Records Management: NHS Code of Practice (Scotland)*. See Bibliography for further details of these codes of practice.
2. The Department of Health, in its published codes of practice covering records management in the NHS referred to in paragraph 1 above, sets 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 Connecting for Health and stakeholders, will be developing proposals throughout 2009/2010 for an appropriate electronic records retention policy for the NHS; proposals will need to be shown 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 at www.connectingforhealth.nhs.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. 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 e-mail or another directly transmitted electronic format. With explicit and formal agreement between the hospital Trust, primary care Trust (PCT) 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 should be provided and operated in accordance with recommendations from the Medical and Healthcare products Regulatory Agency (MHRA) (DB 2002(03) *Management and Use of IVD Point of Care Test Devices*). They should therefore be operated under the guidance and control of a pathology laboratory. The guidelines on storage of specimens and records that apply to a pathology laboratory should also, in general, apply to the 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.
4. Some POCT services are offered to generate a rapid result for guidance of immediate patient care. These are not necessarily subject to accreditation and quality control procedures that are as rigorous as those which would be expected in a routine laboratory. If results from such a service enter a patient's medical record, that record should make it obvious to any subsequent user of the information that those results are from a POCT system that is not necessarily 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 such as encryption and password protection. They also carry different risks of corruption or loss than do hard-copy records and arrangements for regular, accurate back-up are essential. The speed of change in IT provision for health services makes it essential to ensure that such records remain accessible for the full period of their retention and possible use. Laboratory professionals should ensure that electronic record-keeping and transfer are encompassed by, and compliant with, their organisations' overall IT security policies, including the safe-keeping and regular updating of passwords and encryption keys.

Laboratory working records: reports and documentation for internal use

6. These include:
 - request forms
 - protocols of procedures
 - day books
 - worksheets
 - batch records (of reagent batches linked to series of specimens; also specimens analysed as cohorts on automated instruments)
 - graphic output from instruments
 - photographic records
 - catalogues of the pathological archive or museum
 - bound copies of reports and records
 - point-of-care test data
 - correspondence
 - records of telephoned, faxed and e-mailed reports
 - equipment maintenance logs
 - quality control and quality assurance records
 - standard operating procedures
 - accreditation documents
 - records of inspections
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 and blots
 - museum specimens
 - test cards (neonatal screening [Guthrie test card], 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. 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 safe keeping of these records is primarily the responsibility of hospital records departments or recipient general practitioners or private practitioners, once the pathologist has issued the 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.
12. Where storage of material is no longer required for clinical purposes, but is desirable for teaching, 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 may be influenced by the presence or absence of appropriate consent or by rendering the specimens non-identifiable. This will depend on the intended future use.
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. 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 the HTA, 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 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.
- Quality control.
- Teaching and training healthcare staff.
- Epidemiology.
- Analysis of data (such as case mix) for administrative or other purposes.
- Direct evidence in litigation.
- Individual, active research studies for which data or samples are suitably anonymised **and** current approval is in place for the purpose, given by a recognised Research Ethics Committee (REC). 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 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.nres.npsa.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; appropriate generic consent for research storage must be in place for material accrued after 1 September 2006).

17. It is nevertheless appropriate, 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. Communication of such decisions, and specimen tracking within laboratories, must 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. 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 under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 apply to retention of donor material (cells, tissues, serum etc.) from deceased individuals for the future potential benefit of the matching recipients of cadaveric tissue transplants (see Bibliography).
20. The following reasons for retention were listed in previous 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 Authority in respect of tissue. It is not necessarily the case that consent must be explicit or 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 adequately 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 (National Blood Service, Scottish National Blood Transfusion Service, etc.), the Health Protection Agency, 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.
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. This will necessitate careful organisation, but also 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 medico-legal 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.
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. It may be desirable to dispose of such data and samples, but 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. There is no legal requirement to dispose of data and samples relating to patients who have *subsequently* died, even if they have no foreseeable future use.
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 Department of Health guidance (see *Records Management: NHS Code of Practice*). Wherever possible, pathological preparations and any documentation pertaining to them should be kept for the same period of time, but see above.

A Documents, electronic and paper records

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

30. 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.

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

Request forms

32. 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.
33. 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 38 and 39 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.
34. 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 30 years together with the primary request documentation and explanation of the reason for discard. Further guidance on specimen identification and acceptance criteria are available from the Institute of Biomedical Science (see Bibliography).

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

35. Two years from specimen receipt.

Mortuary registers

36. Retain for 30 years.

Protocols of standard operating procedures

37. 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

38. 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 re-testing, keep at least until the final report has been authorised.

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

39. 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 specialities and departments, consideration should be given to the potential audit or medico-legal value of storing such working records for 30 years, as for other primary records.

Records of telephoned or faxed reports

40. 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 44). 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 Institute of Biomedical Science (see Bibliography).

Reports and copies (physical or electronic)

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

Surgical (histological) reports

42. 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

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

Correspondence on patients

44. 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, and ensuring entry into the patient's notes is not primarily the responsibility of laboratory staff. 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 e-mail 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 all e-mail correspondence but the times may vary according to local policy.

Some laboratory information management systems can store e-mail correspondence linked to specimen records and this – or alternative systems for comprehensive storage (and retrieval, when required) of e-mails – should be explored. Until explicit guidance is available from the Department of Health, laboratories should ensure that they comply with their institution’s medical records and IT policies with regard to the status of e-mail correspondence.

Point-of-care test data

45. 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.

Bound copies of reports and records, if made

46. At least 30 years.

Pathological archive or museum catalogues

47. 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

48. Where images represent a primary source of information for the diagnostic process, whether conventional photographs or digital images, they should be kept for at least 30 years. In practice, these will represent material from which neither the primary tissue(s) nor subsequent tissue blocks, slides or cell suspensions have been stored and will include images from post-mortem examinations.
49. In some circumstances, images of pathological specimens may be produced as an alternative to storing the specimen itself. This should be done only where it is possible to be confident that the image contains all the diagnostic information in the original specimen, and that its storage will satisfy any possible future requirements, of a medico-legal as well as of a clinical nature. In such circumstances, the images should be stored for at least as long as is recommended for the specimens from which they are derived, with continued accessibility and assured storage conditions to avoid deterioration in quality over time.
50. 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, they should be kept for at least 30 years, with security of storage and maintained accessibility guaranteed.
51. 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

52. At least 10 years.

Internal quality control records

53. At least 10 years.

External quality assessment records

54. Subscribing laboratories or individuals: 5 years to ensure continuity of data available for laboratory accreditation purposes. Records will be kept for longer periods by organisations providing external quality assessment schemes (see paragraphs 134–136).

Accreditation documents and records of inspections

55. Ten years, or until superseded.

Equipment maintenance logs

56. Lifetime of instrument; minimum of 10 years.

Records of service inspections and instrument maintenance

57. Lifetime of instrument; minimum of 10 years.

Records relevant to production of diagnostic products or equipment

58. Comprehensive records relevant to procurement, use, modification and supply: at least 10 years.

Research data

59. See below.

Records relating to cell/tissue transplantation

60. 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.

Records relating to retention of semen or ova

61. Records not otherwise kept or issued to patient records that relate to investigations or storage of specimens of semen or ova should be kept for at least 30 years.

B Specimens and preparations

(See also Sections C, D and E, relating to blood transfusion laboratories, forensic material and certain genetic services.)

Legal issues

62. With a few exceptions, the Human Tissue Act 2004 prohibits the storage of any material obtained after death and containing human cells, including fluid samples, for a scheduled purpose (see Appendix) unless undertaken on premises that have an appropriate licence from the Human Tissue Authority and with appropriate consent in place. The need for a licence for storage of material removed *before* death is more limited, being confined mainly to storage for future unspecified research use (research tissue banking) and some forms of transplantation. Detailed advice on licensing may be obtained from the Human Tissue Authority. The position in Scotland is somewhat different and is set out at the end of this section. There are also some minor variations in relation to Northern Ireland; see www.dhsspsni.gov.uk/index/hss/hoi-home.htm

63. Under the Human Tissue Act, 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.
64. Appropriate consent (as defined in the Act and elaborated in the relevant Human Tissue Authority Codes of Practice: see www.hta.gov.uk/guidance/codes_of_practice.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).
65. 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.
66. Post-mortem samples of human tissue (including fluids, blocks and microscope slides) may be retained without consent for so long as that material is required for purposes of functions of a Coroner or under the authority of a Coroner. 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 prepared 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.
67. 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; further advice may be obtained from the Forensic Science Regulator (see Bibliography), from the Crown Prosecution Service or the National Policing Improvement Agency. 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.
68. 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). 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 under the Human Tissue Act. The Human Tissue Authority has provided advice, in the form of a Code of Practice (Code 5; see paragraph 66 above and www.hta.gov.uk/guidance/codes_of_practice.cfm), on the length of time for which such material should be retained pending clarification of the wishes of the relatives.
69. 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).
70. **The Human Tissue Act 2004 does not apply in Scotland** (other than Section 45 and Schedule 4, which relate to the non-consensual analysis of DNA). The position in Scotland is

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

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.

71. 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.
72. 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.
73. The provisions of the Control of Substances Hazardous to Health Regulations 2002 (COSHH) and of current Health and Safety at Work legislation must be observed.

Plasma and serum

74. Keep for 48 hours after the final report has been issued by the laboratory. If there is a requirement to store for longer, specimens that have been centrifuged but not separated should be separated to prolong stability.
75. 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.
76. Serum from the first pregnancy booking visit should be kept for two years by microbiology/virology and other relevant laboratories 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 are in development by the UK national screening committee for the Infectious Diseases in Pregnancy Screening Programme.
77. 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.
78. Serum taken after needlestick injury or other hazardous exposure should be kept for a minimum of 2 years.

79. 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. 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. Storage of samples with the *intention* of human DNA analysis without appropriate consent may be an offence under the Human Tissue Act. See also Section C.

Newborn blood spot screening cards

80. A minimum of 5 years storage is indicated for quality assurance purposes, with longer-term storage recommended in accordance with the *Code of Practice of the UK Newborn Screening Programme Centre* (2005) – see <http://newbornbloodspot.screening.nhs.uk/>

Faecal occult blood screening cards and derived faecal suspensions

81. 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 re-testing of equivocal results and should be stored for at least 2 weeks; frozen at -20⁰c.

Body fluids, aspirates and swabs

82. 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

83. Retain specimens for 24 hours.

Donor lymphocyte preparations in cell or tissue transplantation

84. Donor lymphocytes and relevant identifying documentation should be retained for the lifetime of all recipients of cell or tissue grafts from that donor.

Frozen tissue for immediate histological assessment (frozen section)

85. 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

86. Keep for at least 10 years and preferably longer if storage facilities permit. This advice includes EBV-transformed and fibroblast cell lines. Retention for at least 3 months (longer if space permits) is recommended for cytogenetic cell suspensions in fixative.

Paraffin wax or resin embedded blocks for histology

87. Storage for at least 30 years is recommended, if facilities permit. If not, review the need for archiving at 10 years (and at similar intervals thereafter). and select representative blocks, showing the relevant pathology, for permanent retention, Blocks representing rare

pathologies 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 the full minimum of 30 years.

88. 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 3 years after the patient's death.
89. 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).
90. 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 84 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.
91. 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 systems, operating in both the sending and receiving hospitals, that can be audited 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/pdf/q083_interdeptdispatch_feb09.pdf

Blocks for electron microscopy

92. Keep for at least 30 years.

Grids for electron microscopy

93. Requirements in different specialities differ. Grids prepared for human tissue diagnosis (e.g., renal, muscle, nerve or tumour) should be kept for 10 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)

94. For surgical specimens from living patients, keep for 4 weeks after issue of final report. For cases in which a supplementary report is anticipated after additional 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.

95. For post-mortem specimens, appropriate consent 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.
96. In the case of post-mortem samples retained before the implementation of currently acceptable consent procedures, the moratorium on disposal has now been lifted. Detailed guidance is available in the HTA's Code of Practice 5: *Removal, Storage and Disposal of Human Organs and Tissue*: (www.hta.gov.uk/guidance/codes_of_practice.cfm). However, this is intended to permit carefully planned disposal of samples where there is no foreseeable future use, and specimens where there is a legitimate foreseeable future use (such as teaching) need not be destroyed.
97. In Scotland, a formal 5-year period began on 18 April 2002 under which families were entitled to reclaim organs, tissue blocks and slides retained under past post-mortem practice, by which is understood cases from before 2000 where there is some doubt about the extent to which families were involved in agreeing to retention. The Scottish Executive accepted the recommendation of the Review Group on Retention of Organs at Post-Mortem that organs and tissue unclaimed at the end of the 5 years should be legally deemed to come under the authority of the relevant hospital, which should be able to make use of it for legitimate research or educational projects. Where organs or tissues are not considered necessary or suitable for those purposes, the hospital should ensure their respectful disposal. The 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 Research Ethics Committee approval.

Museum specimens, where these are generally accessible for undergraduate or postgraduate study (teaching collections)

98. 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.
99. There is no consent requirement for use of museum specimens obtained **before** the implementation of the Act on 1 September 2006, although a license is required for use of tissue from obtained from a deceased person for a scheduled purpose such as this, 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).
100. If specimens are stored under conditions that can be regarded as representing public display, the Human Tissue Act requires that consent must be given in writing by the patient 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 for public display is also required.

Stained slides

101. 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/guidance/licensing_guidance/definition_of_relevant_material.cfm
102. Microbiological (e.g. cerebrospinal fluid preparations, malarial blood films, blood culture films, acid-fast bacilli cultures): 7 days after final report. Standard Gram-stained preparations from culture plates may be discarded immediately after use.
103. Blood films, routine: 7 days after final report.
104. Cytogenetic preparations: 2 years after final report, if photographic or digitised record kept; 5 years otherwise. If photographed or digitised, the image should be stored with maintained accessibility for 30 years.
105. 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. Long-term storage of fluorescently stained slides is problematical but these should be retained at least until the final written report has been authorised and issued.
106. Bone marrow films: 20 years minimum; ideally for the lifetime of the patient.
107. Cytology, including population screening: 10 years minimum, and longer if possible, to cover at least one recall visit. 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.
108. Histology: at least 10 years, 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 pathology. If the disposal of slides at 10 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. focal pathology 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 paragraph 87 regarding selection of material apply equally to diagnostic slides. The utility of digital slide scanning and retention of the images as an alternative to retaining the physical slides has yet to be evaluated.
109. 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 91).
110. 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

111. Keep for a minimum of 4 weeks after final report for diagnostic specimens; 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, although the exceptions do include analysis for the benefit of the person whose body manufactured the DNA/RNA. Accordingly, the need for retention of diagnostic specimens should ideally be assessed at the time of sampling, and appropriate consent obtained. 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.

112. Long-term storage of extracted DNA and RNA in increasing volumes as molecular pathology expands raises logistical and environmental concerns. Laboratories of all sub-specialities within pathology will need to address providing appropriate storage facilities. To guarantee maintenance of specimen quality, nucleic acids should ideally be stored in ultra-low temperature (-80⁰c) freezers with systems in place to ensure continuity of power supply at all times. Laboratories making extensive use of such storage, particularly regional reference laboratories, should investigate using alternatives such as freeze-drying.

Microbiological cultures

113. 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.
114. 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 resistant or methicillin resistant *Staph. aureus*, ‘outbreak’ strains, *M. tuberculosis*, Group A streptococci and unusual pathogens of clinical significance) should be retained for at least 7 days. Where isolates have been referred to reference laboratories, they should be retained until receipt of the reference laboratory’s final report; longer retention locally, with potential for hazard, is not needed under these circumstances and the reference sample in most cases remains available as a reserve.
115. Whenever cultures are stored, pathology staff have a duty to ensure that specimens are held safely and securely, so as 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.
116. 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 guidance provided for human DNA and RNA (see paragraphs 111–112).

Freeze-dried or other permanently preserved cultures

117. 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

118. Keep for 5 years, unless digital images are taken. If digital images of adequate quality for diagnosis are taken, then the original preparations may be discarded after 2 years. The images should then 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

119. Retain for one month.

Worksheets

120. 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 (donation or discard); for most hospital laboratories, this will start from receipt of products from the 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

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

Blood Bank Register, blood component audit trail and fates

122. 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

123. These should be kept for 15 years.

Records of serious events

124. 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)

125. These should be kept for 15 years.

Specimens and preparations

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

126. Keep for a minimum of 7 days from group and screen, stored at 4°C. Samples must be available post-transfusion for investigation of acute transfusion reactions. Preferably, store for 7 days post-transfusion to enable investigation of a delayed transfusion reaction. Revision of the British Committee for Standards in Haematology (BCSH) Guidelines for Compatibility Procedures in Transfusion Laboratories is currently in progress (July 2009); the balance of risk between inability to investigate a late adverse reaction and accidentally re-testing an unsuitable sample after lengthy storage is an important topic among those being considered by the BCSH working party. Their advice is anticipated by the end of 2009; see www.bcsguidelines.com for current guidance.

Separated serum or plasma, stored for transfusion purposes

127. No minimum storage time is recommended for recipient patient samples. Storage of donated serum/plasma should optimally be at -30°C or colder. These materials may be stored for up to 6 months, but guidelines for the timing of sample collection prior to blood transfusion must be followed (see Bibliography). Archived blood donor samples should be stored by blood services for at least 3 years, and preferably longer if it is practicable, in order to facilitate 'look-back' exercises.

D Forensic material

Criminal cases

128. 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

129. 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 in respect of such materials, are covered in earlier sections of this document.

130. 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

131. 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. More recent guidance in this area can also be found in *Consent and Confidentiality in Genetic Practice* (see Bibliography).
132. The House of Lords Select Committee on Science and Technology has recommended that the provisions of the Data Protection Act 1998 should be the primary means of regulating human genetic databases (Recommendation 3.17). The Human Genetics Commission (www.hgc.gov.uk) has recently consulted on this topic. The resultant report (*Inside Information* – see Bibliography) provides recommendations on confidentiality and the use of genetic samples and data but does not specifically consider duration of storage.

Storage of material following analyses of nucleic acids

133. Developing technologies means that there are now a variety of hard copy and/or electronic outputs associated with the analysis and interpretation of diagnostic tests using nucleic acids. It is recommended that all such outputs should be stored for at least 30 years unless the information is 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 the lifetime of the instrument, with a minimum of 10 years, is recommended. 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 (e.g. prenatal diagnoses).
- 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

134. Most external quality assessment (EQA) providers maintain the capacity to regenerate reports of participants' performance rather than the individual records themselves. This capacity should be maintained for at least 5 years to allow for retrieval of any data needed for the participants' next cycle of CPA accreditation. It 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 (Section 1).
135. Additional records to be kept by EQA providers:
- participants' returns (electronic or hard copy)
 - communications/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 10 years.

136. Retention times for materials stored by EQA providers:

- cells, tissues and other materials stored prior to preparation and circulation
- reference samples of the materials distributed to participants (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 10 years if the material represents, or can be converted to (e.g. by freezing) a valid "permanent" preparation. Degradable materials should be kept, if possible, for 1 month after the relevant circulation has been assessed.

Disposal of human tissue

General

137. 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/guidance/codes_of_practice.cfm).

138. 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.

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

Fetal tissues

140. Currently fetal remains of less than 24 weeks' gestation are not defined as human remains and are therefore not covered by current burial and cremation legislation. The Human Tissue Authority has produced specific guidance in this area within Code of Practice 5, which should be followed:

[www.hta.gov.uk/db/documents/2006-07-04 Approved by Parliament - Code of Practice 5 - Removal.pdf](http://www.hta.gov.uk/db/documents/2006-07-04%20Approved%20by%20Parliament%20-%20Code%20of%20Practice%205%20-%20Removal.pdf)

The HTA is currently (July 2009) considering further issues regarding consent to examination and disposal of fetal tissues and their updated advice is anticipated.

141. 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 disposal. The option of taking away the material for a private funeral should be offered. Although a sensitive topic, it should be made clear that no ashes will remain from cremation of such tissue. Where the wishes of parents are known, they should be followed.

142. 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 January 2005, the Department of Health document '*Q and A on Disposal following Pregnancy Loss Before 24 Weeks Gestation*' and the relevant Code of Practice of the Human Tissue Authority. See Bibliography.
143. 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.
144. 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.
145. 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.

Medico-legal value of archived material

146. 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.
147. 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.
148. 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 (e.g. in exfoliative cytology) are being commissioned. In such circumstances, the material used must usually be patient-identifiable, but precautions should be taken to secure appropriate confidentiality. Under the General Medical Council's powers to regulate fitness-to-practise of individual pathologists, both documentary and specimen archives may be scrutinised.

Specimens and records for teaching

149. 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 so-called "linked anonymisation".

150. Under the Human Tissue Act 2004, the public display of human biological samples, even if anonymised, is a criminal offence unless the patient (not a relative) has given explicit consent in writing and the consent process has been witnessed. A Human Tissue Authority licence is also required. These requirements do not apply to material already held before 1 September 2006.

Research data and records

151. Confidential named patient data (documentation) collected in the course of investigation and held separately from patients' records should be destroyed or anonymised 6 months after the research has been completed, the data have been analysed and final publication of findings has been made. If further recourse to identifiable information is anticipated, it should be kept for as long as such a need may exist, if this is permissible under the Data Protection Act (1998); advice should be sought.
152. Working records and other research data should be retained for at least 10 years to rebut allegations of scientific fraud but, wherever possible, these records should not include patient-identifiable data unless consent for such retention has been obtained. Records and clinical trial data on medicines must be kept for at least 15 years. The provisions of the Data Protection Act (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

153. 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.
154. Confidential information on patients may be transmitted by fax or from one computer to another. 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.
155. Confidential data transmitted electronically, especially over the internet, for example by e-mail, 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. e-mail 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, but pathologists should be

aware that if confidential information is accessed by an unauthorised person, it is likely to be taken as evidence of negligence.

156. 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

157. 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 published code of practice on records management for Scotland [2008]). In Wales, the definitive circular on *Managing Records in Trusts and Health Authorities* is WHC(2000)71. See Bibliography.
158. Pathologists and other laboratory professionals should be prepared to cause 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 157, 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.
159. 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 corresponding Code of Practice for Scotland applies).
160. 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.

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Forensic Science Regulator – guidance relating to standards and procedures for forensic science providers: http://police.homeoffice.gov.uk/operational-policing/Quality_Standards_for_FSSPs1.pdf

The Human Tissue Act 2004: www.opsi.gov.uk/acts/acts2004/20040030.htm with explanatory notes at www.opsi.gov.uk/acts/en2004/2004en30.htm

The Human Tissue Act (Scotland) 2006:

www.opsi.gov.uk/legislation/scotland/acts2006/asp_20060004_en.pdf, with guidance for the implications of the Act for NHS Scotland at www.show.scot.nhs.uk/sehd/mels/HDL2006_46.pdf

The Human Tissue Authority: *Designated Individuals and Licence Holders under the Human Tissue Act*:

www.hta.gov.uk/licensingandinspections/peopleatlicensedestablishments/disandlicenceholdersunderthehumantissueact2004.cfm

The Human Tissue Authority. www.hta.gov.uk. Codes of Practice and information about licensing can be found under 'Guidance': www.hta.gov.uk/guidance/codes_of_practice.cfm

The current codes of practice are:

[Code of Practice 1 Consent](#)

[Code of Practice 2 Donation of organs, tissues and cells for transplantation](#)

[Code of Practice 3 Post-mortem examination](#)

[Code of Practice 4 Anatomical examination](#)

[Code of Practice 5 Removal, storage and disposal of human organs and tissue](#)

[Code of Practice 6 Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation](#)

[Guidance 7 Public display](#)

[Code of Practice 8 Import and export of human bodies, body parts and tissue](#)

[Code of Practice 9 Research](#) (consultation document only, as at July 2009)

(Note: a final version of Code 9 and revisions of Codes 1-7 are awaited following consultation that closed in November 2008. Final HTA and Parliamentary approval of the new and revised codes, anticipated in September/October 2009, may involve minor changes in title or numbering, which may be reflected in alterations in these links. Access to the individual codes will continue to be available via links from www.hta.gov.uk/guidance/codes_of_practice.cfm).

APPENDIX: 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.